						_	
	OF DEFICIENC ES F CORRECTION	(X1) PROVIDER/SUPPLIER/C IDENTIFICATION NUMB		1	PLE CONSTRUCTION	(X3) DATE SUI COMPLET	
		СРН88933	39	B. WING		04/2	2/2021
NAME OF PR	OVIDER OR SUPPL ER		STREET ADD	RESS, CITY, ST.	ATE, ZIP CODE		
CDPH BR	ANCH LABORATOR	Υ	28454	LIVINGSTO	NAVE		
				ICIA, CA 91			
040.5	OLIMAN DV O	TATEMENT OF DEFICIENCE		, In	DDOU/DEDIG DLAN OF CODDECT	ION	(X5)
(X4) D PREFIX TAG	(EACH DEFICIENCY MUS	TATEMENT OF DEFICIENC ES IT BE PRECEDED BY FULL RE ENTIFYING NFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTI (EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPRO DEFICIENCY)	_D BE	COMPLETION DATE
D5200	GENERAL LABORA	TORY SYSTEMS		D5200	D5200 -		2) (2004
	CFR(s): 493.1230						3May2021
					CDPH Branch Laboratory had both Training/Orien PER-SOP-001) and Competency (CA-PER-SOP-00		
	Each laboratory that	performs nonwaived te	sting		procedures, which have been recently enhanced to	more clearly	
	-	able general laboratory	•		delineate the different requirements for training as		
		ts in §§493.1231 through			competency assessment. Please note that on 02/07/ 02/08/2021, no staff were due for 6-month or 12-m		
	493.1236, unless HHS approves a procedure,				competency assessment because the laboratory had	l been open less	
specified in Appendix C of the State Operations					than 6 months. The roster provided on 2/8/2021 was one, an issue being addressed through audit prepar		
	Manual (CMS Pub. 7), that provides equivalent				and exercises. A review of our records found that 4	12 / 412 (100%)	
	quality testing. The laboratory must monitor and				of employees involved in the testing process have d training; however, a limited number of delays in ca		
	evaluate the overall		ana		documentation were noted. These delays did not at	ffect the Data	
	laboratory systems and correct identified				Analysts, who are the only staff who report patient whom 21/21 (100%) had no delay in training docur		
	problems specified in §493.1239 for each				whom 21/21 (100/6) had no delay in daming docum	mentation.	
	specialty and subspecialty of testing performed.						
specialty and subspecialty of testing performed.							
	This Condition is not met as evidenced by: Based on the severity of the deficiencies cited herein, the Condition: General Laboratory						
	System was not met.	•					
	Findings included:						
	The laboratory failed	to establish and follow					
	written policies and p	rocedures to assess					
	competency for 236	out of 426 (approximate	ely				
	55%) of the total laboration	oratory staff prior to					
	processing, testing a	nd reporting patient sai	mples				
	for SARS-CoV-2 RT-						
D5209		PETENCY ASSESSME	NT	D5209			
20200	POLICIES	ETENOT ACCESSIVE					
	CFR(s): 493.1235						
	O1 11(0). 100.1200						
	As specified in the pe	ersonnel requirements	in				
		atory must establish an					
	•	and procedures to ass					
	employee and, if app						
	competency.						
1							
This Standard is not met as evidenced by: Based on interviews conducted with the							
		2/07/2021 and 02/08/29	121				
	laboratory stair off 02	10112021 allu 02/00/23	۲ <u>۲</u> ۱,				
LABORATORY	DIRECTOR'S OR PROVIDER	SUPPL ER REPRESENTATIV	E'S SIGNATURE		TITLE		(X6) DATE
				Atosenille	Laboratory Director	0	3May2021

Any deficiency statement ending with an asterisk (*) denotes a deficiency which he institu ion may be excused from correcting providing it is determined that o her safeguards provide sufficient protection to the patients . (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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	OF DEFICIENC ES F CORRECTION	(X1) PROVIDER/SUPPLIER/C IDENTIFICATION NUMBI	ER:	A. BUILDING	PLE CONSTRUCTION	(X3) DATE SUF COMPLETI	
NAME OF PR	OVIDER OR SUPPL ER	<u> </u>	STREET ADDR	RESS, CITY, ST	ATE. ZIP CODE		
	ANCH LABORATOR	Y	28454 L	IVINGSTON	AVE		
(X4) D PREFIX TAG	(EACH DEFICIENCY MUS	TATEMENT OF DEFICIENC ES IT BE PRECEDED BY FULL RE ENTIFYING NFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF CORRECT (EACH CORRECTIVE ACTION SHOUI CROSS-REFERENCED TO THE APPRO DEFICIENCY)	.D BE	(X5) COMPLETION DATE
D5209	review of electronic of personnel files maile Laboratory Field Ser 02/11/2021, test reconstruction 12/07/2020 to 01/13/1 test records reviewed laboratory failed to for procedures to assess 426 (approximately 5 staff prior to process patient samples for 5 Findings included: 1. Review of the laprocedures (SOP # Quality Management 03/01/2021) section Resource Management Assessment of Compersonnel competent following times for the job processes and prior independently 1. Initially- after traindependently 1. Initially- after traindependently 1. Initially- after traindependently 2. Non-technical emplois assessments may be discretion of the laboratory tenurous assessments may be discretion assessments may be discretion of the laboratory tenurous assessments may be discretion of the laboratory tenurous assessments as a second process and processments as a second process as a second process and pr	document control syster d by CDPH-Branch Lab vices (LFS) office on ords covering the period (2021, for 30 out of 30 pd, it was determined that ollow written policies and scompetency for 236 of (55%) of the total laborating, testing and reporting (ARS-CoV-2 RT-PCR.) boratory policies and CA-QM-SOP-001, Title Plan, V2, Effective Data (6.2 Personnel/Human ent, subsection 6.2.1 petence stated that, ce is assessed at the eir existing, new, or characteristic and 12 months from the analysis and 12 months from the after the first 12 months and assessment reveals ement.	o at I from Patient Pa	D5209	Finding 1 Per the CLIA regulation, \$493.1445 (12-13) the La Director has a responsibility to ensure that prior t patients' specimens, all personnel have the appropriate experience, receive the appropriate training for complexity of the services offered, and have demo they can perform all testing operations reliably to report accurate results. This is accomplished by e policies and procedures for monitoring individual preanalytical, analytical and postanalytical phases CDPH Branch Laboratory had both Training/Orie PER-SOP-001) and Competency (CA-PER-SOP-001) and Competency (CA-PER-SOP-01) to 240CT2020. The original wording of the Qualier Plan (CA-QM-SOP-001 v1 01NOV2020) states the completed job specific training is documented on competency form or equivalent and that compete conducted semi-annually in the first year of testin and 12 months and annually thereafter). The forrassess training were originally intended to document training that provided the evidence that personne their specific testing tasks reliably and to document training that provided the evidence that personne their specific testing tasks reliably and accurately. laboratory acknowledges that the form document and competency did not clearly differentiate the trior to receipt of CDPH Inspection results on 2: alaboratory had already identified the need to revisicality to these two SOPS during the process map upcoming 6-month competency assessments that April (see Attachments D5209_1a, D5209_1b and Please note that on 02/07/2021 and 02/08/2021, note 6-month or 12-month competency assessment that April (see Attachment D5209_1a, D5209_1b and value) as a separate competency, the mis statement that both a separate competency, the mis statement that both a separate competency in add training documentation attesting that the individu competent to perform the tasks was removed. (See the QMP: Attachment D5209_1c) Personnel competence is assessed at the following existing, new, or changed job processes and procedure to the processes and procedure to the p	o testing riate education or the type and on the type and ty	3May2021

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	OF DEFICIENC ES F CORRECTION	(X1) PROVIDER/SUPPLIER/C IDENTIFICATION NUMBE			PLE CONSTRUCTION	(X3) DATE SUR COMPLETE	
		СРН88933	9	B. WING		04/22	2/2021
NAME OF PR	OVIDER OR SUPPL ER		STREET ADDR	RESS, CITY, ST	ATE, ZIP CODE		
	ANCH LABORATOR	v	28454	IVINGSTO	JAVE		
CDITIBIO	ANOTI LABORATOR			CIA, CA 913			
(X4) D PREFIX TAG	(EACH DEFICIENCY MUS	TATEMENT OF DEFICIENC ES T BE PRECEDED BY FULL RE ENTIFYING NFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTI (EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPROI DEFICIENCY)	D BE	(X5) COMPLETION DATE
D5209	Continued From pag	e 2		D5209	Continued from page 2		
	asked to provide its most recent personnel list from preanalytic, analytic, and postanalytic processes. 3. One of the general supervisors printed the laboratory's most recent personnel roster for the following 2 shifts:				(1) Immediate Corrective Action: The Personnel and Onboarding procedure (CA-PER-SOP-001 v2 has been updated to reflect and enhance current particles of the comparison of training checklists (previously titled Competency Assessment) have been updated to in of training (see D5209_1d). In addition, a roster we status by shift is placed in each lab area so that any easily see training status (see example in Attachme	, 14Mar2021) ractice (see -day orientation Training and clude all aspects ith training Supervisor can	
	i. Saturday to Tuesday (Day and Night Shift) a. Accessioning b. Extraction c. PCR d. Data Analysis				The Competency Assessment procedure (CA-PER effective 3/8/2021 and v4 effective 4/11/2021, Atta D5209_1b) was updated to define the process for assessment more clearly. Competency assessment redesigned (in advance of 6-month competency winclude all aspects of competency assessment as sp CFR 493.1451(b)(8). This required adding problen testing of known (previously tested) samples to the than capturing this assessment separately which w required if the original form had been retained.	chment competency forms were indow) to recified by 42 in solving and e forms, rather	
	ii. Wednesday to Fa. Accessioningb. Extractionc. PCRd. Data Analysis	riday (Day and Night S	hift)		(2) Patient Impact: Dr. Adam Rosendorff, Labora has determined that the changes made were organ improve understanding of these two processes (tracompetency) and that there is no impact on patien patient harm as procedures for employee training attestation of the ability of employee to perform print place at the time of initial employee training.	izational to uning versus at care or any and supervisor rocedures were	
	4. Review of the personnel records mailed to Laboratory Field Services office on 02/11/2021, i was determined that the laboratory failed to follow its written policies and procedures by allowing 236 out of 426 laboratory staff to work independently while the laboratory's documentation indicated that its training and competency protocols had not been completed as specified in its Quality Management Plan.		21 , it follow ng		(3) Preventative Measure: A summary PowerPoin all Managers and Supervisors explaining the changand updated forms on April 1, 2021 before the star competency assessments of the technical staff on A Members of the Quality Team met with each Superforming 6-month competency assessments before assessments and several times during assessments understood the changes to the process (see Attach D5209_1f). (4) Monitoring Mechanism: Personnel and comprocedures will be updated as needed. The Quality continue to work with Managers and Supervisors questions regarding what assessment needs to be dilaboratory staff.	ges and the new rt of 6-month April 21, 2021. rvisor ore they began to ensure they ment betency r team will to answer	
	i. Saturday to Tuesday (Day Shift)a. Accessioninga.1. 1 out of 1 supervisor (resigned)				Findings 2 and 3: During the February 7 and February 8 investigatio roster used for convenience in the laboratory was 1 this time, the CDPH Branch Laboratory has developrocedures that specify what laboratory document and the manner in which they are to be given to reagencies.	presented. Since pped audit s may be shared gulatory	
	a.2. 37 out of 37 acce	essioning staff- complet	ted		(1) Immediate Corrective Action: A current roste (Extraction, PCR, and Data Analysis) and non-tecl (Accessioning) staff is used to provide training doc The lists are very similar but do have a few differer D-5209 Findings 4 and 5).	hnical cumentation.	

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STATEMENT	OF DEFICIENC ES	(X1) PROVIDER/SUPPLIER/C	LIA			NSTRUCTION			(X3	(X3) DATE SURVEY	
AND PLAN O	F CORRECTION	IDENTIFICATION NUMBE	ER:	A. BUILDING						COMPLE	TED
		CPH88933	9	B. WING						04/2	22/2021
NAME OF PR	OVIDER OR SUPPL ER		STREET ADD	RESS, CITY, STA	ATE, ZI	IP CODE					
CDPH BR	ANCH LABORATORY	_Y	28454 L	IVINGSTON	I AVI	E					
			VALEN	CIA, CA 913	355						
(X4) D PREFIX TAG	(EACH DEFICIENCY MUST	TATEMENT OF DEFICIENC ES T BE PRECEDED BY FULL RE ENTIFYING NFORMATION)		ID PREFIX TAG			ER'S PLAN RRECTIVE ERENCED DEFICI	ACTION SH TO THE AP	HOULD BE		(X5) COMPLETION DATE
D5209	Continued From pag	e 3		D5209	Cont	inued from page	3				
	b. Extraction				(2) Patient Impact: The unofficial roster is used by Managers and						
	b.2. 2 out of 2 superv	risors - no competency			(2) Patient Impact: The unofficial roster is used by Managers and Supervisors as a reference for staff on shifts or in areas with which						
	assessment					hey do not work directly. Inaccuracies in this roster may result in nconvenience for laboratory staff, therefore, there is no impact					
	b.1. 17 out of 38 extra	action staff- no compete	ency			itient care.	oratory star	i, dicretore,	diere is in	o impact	
	assessment				(3) P	reventative Mea	sure. An in	spection wo	rk instruc	tion has	
	c. PCR				been been Super	drafted by the C used as starting rvisors, Manager	DPH Branc point for Ques, and the L	h Laborator iality team i aboratory D	y. This dra members, Director to	aft has have a	
	c.1. 1 out of 1 supervisor- no competency assessment			group training session on conducting an efficien training sessions and mock inspection drills hav						been completed	
				(see Attachments D5209_2a and D52 challenges of these mock drills are be							
					Inspection Work Instruction. Techniques from this training were						
	c.2. 4 out of 13 PCR	staff - no competency			used to efficiently meet requests from Laboratory Field Services during an on-site visit in March 2021.						
	assessment										
	d. Data Analysis d.1. 1 out of 1 Sign or	ut manager (not indicate	(4) Monitoring Mechanism: Additional mock inspection of will be held on all shifts. Team performance during any audinspection is reviewed during post audit conference (as stip in the work instruction). Areas of effectiveness as well as an improvement will be documented and enter into the Continumprovement process (CAPA).					y audit or s stipulated as areas for			
	d 2 4 out of 4 data ar	nalysis staff- no compet	encv		_	-	` ′				
	assessment	narysis stair- no compet	ericy		Find	ings 4 and 5.					
	doccoment					oster provided of fore, the following					
	ii. Saturday to Tuesda	ay (Night Shift)			vary 8 412 /	slightly (see Find 412 (100%) of ed documented train	ling 3). A re mployees in	view of our	records fo	ound that	
	 a. Accessioning 						Sun -	Tue	Wed	d-Fri	Total
								_		Night	
	a.1. 1 out of 1 superv	isor- no competency			-	Accessioning	34/34		46/46		150
	assessment				по	Reformatter	35/35 (37 total)	46 / 46 (55 total)	38/38 (40 total)	48/48 (51 total)	183
	a.2. 1 out of 42 accessioning staff -no competency assessment				Extracti	Reformatter Chemagic	36/36 (37 total)	41/41 (55 total)	38/38 (40 total)	48/48 (51 total)	
	b. Extraction				RT-PCR Set-up	11/11	14/14	12/12	11/11	NB	
	D. EXITACTION				R	AJ PCR	11/11	14/14	12/12	11/11	48
	b.1. 1 out of 1 supervisor- no competency assessment				T. I WATER CO. II	7/7	5/5	6/6	3/3	21	
					Analysis Total	89	117	104	102	412	
						Ivai	03	11/	104	102	1
	b.2. 42 out of 57 extraction staff- no competency assessment										

c. PCR

	OF DEFICIENC ES F CORRECTION	(X1) PROVIDER/SUPPLIER/CI IDENTIFICATION NUMBE			PLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED	
		СРН88933	9	B. WING		04/22	2/2021
NAME OF PR	OVIDER OR SUPPL ER		STREET ADDF	RESS, CITY, STA	ATE, ZIP CODE		
CDPH BR	ANCH LABORATOR	Y		IVINGSTON CIA, CA 913			
(X4) D PREFIX TAG	(EACH DEFICIENCY MUS	TATEMENT OF DEFICIENC ES IT BE PRECEDED BY FULL REI ENTIFYING NFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOUL) CROSS-REFERENCED TO THE APPROFILIENCY)	D BE	(X5) COMPLETION DATE
D5209	Continued From pag	je 4		D5209	Continued from page 4		
	c.1. 1 out 1 supervisor- no competency assessment c.2. 7 out of 13 PCR staff - no competency assessment				Due to the large number of staff onboarded in a sh time to meet the emergency demands for COVID-capacity, there was a delay in entering training doc in the new document control system. This made it track what was still needed. Efforts to collect and d training were delayed. Subsequently, notifications and Managers regarding forms that were not comp delayed. In addition, delays in providing records u request were due to limitations of the document cobeing able to download a large number of documer.	19 testing cumentation difficult to occument to Supervisors bleted was pon audit ontrol system	
	d. Data Analysis			of onsite inspection.	no at the time		
	d.1 Sign out manager (not indicated) d.2. 2 out of 2 data analysis staff- no competency assessment iii. Wednesday to Friday (Day Shift) a. Accessioning				Data Analysis It is important to note that technologists in the An are the only staff who report patient results. 21/21 Data Analysts, as well as the Sign-Out Manager, ha documented training prior to reporting patient results documented on the Data Analysis (CA-PER-FM-0 training assessment form. Copies of this form, as we related but redundant form (see below) are provided Attachments D5209_3a, D5209_3b and D5209_3z were provided to LFS via email on February 8 as re Confirmation of the sent email is provided in Attact D5209_3zb. Due to uncertainty about workflow ah laboratory opening, two forms were created (prior employee onboarding) to capture training needed	(100%) of the dd ults as 15) initial rell as a ed in These records requested. chment lead of the to any	
	a.1. 1 out of 1 superv assessment	isor- no competency			analyze data after completion of RT-PCR: - Data Extraction (CA-PER-FM-014) - Data Analysis (CA-PER-FM-015)		
	a.2. 47 out of 47 acce competency assessn	-			These tasks were separate to allow PCR technologi data prior to submitting for analysis; however, this never implemented in this laboratory. Both forms completed for most analysts; however, four data ar had only the Data Analysis form	workflow was were	
	b. Extraction				(CA-PER-FM-015) completed. The redundant Dat form (CA-PER-FM-014) was initially maintained we thought that the workflow could be implemented we	with the when sample	
	assessment	risors- no competency			volumes increased; however, this was not necessary PCR All PCR technologists (48/48; 100%), as well as all Supervisors (4/4), had documented training prior	PCR to processing	
	assessment	action staff- no compete	ency		patient samples (Attachments D5209_3c - D5209_ of records did reveal a minor anomaly in the traini several individuals training in PCR, the training fo completed and signed for the RT-PCR Set-up on the (CA-PER-FM-012); however, the form for the RT-	ng record. For rm was ne Janus G3 PCR AJ	
	c. PCR				thermocycler (CA-PER-FM-013) is not in the train review of records indicates that technologists prep- batch on the RT-PCR Set-up and loaded the PCR p	ared the PCR	
	c.1 2 out of 2 supervisor- no competency assessment				Thermocycler. Training on the RT-PCR Set-up, as review, were completed by the trainer. These record that the AJ thermocycler was loaded and started cothese are the tasks assessed for training, the individ-	well as data ds indicate orrectly. Since	
	c.2. 5 out of 15 PCR	staff- no competency			assessed performed the task correctly but the labor properly document this aspect of the training.		

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assessment

D5209 Continued From page 5 d. Data analysis d.1. 1 out of 1 Sign out manager iv. Wednesday to Friday (Night Shift) a. Accessioning a.1. 1 out of 1 supervisor- no competency assessment a.2. 31 out of 3 accessioning staff-no competency assessment b. Extraction b. Extraction competency assessment b. Extraction competency assessment c								
STREET ADDRESS, CITY, STATE, ZIP CODE				1				
CAD D SUMMARY STATEMENT OF DEFICIENCE S CAD SUMMARY STATEMENT OF DEFICIENCE S CAD			СРН88933	39	B. WING		04/22	2/2021
VALENCIA, CA 91356 VALENCIA, CA 91356	NAME OF PR	OVIDER OR SUPPL ER		STREET ADDF	RESS, CITY, STA	ATE, ZIP CODE	,	
D5209 Continued From page 5 d. Data analysis d.1. 1 out of 1 Sign out manager iv. Wednesday to Friday (Night Shift) a. Accessioning a.1. 1 out of 1 supervisor- no competency assessment iv. Wednesday to Friday (Night Shift) b. Extraction b. Extraction b. Extraction b. Extraction b. Extraction b. Extraction competency assessment c. PCR c. 10 out of 4 supervisor- no competency assessment c. PCR c. 10 out of 5 supervisor- no competency assessment c. PCR c. 10 out of 6 extraction staff- no competency assessment c. PCR c. 10 out of 1 supervisor- no competency assessment c. PCR c. 10 out of 1 supervisor (open position) c. 2. 9 out of 14 PCR staff- no competency assessment d. Data analysis d. Display there is good event be the chamagic attention of training from was recised and the time of training are considered to experiment the training was completed that alignature was not obtained to experiment to possessment and the competency assessment and the competency and	CDPH BR	ANCH LABORATOR	Y					
d. Data analysis d.1. 1 out of 1 Sign out manager d.2. 2 out of 3 data analysis staff- no competency assessment iv. Wednesday to Friday (Night Shift) a. Accessioning a.1. 1 out of 1 supervisor- no competency assessment a.2. 31 out of 37 accessioning staff- no competency assessment b. Extraction b. Extraction b. Extraction b. Extraction b. 1. 1 out of 1 supervisor- no competency assessment competenc	PREFIX	(EACH DEFICIENCY MUS	ST BE PRECEDED BY FULL RE		PREFIX	(EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPROI	D BE	COMPLETION
d. Data analysis d.1. 1 out of 1 Sign out manager d.2. 2 out of 3 data analysis staff- no competency assessment iv. Wednesday to Friday (Night Shift) a. Accessioning a.1. 1 out of 1 supervisor- no competency assessment a.2. 31 out of 37 accessioning staff-no competency assessment b. Extraction b. Extraction b. Extraction b. Extraction b. Extraction b. Extraction competency assessment c. PCR c. 1 0 out of 1 supervisor- no competency assessment c. PCR c. 1 0 out of 0 supervisor (open position) c. 2. 9 out of 14 PCR staff- no competency assessment d. Data analysis d. Data analysis d. 1. Sign out manager (not indicated) Extraction b. La sign out manager (not indicated) Extraction In the Extraction area, some staff currently perform only the Reformatic ration and plant and sign procedure or the chemagic automated incides and extraction procedure, therefore, the chemagic automated in staff and remaining automated in staff and remaining and indication from the trainer to out the staff and sign procedure or the chemagic automated incides acid extraction. or 183 staff members in Extraction: 184 164 staff members in Extraction: 285 173 have been trained to use the chemagic automated nucleic acid extraction. Staff without cruent training for an instrument are not permitted to operate that instrument and incide and that for the Reformation of training. 197 1/13 had completed training records at the time of training. 198 1/17 have found to have inadequate documentation of training. A review or records found that for the chemagic. 199 1/16 had completed training records at the time of training. 198 1/16 had completed training records at the time of training. 199 1/16 had completed training records at the time of training. 199 1/16 had completed training records at the time of training. 199 1/16 had completed training records at the time of training. 199 1/16 had an indication from the trainer that training was completed out a signature was not obtained. 199 1/16 had completed training re	D5209	Continued From pag	je 5		D5209	Continued from page 5		
d.1. 1 out of 1 Sign out manager d.2. 2 out of 3 data analysis staff- no competency assessment iv. Wednesday to Friday (Night Shift) a. Accessioning a.1. 1 out of 1 supervisor- no competency assessment a.2. 31 out of 37 accessioning staff-no competency assessment b. Extraction b. Extraction b. Extraction b. Extraction competency assessment competency assessment assessed again by the Sign Outs and Data Analysis forms, for any missing Otta Extraction and Data Analysis forms, for any missing Data Extraction and Data Analysis forms, for any missing Data Extraction and Data Analysis forms, for any missing Data Extraction and Data Analysis forms, for any missing Data Extraction and Data Analysis forms, for any missing Data Extraction and Data Analysis forms, for any missing Data Extraction and Data Analysis forms, for any missing Data Extraction and Data Analysis forms, for any			,			Continued from page 5		
iv. Wednesday to Friday (Night Shift) a. Accessioning a. Accessioning a. 1. 1 out of 1 supervisor- no competency assessment a. 2. 31 out of 37 accessioning staff-no competency assessment b. Extraction b. Extraction b. 1. 1 out of 1 supervisor- no competency assessment competency assessment		d.1. 1 out of 1 Sign o	ign out manager ata analysis staff- no competency			In the Extraction area, some staff currently perforn Reformatter automated liquid handling procedure chemagic automated nucleic acid extraction proce- the total number of training records for each is sm total number of individuals in that area. A detailed	or the dure, therefore, aller than the	
a.1. 1 out of 1 supervisor- no competency assessment a.2. 31 out of 37 accessioning staff-no competency assessment b. Extraction b.1. 1 out of 1 supervisor- no competency assessment b. Extraction b.1. 1 out of 1 supervisor- no competency assessment competency associated the time of training and indication from the trainer associated the time of training associated associated associated associated associated associated associat		iv. Wednesday to Fri				Of the 183 staff members in Extraction: • 173 have been trained to use the Reformatter liquid handler		
assessment a.2. 31 out of 37 accessioning staff-no competency assessment b. Extraction b.1. 1 out of 1 supervisor- no competency assessment b.2. 34 out of 46 extraction staff- no competency assessment b.2. 34 out of 46 extraction staff- no competency assessment c. PCR c.1 0 out of 0 supervisor (open position) c.2. 9 out of 14 PCR staff- no competency assessment d. Data analysis d. Data analysis d. Data analysis d.1. Sign out manager (not indicated) A review of records found that for the chemagic: 17/173 had ompleted training records at the time of training was completed but a signature was not obtained training records at the time of training to 10/166 were found to have inadequate documentation of training to 10/166 were found to have inadequate documentation of training to 10/166 were found to have inadequate documentation of training form was not captured was re-assessed for the Individual or that individual was removed from that testing process until reassessment could be completed. Analysis: Despite the redundancy between the Data Extraction and Data Analysis forms, for any missing Data Extraction documentation, the analysis of all bata individuals was recovered or 10Apr2021 due to overlap with the Data Analysis form. PCR: Although there is good evidence from the successful training run that the individuals lacking a signature for the Al Thermocycler training from did complete training, the affected individuals were re-assessed when the omission was discovered. All staff, including the PCR Supervisors (see Attachment D5209_3z), were found to be adequately trained.		a. Accessioning				 Staff without current training for an instrum 	nent are not	
a.2. 31 out of 37 accessioning staff-no competency assessment b. Extraction b. Extraction b. 1. 1 out of 1 supervisor- no competency assessment c. 23 / 173 were found to have inadequate documentation of training b.2. 34 out of 46 extraction staff- no competency assessment c. PCR c.1 0 out of 0 supervisor (open position) c.2. 9 out of 14 PCR staff- no competency assessment d. Data analysis d. Data analysis d. 1. Sign out manager (not indicated) was completed but a signature was not obtained • 13 / 173 were found to have inadequate documentation of training a review of records found that for the chemagic: • 149 / 166 had completed training rore data the time of training 7 / 166 had an indication from the trainer that training was completed but a signature was not obtained • 10 / 166 were found to have inadequate documentation of training 7 / 166 had an indication from the trainer that training was completed but a signature was not obtained • 10 / 166 were found to have inadequate documentation of training 7 / 166 had complete training rows and obtained • 10 / 166 were found to have inadequate documentation of training 7 / 166 had ompleted training rows and obtained • 10 / 166 were found to have inadequate documentation of training 7 / 166 had ompleted training rows and obtained • 10 / 166 were found to have inadequate documentation of training 7 / 166 had ompleted training rows and obtained • 10 / 166 were found to have inadequate documentation of training 7 / 166 had ompleted training rows and obtained • 10 / 166 were found to have inadequate documentation of training 7 / 166 had ompleted training rows and obtained • 10 / 166 were found to have inadequate documentation of training 7 / 166 had ompleted training rows and obtained • 10 / 166 were found to have inadequate documentation of training 8 / 10 / 166 were found to have inadequate documentation of training 9 / 166 were found to have inadequate documentation of training 10 / 16 were found to have inadequate documentation o			isor- no competency			 133 / 173 had completed training records at training 	the time of	
b. 1. 1 out of 1 supervisor- no competency assessment b. 2. 34 out of 46 extraction staff- no competency assessment c. PCR c. 1 0 out of 0 supervisor (open position) c. 2. 9 out of 14 PCR staff- no competency assessment d. Data analysis d. Data analysis d. 1. Sign out manager (not indicated) e 149 / 166 had an indication from the trainer that training was completed but a signature was not obtained e 7 / 166 had an indication from the trainer that training was completed but a signature was not obtained e 10 / 166 were found to have inadequate documentation of training e 7 / 166 had an indication from the trainer that training was completed but a signature was not obtained e 10 / 166 were found to have inadequate documentation of training e 7 / 166 had an indication from the trainer that training was completed but a signature was not obtained e 10 / 166 were found to have inadequate documentation of training e 7 / 166 had an indication from the trainer that training was completed but a signature was not obtained e 10 / 166 were found to have inadequate documentation of training e 7 / 166 had an indication from the trainer that training was completed but a signature was not obtained e 10 / 166 were found to have inadequate documentation of training e 10 / 166 were found to have inadequate documentation of training form was not obtained e 10 / 166 were found to have inadequate documentation of training was completed but a signature for that individuals are reassessed or the individual or that individual are reassessed or the individual or that individual are reassessed and individual are reassessed when the obtaining, the affected individual was reassessed when the one obtained was part of laboratory procedure. The Data Extraction form was retired on 10Apr2021 due to overlap with the Data Analysis form. e 149 / 166 hate are found to have inadequate documentation of training was completed but a signature from that training was reassessed or the individual are training to that individual are tra			-			 was completed but a signature was not obta 23 / 173 were found to have inadequate doc 	ined	
b.1. 1 out of 1 supervisor- no competency assessment b.2. 34 out of 46 extraction staff- no competency assessment c. PCR c.1 0 out of 0 supervisor (open position) c.2. 9 out of 14 PCR staff- no competency assessment d. Data analysis d. Data analysis d.1. Sign out manager (not indicated) e 7 / 166 had an indication from the trainer that training was completed but a signature was not obtained e 10 / 166 were found to have inadequate documentation of training (1) Immediate Corrective Action: Any task for which a training form was not captured was re-assessed for the individual or that individual was removed from that testing process until re-assessment could be completed. Analysis: Despite the redundancy between the Data Extraction and Data Analysis forms, for any missing Data Extraction documentation, the analysts were assessed again by the Sign Out Manager since this was part of laboratory procedure. The Data Extraction form was retired on 10Apr2021 due to overlap with the Data Analysis form. PCR: Although there is good evidence from the successful training run that the individuals lacking a signature for the AJ Thermocycler training form did complete training, the affected individuals were re-assessed when the omission was discovered. All staff, including the PCR Supervisors (see Attachment D5209_3z), were found to be adequately trained.		b. Extraction				 149 / 166 had completed training records at 	the time of	
assessment c. PCR Analysis: Despite the redundancy between the Data Extraction and Data Analysis forms, for any missing Data Extraction documentation, the analysts were assessed again by the Sign Out Manager since this was part of laboratory procedure. The Data Extraction form was retired on 10Apr2021 due to overlap with the Data Analysis form. c.2. 9 out of 14 PCR staff- no competency assessment d. Data analysis d. Data analysis d. Data manalysis d. 1. Sign out manager (not indicated) form was not captured was re-assessed for the individual or that individual was removed from that testing process until re-assessed the individual serving process until re-assessed again by the Sign Out Manager since this was part of laboratory procedure. The Data Extraction form was retired on 10Apr2021 due to overlap with the Data Analysis form. PCR: Although there is good evidence from the successful training run that the individuals lacking a signature for the AJ Thermocycler training form did complete training, the affected individuals were re-assessed when the omission was discovered. All staff, including the PCR Supervisors (see Attachment D5209_3z), were found to be adequately trained.			isor- no competency			 completed but a signature was not obtained 10 / 166 were found to have inadequate doc 		
c. PCR Analysis: Despite the redundancy between the Data Extraction and Data Analysis forms, for any missing Data Extraction documentation, the analysts were assessed again by the Sign Out Manager since this was part of laboratory procedure. The Data Extraction form was retired on 10Apr2021 due to overlap with the Data Analysis form. PCR: Although there is good evidence from the successful training run that the individuals lacking a signature for the AJ Thermocycler training form did complete training, the affected individuals were re-assessed when the omission was discovered. All staff, including the PCR Supervisors (see Attachment D5209_3z), were found to be adequately trained.			action staff- no compete	ency		form was not captured was re-assessed for the indi individual was removed from that testing process of	vidual or that	
Analysis: Despite the redundancy between the Data Extraction and Data Analysis forms, for any missing Data Extraction documentation, the analysts were assessed again by the Sign Out Manager since this was part of laboratory procedure. The Data Extraction form was retired on 10Apr2021 due to overlap with the Data Analysis form. PCR: Although there is good evidence from the successful training run that the individuals lacking a signature for the AJ Thermocycler training form did complete training, the affected individuals were re-assessed when the omission was discovered. All staff, including the PCR Supervisors (see Attachment D5209_3z), were found to be adequately trained.		c. PCR				•		
c.2. 9 out of 14 PCR staff- no competency assessment the Data Analysis form. PCR: Although there is good evidence from the successful training run that the individuals lacking a signature for the AJ Thermocycler training form did complete training, the affected individuals were re-assessed when the omission was discovered. All staff, including the PCR Supervisors (see Attachment D5209_3z), were found to be adequately trained.						and Data Analysis forms, for any missing Data Ext documentation, the analysts were assessed again b Manager since this was part of laboratory procedu	raction y the Sign Out re. The Data	
assessment d. Data analysis d. 1. Sign out manager (not indicated) PCR: Although there is good evidence from the successful training run that the individuals lacking a signature for the AJ Thermocycler training form did complete training, the affected individuals were re-assessed when the omission was discovered. All staff, including the PCR Supervisors (see Attachment D5209_3z), were found to be adequately trained.		c.2. 9 out of 14 PCR	staff- no competency				mini wini	
d. Data analysis d. Data analysis d. Data malysis d.1. Sign out manager (not indicated) training run that the individuals lacking a signature for the AJ Thermocycler training form did complete training, the affected individuals were re-assessed when the omission was discovered. All staff, including the PCR Supervisors (see Attachment D5209_3z), were found to be adequately trained.						PCR: Although there is good evidence from the su	ccessful	
u.i. Sign out manager (not indicated)			ata analysis		training run that the individuals lacking a signatur Thermocycler training form did complete training individuals were re-assessed when the omission wa All staff, including the PCR Supervisors (see Attack	e for the AJ , the affected as discovered.		
I m		d.1. Sign out manage	∍r (not indicated)			- "		
d.2. 3 out of 3 data analysis staff- no competency assessment Extraction: For the 23 / 173 (13%) that were identified in mid-December to have a missing training document for the Reformatter automated liquid handler: 11 of these individuals were re-assessed by a Supervisor in December 2020 and found to be adequately trained			nalysis staff- no compet	tency		have a missing training document for the Reforma liquid handler: • 11 of these individuals were re-assessed by a	tter automated a Supervisor in	

5. There was no evidence submitted showing

STATEMENT OF DEFICIENC ES AND PLAN OF CORRECTION	, ,			PLE CONSTRUCTION	(X3) DATE SUR COMPLETE	
	CPH88933	39	B. WING		04/22	2/2021
NAME OF PROVIDER OR SUPPLIER		STREET ADDR	RESS, CITY, ST	ATE, ZIP CODE		
CDPH BRANCH LABORATORY	Y		IVINGSTON CIA, CA 913			
PREFIX (EACH DEFICIENCY MUS	TATEMENT OF DEFICIENC ES T BE PRECEDED BY FULL RE ENTIFYING NFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTIV (EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPROI DEFICIENCY)	D BE	(X5) COMPLETION DATE
D5209 Continued From pag	e 6		D5209	Continued from page 6		
completed competen of 426 (approximately	completed competency assessment for 236 out of 426 (approximately 55%) of the total laboratory staff, prior to processing, testing, and reporting			 2 were removed from testing and re-assessed 2021 and found to be adequately trained 10 of these individuals were reassessed in Ja February (7) and March (1) and found to be trained. 	nuary (2),	
6. The following ar the 30 randomly revie covering the period fr 01/13/2021, wherein reported 30 out of 30 samples but failed to Quality Management procedures for composition of the samples of the samp	the laboratory tested at SARS-CoV-2 patient ensure it followed the Plan policies and etency assessment. poratory director's email ratory has processed 1, 2 patient samples as of n. (PST).	on	D5400	For the 10 / 166 (6%) were found in a mid-Decemb missing training document for the chemagic auton acid extractor: • 4 of these individuals were re-assessed by a December 2020 and found to be adequately • 6 of these individuals were reassessed in Feb March (1) and found to be adequately trained Attachment D5209_3z). Accessioning: Accessioning consists mainly of bar All unsatisfactory specimens are checked by a supe rejecting the sample. Upon assessment, no perform were identified, therefore, there is no impact on pa process: The ability to download records in bulk hapatient care. Accessioning: The accessioning process for this lab requires: - Scanning of the barcode on the sample. Batching into groups of 94 samples fo Identifying unsatisfactory samples Although some accessioning staff performed heat i prior to February 2021, most were trained in this p February 2021 (see Attachments D5209_3q - D52(Review of records showed that 47 / 160 training redelayed; however, all have been completed. These disjunctures were spread across the four shifts. Train accessioning staff for heat inactivation was docum appropriately by February 2021 for 158 / 160 of the staff. No staff were found to have deficiencies in tratachments D5209_3q - D5209_3y). Audit process: Paper copies of personnel files have aide in timeliness of audit responses. (1) Patient Impact: Data Analysts and the Sign-Out Manager. Training 21/21 data analysts and the Sign-Out Manager. Training 12/21 data analysts and the Sign-Out Manager. Training 21/21 data analysts and the Sign-Out Manager. Training 12/21 data analysts and	Supervisor in trained oruary (5) and ed. I (see code scanning. rivisor prior to hance issues tient care. Audit as no impact on oratory e r testing inactivation rocedure in 190–3y). 100–3y) cords were delayed ing of ented e accessioning raining (see been created to se data are the g records for e completed, e impact of the CA-PER- between Data ithout Data orustivation to the control of the control of the care, seed training tient, there is care. seed training tient care since	

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STATEMENT OF DEFICIENCES AND PLAN OF CORRECTION (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:				PLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED			
		СРН88933	39	B. WING		04/22	2/2021	
	OVIDER OR SUPPLIER ANCH LABORATOR	Y	28454 L	DRESS, CITY, STATE, ZIP CODE LIVINGSTON AVE NCIA, CA 91355				
(X4) D PREFIX TAG	(EACH DEFICIENCY MUS	TATEMENT OF DEFICIENC ES T BE PRECEDED BY FULL RE ENTIFYING NFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTI (EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPROI DEFICIENCY)	D BE	(X5) COMPLETION DATE	
D5209	D5209 Continued From page 6 completed competency assessment for 236 out of 426 (approximately 55%) of the total laboratory staff, prior to processing, testing, and reporting patient results. 6. The following are the accession numbers of the 30 randomly reviewed patient test records covering the period from 12/07/2020 to 01/13/2021, wherein the laboratory tested and reported 30 out of 30 SARS-CoV-2 patient samples but failed to ensure it followed the Quality Management Plan policies and procedures for competency assessment. Accession Number 7. Based on the laboratory director's email on 03/25/2021, the laboratory has processed 1, 943,252 SARS-CoV-2 patient samples as of 03/25/2021, 6:43 p.m. (PST). ANALYTIC SYSTEMS		D5209	Accessioning: Accessioning consists mainly of bar All unsatisfactory specimens are checked by a suprejecting the sample. Upon assessment, no perforr were identified, therefore, there is no impact on particular and impact on patient care. (3) Preventative Measure: A more formal training new technologists has been put in place. Since the has many performing employees there is more opinew staff to observe procedures and work with trasupervisors. The redesigned training forms present help to facilitate this process. Paper copies of all personnel records have been creacilitate audit requests more quickly and efficient (4) Monitoring Mechanism: A review of records December to present indicates: There continues to be no documentation is Data Analysts who are reviewing and releas. In the PCR area, all 18 staff trained from m 2020 to present have all training document completed In Extraction, of the 42 individuals trained December or later, 42/42 were properly document chemagic automated nucleic acid extraction. An insufficient number of new hires in Acc started since mid-December to assesses effenowever, effectiveness will be assessed as no made. In addition to mock audit exercises, the mo audits conducted as part of the monthly au assess whether personnel documentation is complete.	ervisor prior to nance issues attent care. bulk has no g program for laboratory now portunity for iners or ted in Finding eated to ly. from midsues with the ing results, id-December attion properly in midsumented for nd 41/42 (one ted for the procedure, essioning ctiveness; ew hires are			
D5400			,	D5400	Finding 6: Of the 30 randomly selected samples: • 5/5 Accessioning personnel have complete to documentation • 5/5 Extraction personnel have complete train documentation. 1/5 had a delayed signature Reformatter training at the time she ran 10 shown here; however, she was reassessed proceeding the remaining 11 / 21 samples. Upon reassed determined to be adequately trained and all ran were successful. • 3/3 PCR personnel have complete training deceeding training deceeding to the successful of the successful training deceeding to the successful of	ning for / 21 samples for to running ssment she was samples she documentation ocumentation		
	CFR(s): 493.1250	performs nonwaived te	esting		(3) Preventative Measure: See findings 4 and 5. (4) Monitoring Mechanism: See findings 4 and 5.			

(4) Monitoring Mechanism: See findings 4 and 5.

STATEMENT	OF DEFICIENC ES	(X1) PROVIDER/SUPPLIER/C	:LIA	(X2) MULTIF	PLE CONSTRUCTION	(X3) DATE SUF	RVEY		
AND PLAN O	F CORRECTION	IDENTIFICATION NUMBI	ER:	A. BUILDING	S	COMPLETI	ĒD		
		СРН88933	39	B. WING		04/22	2/2021		
NAME OF PR	OVIDER OR SUPPL ER		STREET ADDR	DRESS, CITY, STATE, ZIP CODE					
CDPH BR	ANCH LABORATOR	Y		IVINGSTON CIA, CA 913					
(X4) D PREFIX TAG	(EACH DEFICIENCY MUS	TATEMENT OF DEFICIENC ES T BE PRECEDED BY FULL RE ENTIFYING NFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTI (EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPROI DEFICIENCY)	D BE	(X5) COMPLETION DATE		
D5209	Continued From page 6 completed competency assessment for 236 out of 426 (approximately 55%) of the total laboratory staff, prior to processing, testing, and reporting patient results. 6. The following are the accession numbers of the 30 randomly reviewed patient test records covering the period from 12/07/2020 to 01/13/2021, wherein the laboratory tested and reported 30 out of 30 SARS-CoV-2 patient samples but failed to ensure it followed the Quality Management Plan policies and procedures for competency assessment. Accession Number		ratory ing ers of ds nd	D5209	Continued from page 6 • 2 were removed from testing and re-assessed 2021 and found to be adequately trained • 10 of these individuals were reassessed in Ja February (7) and March (1) and found to be trained. For the 10 / 166 (6%) were found in a mid-Decembration of the chemagic automacid extractor: • 4 of these individuals were re-assessed by a December 2020 and found to be adequately 6 of these individuals were re-assessed in February 10 and found to be adequately trained Attachment D5209_3z). Accessioning: The accessioning process for this lair requires: • Scanning of the barcode on the sample • Batching into groups of 94 samples for testing into groups of 94 samples and in this prebruary 2021 (see Attachments D5209_3q – D5209. Review of records showed that 47 / 160 training redelayed; however, all have been completed. These of signatures were spread across the four shifts. Train accessioning staff for heat inactivation was documentable appropriately by February 2021 for 158 / 160 of the staff. No staff were found to have deficiencies in the Attachments D5209_3q – D5209_3y). Audit process: Paper copies of personnel files have to aide in timeliness of audit responses. (1) Patient Impact: Data Analysts and the Sign-Out Manager. Training 21/21 is minimal because: • There is complete overlap in the tasks betwee Extraction and Data Analysis • Data Analysis cannot be completed without Extraction and PCR: Training for all PCR staff was adequately called the process.	nuary (2), a adequately per to have a mated nucleic Supervisor in trained or			
D5400	03/25/2021, the labor 943,252 SARS-CoV- 03/25/2021, 6:43 p.m ANALYTIC SYSTEM CFR(s): 493.1250	ratory has processed 1 2 patient samples as o n. (PST).	f	D5400	for one for four individuals. Since the data show the carried out correctly and the data were accepted by there is evidence that this omission did not impact Extraction: The limited number of instances of midocumentation identified are unlikely to impact pathe assay steps performed in extraction do NOT in review or analysis.	the trainer, patient care. ssed training tient care since			

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(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENC ES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY A. BUILDING AND PLAN OF CORRECTION IDENTIFICATION NUMBER: COMPLETED **CPH889339** B. WING 04/22/2021 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLER CDPH BRANCH LABORATORY 28454 LIVINGSTON AVE VALENCIA, CA 91355 (X5) COMPLETION SUMMARY STATEMENT OF DEFICIENC ES PROVIDER'S PLAN OF CORRECTION (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX **PREFIX** (EACH CORRECTIVE ACTION SHOULD BE DATE OR LSC DENTIFYING NFORMATION) CROSS-REFERENCED TO THE APPROPRIATE TAG TAG DEFICIENCY) D5400 D5400 Continued From page 7 D5407 - The CDPH Branch Laboratory recognizes the Janus G3 3May2021 must meet the applicable analytic systems instrument protocol (CA-PCR-SOP-001) did not have detailed instructions on manual pipetting to accomplish the needed reagent requirements in §§493.1251 through 493.1283, transfer, it also did not expressly prohibit the technologist from unless HHS approves a procedure, specified in doing so. Detailed instructions were added in a later version of protocol. Similarly, CDPH review of the Sample Transfer Using Appendix C of the State Operations Manual the Janus G3 protocol (CA-EXT-SOP-003) recognized that this (CMS Pub.7), that provides equivalent quality SOP did not have specific guidance for situations with insufficient the sample volume. The determination that it could be a future testing. The laboratory must monitor and need, the Laboratory Director requested an updated SOP. The evaluate the overall quality of the analytic Laboratory recognizes the Issuing Amended or Corrected Reports protocol (CA-SOP-RPT-003) version 1.0 was in draft mode and systems and correct identified problems as not signed by the part-time laboratory directors (24Oct2020 specified in §493.1289 for each specialty and 27Jan2021) but was approved by the currently Laboratory Director on 28Jan2021. subspecialty of testing performed. D5779, D5787, D5891 - CDPH Branch Laboratory had two overarching policies and procedures, approved the Laboratory This Condition is not met as evidenced by: Director, to directly address when and how to address problems Based on the number and severity of the that required corrective actions: The Quality Management Plan (QMP) and the Quality Exception Reporting (QER) and CAPA deficiencies cited herein, the Condition: plan. When an error was detected, all stakeholders (Dr. Pan, California Dept of Public Health and Testing Task Force) in the ANALYTIC SYSTEM was not met. testing process were notified. The laboratory acknowledges that a discretionary decision was made in the interest of public health to Findings included: not give a patient conflicting information, but rather inform the patient an error was made and recommend re-testing, therefore, the language in the laboratory record for the repeated test/analysis The laboratory failed to ensure procedure and the result stated on the amended report are different. The CDPH Branch Laboratory is changing the notification procedures manuals were updated, approved, signed, and for amended reports so that Dr. Pan, the ordering clinician, is dated by the current Laboratory Director (See notified of the error and provided an individual record for each affected specimen. D5407). 2. The laboratory failed to ensure it followed corrective action policies to ensure accurate and reliable patient test results (See D5779). The laboratory failed to ensure its test record provided the correct disposition of specimens, its corrected result, with incorrect result (noted as such) for SARS-CoV-2 (See D5787). The laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems (D5791). D5407 PROCEDURE MANUAL D5407 CFR(s): 493.1251(d)

	OF DEFICIENC ES F CORRECTION	(X1) PROVIDER/SUPPLIER/C IDENTIFICATION NUMBER			PLE CONSTRUCTION G	(X3) DATE SUR COMPLETE	
		СРН88933	9	B. WING		04/22	2/2021
NAME OF PR	OVIDER OR SUPPL ER		STREET ADDF	RESS, CITY, ST	ATE, ZIP CODE		
CDPH BR	ANCH LABORATOR	Υ		IVINGSTOI CIA, CA 91:			
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D5407	Procedures and charapproved, signed, ar laboratory director be assed on interviews February 7, and 8, 2 procedures (P/P), quassurance (QA) recopatient test records of 11/06/2020 to 01/13/patient test records of that the laboratory fadirector approved, si procedure for Janus manual pipetting of the automated bench workstation designed set-up, procedure for storage (STO) plate, issuing amended or Findings included: 1. Backup procedumed Manual pipetting of the automated liquid har automated liquid har a. Based on review Exception Reports (002/07/2020 and 02/00 issues with Janus G3 errors on 12/10/2020 technicians were instantial signed.	inges in procedures must and dated by the current efore use. It met as evidenced by: with laboratory staff on 021, review of policies a faility control (QC) and quords, random review of covering the period from 2021, for 208 out of 208 eviewed, it was determined to ensure the laboragned and dated the back G3 instrument, such as reagents and master mixerrors are encountered with the processing low volume and the procedure for corrected reports. The for Janus G3 instruments are encountered with the procedure for corrected reports.	and uality Barned atory kkup Vith e for a ent: Vith try nad ting PCR	D5407	Finding 1 Through the course of laboratory operations and scenarios that had not happened in the jidentified. The solutions to these newly iden are then reviewed with laboratory managem laboratory director for appropriate mitigation same process that is followed at the CDPH ELaboratory. The CDPH Branch Laboratory recognizes the instrument protocol (CA-PCR-SOP-001) we are effective date between 27Oct2020 and 27) not have specific guidance for error situation required manual pipetting of reagents. Throidentification of this scenario and the determit would be a future need, a subsequent updato of the SOP, was reviewed and implemented of the SOP, was reviewed and implemented of the content is based on feedback from the costaff and our then newly hired full-time laboratory. Reference section 11.4 for the specito to the technologists. It is also important to note that manual pipe standard laboratory practice that all technologistic to the technologists. It is also important to note that manual pipe standard laboratory practice that all technologistic to the technologists. In response to finding leat no point did the director or anybody else present during the meeting with LFS on 4/22/2021 (10.40am) maffirmation. This statement is inaccurate. Pleattachment 1. (1) Immediate Corrective Action: The laboratory provide are updated version of the SOP-001 to include error scenarios that requipietting on 27Jan2021. (2) Patient Impact: Upon review, the plate I controls passed as well as the internal controls pa	past are tified items ent and the son. This is the Branch are Janus G3 rsion 1.0 with Janus G3 rsion 1.0 with Janus G1 are Janus G3 rsion 1.0 with Janus G1 are Janus G3 rsion 1.0 with Janus G1 are Janus G2 ratory fic instruction are Janus G2 ratory fic instruction are Janus G2 ratory fic instruction are Janus G3 rsion 1.0 with Janus G1 are Janus G2 rsion 2.0 are Janus G2 rsion 2.0 are Janus G2 rsion 2.0 are Janus G3 rsion 1.0 with Janus G3 rsion 1.0 with Janus G1 are Janus G3 rsion 1.0 with Janus G1 are Janus G3 rsion 1.0 with Janus G1 are Janus G3 rsion 1.0 with Janus G3 rsion 1.	3May2021
	b. Review of the la	boratory policies and			and there would not be patient harm for fail document specific instructions for manual p		

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b. Review of the laboratory policies and

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	OF DEFICIENC ES F CORRECTION	(X1) PROVIDER/SUPPLIER/CI IDENTIFICATION NUMBER		` '	PLE CONSTRUCTION	(X3) DATE SUR COMPLETE	
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NAME OF PR	OVIDER OR SUPPL ER		STREET ADDR	RESS, CITY, ST	ATE, ZIP CODE	•	
CDPH BR	ANCH LABORATOR	Y	28454 L	IVINGSTO	I AVE		
				CIA, CA 913			
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D5407	7 Continued From page 9 procedures (SOP # CA-PCR-SOP-001, Title SARS-CoV-2 RT-PCR Set-up Using Janus G3, Effective Date 11/04/2020) did not include the procedures for manual pipetting of reagents and master mix to the PCR plate whenever there are issues with the automated Janus G3 liquid handler. c. The following are the accession numbers of the 6 randomly reviewed patient test records covering the period from 12/09/2020 to 12/10/2020, wherein the laboratory performed manual pipetting of reagents and master mix to the PCR plate as a backup procedure for the automated Janus G3 liquid handler when it had issues with pipetting error.		G3, ne and e are s of c to ed	D5407	(3) Preventative Measure: Through the course of Laboratory operations situations and scenarios occ not happened or have not been recognized are ider a young laboratory and all possible errors or gaps is cannot be anticipated and/or documented. The so newly identified issues (omissions, discrepancies, econtrolled documents) are reviewed with laborator and the laboratory director for appropriate mitigat incorporation into SOPS, as appropriate. The curro Director participates in regular meetings with tech supervisors and wet laboratory managers to discus and regulatory initiatives. His review and approval process, and procedures in advance of documented retterated regularly. The laboratory staff and superencouraged to make requests for SOP updates with identifying a needed change. In addition, the curre Director participates in regular meetings with the where any issue with document control (QER, Au Gemba (walkthrough) observation) is discussed an with meeting minutes. The quality and laboratory the SOPs and submit it for approval by the laborator (4) Monitoring Mechanism: During any of the auprocesses, if any uncontrolled document is discove has been a change in policy, process, plan or proce a controlled document, that has not been signed of laboratory director and QA manager, this is noted nonconformance and would follow the CAPA corr process. As part of the Quality Management Plan t clinical staff and laboratory director perform blent SOPs to ensure they encompass the best practices I within the laboratory workflow.	cur that have titified. We are in processes lutions to these berrors in yr management ion and ent Laboratory nical, general s improvement of policy, plan, i change is rvisors are along 12 hours of int Laboratory Quality team dit Process, or did documented groups update ory director. Iditing cred or there dure, or use of fiby the as a ective action he laboratory hall review of its	
	 d. Based on the laboratory director's email on 03/25/2021, the laboratory has processed 1, 943,252 SARS-CoV-2 patient samples as of 03/25/2021, 6:43 p.m. (PST). e. The Laboratory Director affirmed (04/22/2021 at 10:40 a.m.) the laboratory failed to ensure the laboratory director approved, signed and dated the backup procedure for Janus G3 instrument, such as manual pipetting of reagents and master mix whenever pipetting errors are encountered with the automated benchtop liquid handler workstation designed to automate-RT-PCR set-up. 		/2021 e the ted ent, aster		Finding 2 This particular finding references 16 patient sample with insufficient volume for a storage (STO) plate. down the specific incident that was not referenced finding, it was determined that this QER-20-031 we volume STO plate issue; rather, a cassette of specint tipped during decapping, prior to extraction, and a of some of the specimen volumes spilled. The Tech Supervisor on site was immediately notified. This windown minor spill, remaining volumes in the sample tubes determined to be adequate, and the specimens were Extraction for processing on the JanusG3 (CA-EXT The reports for these 16 patient samples are attached confirmation (see Attachment B_5). As LFS, an outside auditor, uncovered an omission that they deemed deficient and critical, the CDPH I review the Sample Transfer Using the Janus G3 pro EXT-SOP-003) as we would any external audit resprecognized that this SOP did not have specific guid situations where the sample volume was insufficient initial or the storage (STO) plate. While unsatisfac rejection is a preanalytical activity, through the ident this scenario and the determination that it could be	After tracking in the LFS as not a low sens that was small portion nical vas treated as a swere e submitted to "-SOP-003). ed as in a procedure Laboratory did dtocol (CA-oonse. It was ance for it for either the tory specimen ntification of	

the Laboratory Director requested an updated SOP.

	OF DEFICIENC ES F CORRECTION	(X1) PROVIDER/SUPPLIER/C IDENTIFICATION NUMBI CPH88933	ER:	A. BUILDING	PLE CONSTRUCTION	(X3) DATE SUR COMPLETE			
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D5407	 2. Procedure for processing low volume for a storage (STO) plate a. Based on review of the laboratory Quality Exception Reports (QER) documents on 02/07/2020 and 02/08/2020, the laboratory had an error scenario when there is not enough sample volume for a storage (STO) plate. b. Review of the laboratory policies and procedures (SOP # CA-EXT-SOP-003, Title Sample Transfer Using the Janus G3, Effective Date 12/06/2020) did not include the guidance to the technician for an error scenario when thereis not enough sample volume for a storage (STO) plate. c. The following are the accession numbers of the 16 reviewed patient test records on 12/08/2020, wherein the laboratory had an error scenario when there is not enough sample volume for a storage (STO) plate, and the procedure manual did not include the guidance on how to proceed with this low volume error. d. Based on the laboratory director's email on 		ity nad itive ce to ereis TO) rs of error	D5407	Continued from page 10 In response to finding 2e at no point did the labora anybody else present during the virtual meeting wit 4/22/2021 (10:40am) make this affirmation. This st inaccurate. Please refer to attachment 1. (1) Immediate Corrective Action: For the particul referenced in Finding 2, there is no immediate corredovever, based on the LFS observation, the SOP haversion 6.0, to reflect this scenario (see Attachment section 7.1.1.2 for the specific instruction to the tecminimum sample volume is 270ul and the storage pto be used if needed, there is no action required for volume for the secondary backup storage plate. The referenced in the SOP. Supervisors in the Extraction laboratory conducted in person training with their this update to the SOP as well as to invite discussion situations that testing personnel have questioned. Secondary 2 for evidence of training that is in progress (2) Patient Impact: Only one sample, D-641508700 positive and review of batch QC for this sample as a heatmap did not indicate sample or batch contamin Director, Dr. Rosendorff, there is no change in diagor recommended patient action for the 16 samples this citation and there would not be patient harm. Treported. (3) Preventative Measure: Through the course of C Laboratory operations situations and scenarios occhappened in the past are identified. We are a youn all possible errors or gaps in processes cannot be an solutions to these newly identified items are review laboratory management and the laboratory director mitigation and incorporation into SOPS, as appropeurrent Laboratory Director participates in regular meeting and general supervisors as well as wet-laboratory miscuss improvement and regulatory initiatives. His approval of policy, plan, process, and procedures in implementation is reiterated regularly. The laborat supervisors are encouraged to make requests for SC withing 12 hours of identifying a needed change. In current Laboratory Director participates in regular the Quality team where any issue with document	ar incident ective action. as been updated, A). Reference hnologists. As olate is a backup insufficient is is now n section of the teams to discuss n as to other. See Attachment is as the batch nation. Per Lab gwell as the batch in the results were composed to the results were glaboratory and titicipated. The ed with for appropriate riate. The gwell advance of ory staff and opp updates a addition, the meetings with ontrol (QER, n) is discussed y and			
•	d. Based on the laboratory director's email on 03/25/2021, the laboratory has processed 1, 943,252 SARS-CoV-2 patient samples as of 03/25/2021, 6:43 p.m. (PST).				(4) Monitoring Mechanism: During any of the audif any uncontrolled document is discovered or ther change in policy, process, plan or procedure, or use document, that has not been pre-approved by the L Director and QA lead, then this is noted as a nonco would follow the CAPA corrective action process. A Quality Management Plan the laboratory clinical st laboratory director perform biennial review of its S they encompass the best practices being applied wit laboratory workflow.	e has been a of a controlled aboratory informance and As part of the aff and OPs to ensure			

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	OF DEFICIENC ES F CORRECTION	(X1) PROVIDER/SUPPLIER/C IDENTIFICATION NUMBER			PLE CONSTRUCTION	(X3) DATE SUR COMPLETE	
		СРН88933	39	B. WING		04/2:	2/2021
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D5407	at 10:40 a.m.) the lab laboratory director approcedure that will procedure that will procedure that will envolume sample for streports 3. Procedure for issue reports a. At the time of continuous and procedure the early morning houle laboratory provided the policy and procedure Corrected Reports" (which stated the procedure at CDPH Branch Lab b. The following are the 38 out of 38 revier covering the period fir 11/23/2020, wherein reports without an approcedure to the state of the	Director affirmed (04/22 poratory failed to ensure oproved, signed and darovide guidance to the nocunter error due to locarge plate. Suing amended or corresponding to the district and unsigned titled, "Issuing Amended SOP # CA-SOP-RPT-0 pedural guidelines for issuing dictinical patient test reporatory, Valencia CA. The the accession number the event patient test record to more the laboratory amended proved and signed policuling amended or correct testing amended test	e the ted a www. acted uring d ed or 03) suing ports rs of ds d cy	D5407	·	ersion 1.0 was in tory directors is startup for this postanalytical ne 3rd party reports cited in yeek of dicated fulltime tartup was an inplicated ining of our ne discussions d on 08Feb2021. ulred for the atory director or th LFS on tatement is director on 08Feb2021. at the laboratory he patient and dam ed procedure dreports were procedure. Or the look back by time period pact related to a process, and the regularly. The process, and the regularly of Gemba mented with ps update the lirector. Ternal auditing alled document is ocess, plan or noted as a action process. atory clinical	
					ensure they encompass the best practices being applaboratory workflow.		

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	OF DEFICIENC ES CORRECTION	(X1) PROVIDER/SUPPLIER/CI IDENTIFICATION NUMBE			PLE CONSTRUCTION	(X3) DATE SUR COMPLETE	
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NAME OF PR	OVIDER OR SUPPL ER		STREET ADDR	ESS, CITY, ST	ATE, ZIP CODE	I.	
CDPH BR	ANCH LABORATOR	Y		LIVINGSTON AVE NCIA, CA 91355			
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D5407	03/25/2021, the labo 943,252 SARS-CoV-03/25/2021, 6:43 p.m d. The Laboratory at 10:40 a.m.) the lab laboratory director age the procedure manual corrected reports for CORRECTIVE ACTICER(s): 493.1282(a) Corrective action polibe available and follomaintain the laborator patient specimens in accurate and reliable reports. This Standard is not Based interviews with 02/07/2021 and 02/0 and procedures (P/P quality assurance (Quest records covering to 11/23/2020, for 38 records reviewed, it viaboratory failed to eliaboratory fai	poratory director's email ratory has processed 1, 2 patient samples as of n. (PST). Director affirmed (04/22, poratory failed to ensure oproved, signed, and dail for issuing amended SARS-CoV-2. ONS dicies and procedures moved as necessary to pry's operation for testing a manner that ensures a patient test results and met as evidenced by:	/2021 e the lited ust g I es nd tient 2020 etive	D5407	the test and, the individus results of rep (2) Issue cor promptly to person order and, if applic individual us results. (3) Maintain	es and tres accurate ratory had typproved the tow to address lity in Reporting uality System ity mprovement to capture and tions (QE). The nalytical phase previously the issued when do or amended danges, typically stanalytical drafted (not he laboratory sesed in D5407. document does al with pproval of the merates the procedures. The lab's wered during t to submit an nented as an and laboratory 2-month start- prective action closed and the ded reports t COLOR portal. on (i) of each of that there is no d reports were prized person 1291 Standard: reported detected, the following: reported detected, the following: rotify the erson ordering if applicable, al using the test sorting errors. rected reports the authorized ing the test cable, the sing the test duplicates of report, as well as	3May2021

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` ,		(X1) PROVIDER/SUPPLIER/C IDENTIFICATION NUMBE	ERICLIA		LE CONSTRUCTION	(X3) DATE SURVEY COMPLETED	
		СРН88933	39	B. WING		04/22	2/2021
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CDPH BR	ANCH LABORATORY	1	28454 L	IVINGSTON	I AVE		
			VALEN	CIA, CA 913	355		
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D5779	the early morning hou laboratory provided the policy and procedure Corrected Reports" (5 which stated the procedure of the corrected at CDPH Branch Laboratory are ports, section 5 "Post that a laboratory error Branch Laboratory error Branch Laboratory of affected reports need laboratory director, or responsibility must contain the laboratory failed to drafted policy and procedure directed reports will issue the corrected reports will elaboratory failed to drafted policy and procedure directed reports. Genomics did not have correcting and retracting and re	mplaint investigation during of 02/08/2021, the me drafted and unsigner titled, "Issuing Amende SOP # CA-SOP-RPT-0 edural guidelines for issuid clinical patient test reporatory, Valencia CA. afted laboratory policy a amended or corrected blicy" stated, "In the every is discovered, CDPH of the color genomics of the corrected. The individual with delegate mmunicate the approvito Color. Color Genomed reports." It test records on 02/08/20 ensure it followed the color system in place for the color system in place	d ed or 03) suing ports and ent of the ted rai of nics 2021, elended color r corary close ternet	D5779	Continued from page 13 Copies of both the Original and A Reports for each of these patient stotal) are submitted with this resp. Attachments B_1, B_2 and B_3. COLOR made results available or patient access as allowed by Exect N-52-20. (1) Immediate Corrective Action: The Laboratory has notified Dr. Pan of each original report, the amended report and a leher about the amended report has been subraffected sample. Original and Amended Reports with accompnotification letters for the 38 records cited in observation as well as the same documentatis subsequent incidences are attached (see Atta The attachment also includes the acknowled receipt from Dr. Pan. (2) Patient Impact: With respect to the health of community the Laboratory Director, Dr. Adam Rodetermined the patient impact of those with initiall results but later not detected results would likely repsychological stress due to the diagnosis and need to risolation. There would be minimal patient healtidecision on potential treatments or hospitalization made by the patient's medical provider on the basis rather than a positive test result. With respect to the patient and community the Laboratory Director, Dr. Rosendorff, determined the patient impact of those not detected results but later either detected or prepositive did pose a risk to the patient and the community the Laboratory Director, Dr. Rosendorff, determined the patient impact of those not detected results but later either detected or prepositive did pose a risk to the patient and the community result reported by any laboratory. The College of American Pathology (CAP) field tindicators through their Q-TRACKS program an a statistical median rate of 2.8 test result correctibillable tests. Among results released in 2020 and CDPH Branch Laboratory had ~0.83 and ~0.24 presult corrections which is lower than the median by the CAP Q-TRACKS program, therefore, this determined to not be outside of industry standard D5821). Quality Indicator Monitoring Guidance. College of Pathology, 2011 (see Attachment D5	error. The tter notifying mitted for each panying nitted for each panying mitted for each exhibition for each mitted exhibition for quarantine himpact as the would be so of symptoms ne health of the riter at the would be with initially sumptive munity due to delay in ar to a false extend 11 and determined ons per 10,000 test in 2.8 reported error rate is discontinuous formation in letters and in receipt. The irreport, the general end in the receipt. The individual	
	i. A total of 22 patie	ent test reports were			Reports folder.		

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	OF DEFICIENC ES F CORRECTION	' '	X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:		PLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED	
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D5779	Continued From pag	ge 14		D5779	Continued from page 14		
	originally issued on 1	11/14/2020. Corrected			Continued from page 11		
	reports were subseq	uently issued on 11/25/2	2020,		(4) Monitoring Mechanism: An amended reports		
	11 days after the issu	uance of the original rep	ort.		conducted every month, assessing the QERs associated with each event, the cause, the number of reports, the review of both original		
	There was no evidence submitted to show the amended reports were sent to each patient or to the authorized person who requested the test. ii. The following are the accession numbers of the 22 out of 22 patient test results, which were amended 11 days after the issuance of the original report, with no evidence to show that amended reports were sent to each patient or to				and amended report. See FY2021 Audit Schedule,		
			or to		D5779_1. The Amended Report Audit Plan (see All D5779_2) is updated to include the review of subm		
					and acknowledgement of receipt from Dr. Erica Pa the verification of submission and subsequent ackn	n. In addition,	
					of receipt of amended reports to Dr. Pan has been	added to the	
					monthly Quality Management Review as a POST A quality assessment metric, with a target of 100% or		
			ere		of failure to submit.		
	tne autnorized perso	n who requested the tes	ST.				
	- O!:t	D					
		n Report (QER)-20-012					
		easing the incorrect file					
	uploaded in LIMC.						
	ient t	est report, accession nu	ımher				
		originally issued on					
		cted report was subsequ	iently				
		0, 8 days after the issua					
		•					
		There was no evidence					
		at an amended report w					
		to the authorized perso	n				
	who requested the te	est.				ļ	

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(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENC ES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY AND PLAN OF CORRECTION A. BUILDING COMPLETED IDENTIFICATION NUMBER: CPH889339 B. WING 04/22/2021 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLER **CDPH BRANCH LABORATORY** 28454 LIVINGSTON AVE VALENCIA, CA 91355 (X5) COMPLETION DATE SUMMARY STATEMENT OF DEFICIENC ES PROVIDER'S PLAN OF CORRECTION (X4) D (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX **PREFIX** (EACH CORRECTIVE ACTION SHOULD BE TAG OR LSC DENTIFYING NFORMATION) TAG CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) D5779 D5779 Continued From page 15 d. Quality Exception Report (QER)-20-013 and CAPA-20-004 stated an incorrect assigned data belonging to samples in a different batch were released to a different batch of plate. A total of 15 patient test reports were originally issued on 11/23/2020. Corrected reports were subsequently issued on 12/01/2020, 8 days after the issuance of the original report. There was no evidence submitted to show amended reports were sent to each patient or to the authorized person who requested the test. The following are the accession numbers of the 15 out of 15 patient test results which were amended 8 days after the issuance of the original report, with no evidence to show that amended reports were sent to each patient or to the authorized person who requested the test. 4. Based on the laboratory director's email on 03/25/2021, the laboratory has processed 1, 943,252 SARS-CoV-2 patient samples as of 03/25/2021, 6:43 p.m. (PST).

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D5787	record system that in (a)(1) The positive id (a)(2) The date and to the laboratory. (a)(3) The condition at that do not meet the specimen acceptability (a)(4) The records are testing, including the performed the test(s). This Standard is not Based interviews with 02/07/2021 and 02/0 and procedures (P/P quality assurance (Quality assurance (Quality assurance) (a) test records covering to 11/20/2020, for 38 records reviewed, it valaboratory failed to exprovided the correct corrected result, with such) for SARS-CoV. Findings included: 1. Based on interview on 02/07/2021 and 0 several patient test reto the following: a. Quality Exception	maintain an information icludes the following: entification of the specir ime of specimen receip and disposition of specil laboratory's criteria for ity. In disposition of all speciment identity of the personner identity of the personner. In the period from 11/14/2 is out of 38 patient test was determined that the insure its test record disposition of specimens incorrect result (noted	men. t into mens nel who es nd tient 2020 es, its as	D5787 D5787	Findings 1 and 2 compare the language of original report with the language used to amend the incorrect report. It amended reports to not include the correct disposition o (correct result) with the incorrect result. The finding co the testing errors that were discovered (and documented results had been reported. Theses 3 incidences in Nov/D amended reports are described in detail in D5779 Findin 3c (1 report) and 3d (15 reports). Finding 2 specifically observes that the repeated result in records (which is located in the documented QER's and same as the result on the amended report. Through the poversight by the California Department of Public Health Task Force, all testing collected at California COVID-19 sites during the pandemic is performed under the Prescr Dr. Erica Pan, the Acting State Health Officer. The labor acknowledges that a discretionary decision was made in public health to not give a patient conflicting information inform the patient an error was made and recommend remarks and the result stated on the amended report are. The SOP that was in draft (See D5407 Finding 3 for a detand later approved stated that all amended reports are re "Unable to return results for this sample. The previously (insert original result) is not valid due to a process error. test, and test date of the original report and the original r document." The LFS finding that the first two incidences (1a:22 samp sample) did not contain the original result as part of the is correct. The initial reporting of amended results did ne requested language as stated in the SOP. The stakeholder California Dept of Public Health and Testing Task Force the original and amended results for these patients and the made by the laboratory to not update the amended report would not change the recommendation for the patient to other amended reports generated since these two incider original result and date of testing. This notification and in are being submitted to Dr. Pan., the ordering clinician, to determination as to the appropriateness of pat	states that our f specimen rrectly explains on QERs) after ec that required g 3b (22 reports), the laboratory LIMC) is not the bartnership and and the Testing testing collection ibing Order from atory the interest of n, but rather e-testing, repeated test/different. tailed summary) ported as: reported result The barcode, the esult are in this oles and 1b: 1 amended report to conform to the rs (Dr. Pan, 1) were aware of he decision was rt again as it be retested. All nees contains the until the position of the conform to the return of the ret	3May2021
		ent test reports were 1/14/2020, and correcte	ed		The Laboratory has notified Dr. Pan, through th Public Health, that the original report and a letter all amended results will be submitted to her for a	er of correction for	

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results.

(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENC ES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY A. BUILDING AND PLAN OF CORRECTION IDENTIFICATION NUMBER: COMPLETED **CPH889339** B. WING 04/22/2021 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLER **CDPH BRANCH LABORATORY** 28454 LIVINGSTON AVE VALENCIA, CA 91355 (X5) COMPLETION SUMMARY STATEMENT OF DEFICIENC ES PROVIDER'S PLAN OF CORRECTION (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX **PREFIX** (EACH CORRECTIVE ACTION SHOULD BE DATE OR LSC DENTIFYING NFORMATION) CROSS-REFERENCED TO THE APPROPRIATE TAG TAG DEFICIENCY) D5787 Continued From page 17 D5787 Continued from page 17 reports were subsequently issued on 11/25/2020. Original and Amended Reports with accompanying notification letters for the 38 records cited as well as the same documentation for subsequent incidences (Look The following are the accession numbers of forward from the first two months of operation) are the 14 out of 22 patient test results initially attached (See Attachment C). The attachment also reported as "Positive" on 11/14/2020. includes the acknowledgment of receipt from Dr. Pan. (2) Patient Impact: With respect to the health of the patient and community the Laboratory Director, Dr. Adam Rosendorff, determined the patient impact of those with initially detected results but later not detected results would likely result in patient psychological stress due to the diagnosis and need for quarantine or isolation. There would be minimal patient health impact as the decision on potential treatments or hospitalization would be made by the patient's medical provider on the basis of symptoms rather than a positive test result. With respect to the health of the patient and community the Laboratory Director, Dr. Adam Rosendorff, determined the patient impact of those with initially not detected results but later either detected or presumptive positive did pose a risk to the patient and the community due to the risk of viral The following are the accession numbers of transmission to close contacts and delay in seeking medical the 8 out of 22 patient test results initially reported as "Negative" on 11/14/2020. (3) Preventative Measure: Submission of notification letters and results to Dr Pan occurs by email with request read receipt. The submission email with the accompanying acknowledgment will be electronically stored in the individual event file within the Quality Management archived Amended Reports folder. (4) Monitoring Mechanism: An amended reports audit is conducted every month, assessing the QERs associated with each event, the cause, the number of reports, the review of both original and amended report. See D5791 for the FY2021 Audit Schedule iv. On 11/25/2020, 11 days after the issuance of and the Amended Report Audit Plan, which is updated to include the original report, the report for the 22 patients the review of submission of letters and acknowledgement of receipt from Dr. Erica Pan. In addition, the verification of were amended. submission and subsequent acknowledgement of receipt of amended reports to Dr. Pan has been added to the monthly Quality Management Review as a postanalytical quality The laboratory indicated in the patient test assessment metric, with a target of 100% or no incidences of reports, "Unable to return results for this sample. failure to submit. Please disregard any previous reports as they were issued in error. The following report are no longer valid and hereby rescinded." vi. The amended reports indicated 14 false positive results and 8 false negative results were initially reported on 11/14/2020. Quality Exception Report (QER)-20-012

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stated an error in releasing the incorrect file

uploaded in LIMC.

	STATEMENT OF DEFICIENC ES AND PLAN OF CORRECTION (X1) PROVIDER/SUPPLIEI IDENTIFICATION NUI CPH889		ER:	A. BUILDING	LE CONSTRUCTION	(X3) DATE SUF COMPLET	
NAME OF BB	0//050 00 0//00/ 50		STDEET ADD	RESS, CITY, STA	ATE ZIR CODE		
	OVIDER OR SUPPLER	v		LIVINGSTON			
СОРН ВК	ANCH LABORATOR	Y					
			VALEN	CIA, CA 913			
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D5787	Continued From pag	je 18		D5787			
	 i. One patient was originally issued on 11/20/2020, and corrected report was issued on 11/28/2020. ii. The patient test result was initially reported as "Positive" on 11/20/2020. 						
	Accession number						
	iii. On 11/28/2020, 8 days after the issuance of the original report, the report was amended.						
	iv. The laboratory indicated in the patient test reports, "Unable to return results for this sample. Please disregard any previous reports as they were issued in error. The following report are no longer valid and hereby rescinded."						
		port indicated a false po ported on 11/20/2020.	ositive				
	c. Quality Exception Report (QER)-20-013 and CAPA-20-004 stated an incorrect assigned data belonging to samples in a different batch were released to a different batch of plate.						
	i. A total of 15 patient test reports were originally issued on 11/23/2020, and corrected reports were subsequently issued on 12/01/2020.						
	ii. The following are the accession numbers of the 5 out of 15 patient test results initially reported as "Positive" on 11/23/2020.						

STATEMENT OF DEFICIENC ES (X1) PROVIDER/SUPPLIE		(X1) PROVIDER/SUPPLIER/C	ΙΙΔ	(X2) MULTIP	LE CONSTRUCTION	(X3) DATE SUI	R//EV	
	F CORRECTION	IDENTIFICATION NUMBER		A. BUILDING		COMPLET		
		СРН88933	9	B. WING		04/22/2021		
NAME OF PR	OVIDER OR SUPPL ER		STREET ADD	RESS, CITY, STA	TE, ZIP CODE			
CDPH BR	ANCH LABORATOR	Υ		28454 LIVINGSTON AVE VALENCIA, CA 91355				
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D5787	Continued From pag	ge 19		D5787				
	the 8 out of 15 patier as "Negative" on 11/	e the accession number nt test results were repo	rs of					
	the original report, the were amended. vi. The laboratory in reports, "Unable to re-	8 days after the issuance report for the 15 patient to a conditional transfer to the same of the same	ents est aple.					
	were issued in error.	"	- ,					
	comments in the am	also added thefollowing ended reports.						
	reported result (to a laboratory p Recommendation retested. AMENDED REF	PORT: The previously Detected) is not valid do process error. pn: This patient should be PORT: The previously Not Detected) is not vali	e					

due to

STATEMENT OF DEFICIENC ES AND PLAN OF CORRECTION (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: (X2) MULTIPLE CONSTRUCTION A. BUILDING COMPLETED (X3) DATE SURVE COMPLETED (X4) PROVIDER SUPPLIER CONSTRUCTION A. BUILDING DATE SURVE COMPLETED)
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NAME OF PROVIDED OR OVERLED.	
NAME OF PROVIDER OR SUPPLER STREET ADDRESS, CITY, STATE, ZIP CODE	
CDPH BRANCH LABORATORY 28454 LIVINGSTON AVE	
VALENCIA, CA 91355	
(X4) D SUMMARY STATEMENT OF DEFICIENC ES ID PROVIDER'S PLAN OF CORRECTION PREFIX (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY TAG OR LSC DENTIFYING NFORMATION) TAG OR LSC DENTIFYING NFORMATION) TAG CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D5787 Continued From page 20 D5787 D5791: This particular finding 1 and 2 indicates that the laboratory	3May2021

If continuation sheet Page 21 of 43 YL3M11 State 2567

assurance (QA) records, random review of

AND PLAN OF CORRECTION IDENTIFICATION NUM		(X1) PROVIDER/SUPPLIER/C IDENTIFICATION NUMBE CPH88933	ER:	A. BUILDING	PLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED 04/22/2021	
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CDFH BK	ANCH LABORATOR	1					
			VALENC	CIA, CA 913	100		
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D5791	Continued From page	ie 21		D5791	Continued from page 21		
	patient test records covering the period from 11/14/2020 to 01/13/2021, for 20 out of 20 patient test records reviewed, it was determined that the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in CFR 493.1251 through 493.1283. Findings included: 1. Review of the laboratory's policies and procedures (Policy # CA-QM-SOP-001, Quality Management Plan, Effective 03/01/2021) failed to include an ongoing mechanism to perform or document quality issues regarding the following: a. The laboratory failed to ensure the laboratory director approved, signed and dated the backup procedure for Janus G3 instrument, such as manual pipetting of reagents and master mix whenever pipetting errors are encountered with the automated benchtop liquid handler workstation designed to automate-RT-PCR set-up, procedure for processing low volume for a storage (STO) plate, and the procedure for issuing amended or corrected reports (See D5407). b. The laboratory failed to ensure it followed corrective action policies to ensure accurate and reliable patient test results (See D5779). c. The laboratory failed to ensure its test record provided the correct disposition of specimens, its corrected result, with incorrect result (noted as such) for SARS-CoV-2 (See D5787).			However, As stated earlier, in D5407 Finding observation made by LFS of the low volume prompted a review (following the laboratory improvement and corrective action process a audit observation) of the documented QER at to that particular incident. It was determined particular scenario was not described and the Extraction SOP was updated, version 6.0, to instructions. Reference section 7.1.1.2 for thinstruction to the technologists. This is a go how the laboratory's continuous process improrrective action works. 10 specimens, described in QER-20-010, did amended reports due to a barcode error. O Finding 1a: The discussion about former in the process of	STO plate 's continuous for any external and SOP related d that this e Janus G3 provide e specific od example of provement and		
			led to r ing: atory kup vith		approve the Amended Report SOF described in detail in D5407 Finding Finding 1b: After discovery of the was documented as a QER and cor plan was put into place. Finding 1c: Patients were notified original result had been issued incovere advised to be retested. The rewas not changed due to public heat that changing a result could result on the part of the patient. In additionation the part of the patient. In additionation the original specimen may no long patient's true status. Therefore, the made that the amended report shot that the original report was issued recommend that the patient be re- (1) Immediate Corrective Action: The immediate cactions for each of the items addressed (1a) specific approved by Lab Director (2b) not following correct related to amended reports and (3b) not providing the disposition of specimens are fully addressed in D540 D5787 respectively. (2) Patient Impact: The patient impact for each of addressed (1a) specific procedures not approved by (2b) not following corrective action plan related to a reports and (3b) not providing the correct disposition of specimens or providing the correct disposition are fully addressed in D5407, D5779 and D5787 respectively.	Phas been ng 3. If a graph of the error, the error rective action that their correctly and sult of the test lith concerns in confusion ion, since time to the patient's he result from the reflect the edecision was ald only state in error and tested. Corrective procedures not tive action plan the correct 17, D5779 and the items Lab Director unended on of specimens	
				(3)Preventative Measure: Through the course of CDPH Branch Labora situations and scenarios occur that have not be past are identified. We are a young laborator possible errors or gaps in processes cannot be The solutions to these newly identified items with laboratory management and the laborate appropriate mitigation and incorporation interpretable appropriate. The current Laboratory Director regular meetings with technical, general and supervisors to discuss improvement and reguintitatives.	nappened in the y and all anticipated. are reviewed ory director for o SOPS, as r participates in operational		

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D5791	Continued From page 22 2. The following are the accession numbers of the 20 randomly reviewed patient test records covering the period from 11/14/2020 to 01/13/2021, wherein the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems.			D5791	His review and approval of policy, plan, process, and procedures in advance of implementation is reiterated regularly. The laboratory staff and supervisors are encouraged to make requests for SOP updates withing 12 hours (1 shift) of identifying a needed change. In addition, the current Laboratory Director participates in regular meetings with the Quality team where any issue with document control (QER, Audit Process, or Gemba (walkthrough) observation) is discussed and documented with meeting minutes. The quality and laboratory groups update the SOPs and submit it for approval by the laboratory director prior to implementation. • For Amended Reports: Submission of notification letters and results to Dr Pan occurs by email with request read receipt. The submission email, the original report, the amended report, the individual notification letter and the accompanying acknowledgment will be electronically stored in the individual event file within the Quality Management archived Amended Reports folder. (4) Monitoring Mechanism:		
D5800	03/25/2021, the labor 943,252 SARS-CoV-03/25/2021, 6:43 p.m POSTANALYTIC SYSTEP CFR(s): 493.1290 Each laboratory that must meet the applicate requirements in §493 a procedure, specifie Operations Manual (Composition of the equivalent quality test monitor and evaluate postanalytic systems problems as specified		esting ms proves State des ust	D5800	During any of the auditing processes, if any use document is discovered or there has been a clare process, plan or procedure, or use of a controst that has not been pre-approved by the Labora and QA lead, then this is noted as a nonconfowould follow the CAPA corrective action prothe Quality Management Plan the laboratory and laboratory director perform biennial revito ensure they encompass the best practices by within the laboratory workflow. During the monthly amended report audit, at made of QERs associated with each event, the number of reports, the review of both original report. The FY2021 Audit Schedule and the Report Audit Plan (see Attachments D5779_which is updated to include the review of subletters and acknowledgement of receipt from In addition, the verification of submission an acknowledgement of receipt of amended reports as been added to the monthly Quality Mana as a POST Analytical quality assessment metrof 100% or no incidences of failure to submit Monitoring timely completion of QER and Cadded to the Quality Management Review with documented signature approval of the writter plan targeted for completion within 15 days.	hange in policy, olled document, atory Director ormance and ocess. As part of clinical staff iew of its SOPs being applied ssessment is e cause, the al and amended Amended I and D5779_2) omission of Dr. Erica Pan. In the subsequent orts to Dr. Pan agement Review ric, with a target it. CAPA's has been ith an expected	

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This Condition is not met as evidenced by:

	OF DEFICIENC ES F CORRECTION	(X1) PROVIDER/SUPPLIER/CI IDENTIFICATION NUMBE			PLE CONSTRUCTION	(X3) DATE SUR	
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CDPH BR	ANCH LABORATOR	Y		IVINGSTOI CIA, CA 91:			
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D5800	Based on the severity of the deficiencies cited herein, it was determined that the condition Postanalytic Systems was not met as mandated by CLIA in Subpart K of Title 42 of the Code of Federal Regulation. Findings included: 1. The laboratory failed to ensure its test report provided the correct condition and disposition of specimens that were not tested for SARS-CoV-2 (See D5805). 2. The laboratory failed to ensure it promptly notified and issued amended reports to the individual using the test results (See D5821). 3. The laboratory failed to establish and follow		D5805 - The CDPH Branch Laboratory the laboratory acknowledges that the outcome code for samples that become untestable due to laboratory error did not adequately consider reporting language that would be used when this code was selected. This language will be revised. D5821 and D5891 - The CDPH Branch Laboratory experience delay in sending notification of laboratory error during a 2-wee period in late November and early December. Stakeholders, including Dr. Erica Pan, were notified of the amended results a the delay from time of identifying and solving the problem, retesting, resulting and posting to the Color portal. The CDPF Branch Laboratory strives for improvement which can be seen our median response time in Q1 2021 of 17hours. The quality indicator for amended reports was initially set as a % of reporte tests; no target metric was assigned in November or December. The College of American Pathology (CAP) field tested 11 indicators through their Q-TRACKS program and determined statistical median rate of 2.8 test result corrections per 10,000 billable tests. Among results released in 2020 and in 2021, CDP branch laboratory had ~0.83 and ~0.24 per 10,000 test result corrections which is lower than the median 2.8 reported by the CAP Q-TRACKS program.		hat become ely consider the ode was y experienced a rring a 2-week echolders, ded results and problem, . The CDPH can be seen by The quality % of reported or December. sted 11 determined a per 10,000 n 2021, CDPH test result	3May2021	
D5805	mechanism to monitor indicated, correct propostanalytic systems TEST REPORT CFR(s): 493.1291(c) The test report must (c)(1) For positive parapatient's name and identiful (c)(2) The name and location where the te (c)(3) The test report (c)(4) The test perform (c)(5) Specimen sour (c)(6) The test result of measurement or in (c)(7) Any information disposition of specimilaboratory's criteria for	indicate the following: tient identification, either dentification number, or ier and identification nu address of the laborate st was performed. date. med. rce, when appropriate. and, if applicable, the un terpretation, or both. In regarding the conditio ens that do not meet th	er the a umber. bry units	D5805	Findings 1-5 Samples submitted to the laboratory may be unsatitesting for a variety of reasons including preanalytical steep the container leaking or the container is. During the analytical process a sample may become if the testing fails multiple times and a result canno sample can also become untestable due to a laborat laboratory acknowledges that our code for samples untestable due to laboratory error ("UNSAT6") did consider the reporting language that would be used was selected. These errors include lost, discarded or damaged splaboratory accidents, scanning errors, or mishandli specimen. Although the reporting language does not change the test for the patient since retesting would be nec not accurately reflect the disposition of the sample, acknowledges that the reporting language should be case of laboratory error. (1) Immediate Corrective Action: A request was in Genomics by the Laboratory Director on April 30, the language of the report to say, "Test could not be to laboratory error." It is expected that the change in no later than 01Jun2021.	cal issues such missing swab. e unsatisfactory to be obtained. A tory error. The that become I not adequately I when this code ecimens due to ing of the the outcome of essary, it does. The laboratory e changed in the made to Color 2021, to change e completed due	•

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STATEMENT OF DEFICIENC ES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/C IDENTIFICATION NUMBE		1 1	PLE CONSTRUCTION G	(X3) DATE SUR COMPLETE	
	СРН88933	9	B. WING		04/22	2/2021
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ODI II BILANGII EABORATORI	•		CIA, CA 913			
		VALEN	CIA, CA 913	595		
PREFIX (EACH DEFICIENCY MUST	FATEMENT OF DEFICIENC ES T BE PRECEDED BY FULL RE ENTIFYING NFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF CORRECT (EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPRO DEFICIENCY)	LD BE	(X5) COMPLETION DATE
D5805 Continued From pag	e 24		D5805	(2) Patient Impact: Although the language used p	reviously did not	
Based on interviews of February 7, and 8, 20 procedures (P/P), qual assurance (QA) recompatient test records on 11/06/2020 to 01/13/2 patient test records rethat the laboratory fail provided the correct of specimens that were recorded to the correct of specimens that were recorded to the correct of specimens that were recorded to the lateral provided the correct of the lateral specimens (QER) and Correct (QER) and laboratory had several discarded, and invalid laboratory accident, splates used, and low of the correct of the correct of the correct of the provide the correct of the correct of the provide the correct of the	with laboratory staff on 021, review of policies a ality control (QC) and quirds, random review of overing the period from 2021, for 208 out of 208 eviewed, it was determined to ensure its test recondition and disposition not tested for SARS-Control (Saranda) amples for SARS-Co	enture deposit of the content of the	D5805	(2) Patient Impact: Although the language used p accurately describe that a laboratory error occurre was advised that no result was obtained, and that r recommended. The language used on the report ha patient care since the recommendation did not che (3) Preventative Measure: The Accessioning Supe selected "UNSAT" codes prior to release to ensure has been selected. (4) Monitoring Mechanism: • As this occurrence has entered the CAPA perfectiveness check will be conducted for two days post implementation of the new report language to verify implementation. • Samples unable to be tested due to laborator reported on quality exception reports (QER QERs by the Quality team during weekly sc involves reviewing the incident with the labor Manager (technical supervisor). This proconfirming that the correct "UNSAT" code in the event of a laboratory error. One patie each incident will be viewed to ensure correct code was used, and correct report template. • A daily email goes out to all key stakeholded Dept of Public Health, California Testing T. California Health and Human Services, incl. Pan) that includes the number and type of Unsatisfactory specimens) received and traind shifts. UNSAT Code 6 indicates Labora Attachment D8505_1). • Unsatisfactory Samples are also tracked as a indicator and reported in monthly quality results.	d, the patient etesting was add no impact on ange. Privisor reviews all the correct code to consecutive template ry error are s). Review of heduled meeting oratory section occess will include has been applied nt report from the tunnal fr	

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(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENC ES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY AND PLAN OF CORRECTION **IDENTIFICATION NUMBER:** A. BUILDING COMPLETED CPH889339 B. WING 04/22/2021 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLER **CDPH BRANCH LABORATORY** 28454 LIVINGSTON AVE VALENCIA, CA 91355 (X5) COMPLETION DATE SUMMARY STATEMENT OF DEFICIENC ES PROVIDER'S PLAN OF CORRECTION (X4) D (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX **PREFIX** (EACH CORRECTIVE ACTION SHOULD BE TAG OR LSC DENTIFYING NFORMATION) TAG CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) D5805 D5805 Continued From page 25 a. Lost/Missing/Discarded (e.g. laboratory accident, scanning errors) specimens were reported as "Unsatisfactory sample. Test could not be completed. The specimen failed to produce a valid result after 2 attempts." There was no documentation submitted showing there were two attempts made to get a result, and what were the nature of these attempts. 62 out of 62 patient samples on 11/06/2020 (B0000455). QER 20-006 indicated four sample cassettes were inadvertently discarded. The laboratory reports indicating the samples were unsatisfactory, when in fact the samples were inadvertently discarded is misleading, and failed provide the correct condition and disposition of the specimens.

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AND PLAN C	F CORRECTION	IDENTIFICATION NUMBI	ER:	A. BUILDING		COMPLE	TED
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CDPH BRANCH LABORATORY			28454 I	LIVINGSTON	AVE		
			VALEN	CIA, CA 913	55		
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D5805	Continued From pag	ge 26		D5805			
	(B0000992). QER 20 As new samples wer were being discarded mistakenly discarded unsatisfactory. The la the correct condition specimens.	re being loaded, old sand. Eight samples were d. These samples were aboratory failed to provious and disposition of the mples on 11/26/2020. Oles were inadvertently	nples not de				
	iv. 6 out of 6 patien QER 20-019. The sa the Janus Reformatt discarded. These sa	aboratory failed to provi and disposition of the at samples on 12/11/202 imples were not scanne er. The samples were mples were not aboratory failed toprovi	20. ed on				

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(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENC ES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY A. BUILDING AND PLAN OF CORRECTION IDENTIFICATION NUMBER: COMPLETED CPH889339 B. WING 04/22/2021 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLER **CDPH BRANCH LABORATORY** 28454 LIVINGSTON AVE VALENCIA, CA 91355 (X5) COMPLETION DATE SUMMARY STATEMENT OF DEFICIENC ES PROVIDER'S PLAN OF CORRECTION (X4) D (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX **PREFIX** (EACH CORRECTIVE ACTION SHOULD BE TAG OR LSC DENTIFYING NFORMATION) TAG CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) D5805 Continued From page 27 the correct condition and disposition of the specimens. 4 out 4 patient samples on 12/13/2020. QER 20-023. These four samples were also noted in QER 20-019. The samples were not scanned on the Janus Reformatter. The samples were discarded. These samples were not unsatisfactory. The laboratory failed to provide the correct condition and disposition of the specimens. vi. 3 out of 3 patient samples on 12/22/2020. b. Lost/Missing/Discarded (e.g. laboratory accident, scanning errors) specimens were reported as "Unsatisfactory sample. Test could not be completed. The test could not be completed because the sample was unsatisfactory." 3 out of 3 patient samples on 11/18/2020

STATEMENT OF DEFICIENC ES AND PLAN OF CORRECTION (X1)		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:			LE CONSTRUCTION	(X3) DATE SURVEY COMPLETED		
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D5805	ii. 2 out 2 patient s (iden (iden	camples on 12/04/2020 tiffied missing on 12/07/ tiffied missing on 12/12/ amples on 12/13/2020 tient samples on 12/22/2	2020)	D5805				

STATEMENT OF DEFICIENC ES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:			E CONSTRUCTION		(X3) DATE SURVEY COMPLETED		
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D5805	c. Invalidated (e.g. improperly scanned is reported as "Unsatist not be completed." T produce a valid result was no documentation were two attempts making were the nature of the scanner	incorrect plates, lowvo barcodes) specimens w factory sample. Test con the specimen failed to at after 2 attempts. Ther on submitted showing the ade to get a result, and	vere uld e nere I what	D5805					

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STATEMENT OF DEFICIENC ES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA		` ′	PLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED				
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			VALEN	CIA, CA 913	355					
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D5805	Continued From pag	je 30		D5805	D5821		22.6			
D5805	Continued From page 30 ii. 1 out of 1 patient sample on 01/02/2021 d. Invalidated (e.g. incorrect plates, lowvolume, improperly scanned barcodes) specimens were reported as "Unsatisfactory sample. Test could not be completed." The test could not be completed because the sample was unsatisfactory. i. 16 out of 16 patient samples on 01/13/2021			D5805	This finding states that the laboratory did not promptly notify the authorized person ordering the test and, if applicable, the individual using the test results that an error in reporting had occurred. CFR 493.1291(k) states that the laboratory must perform the activities promptly but does not specifically define the number of days. Upon review of the QERs it was determined that the laboratory took action to provide corrected reports within the timeframes below. QER-20-010 – 3 days from incident to identification of issue; 4 days to perform the investigation and notification to Color Health which included rerunning the sample in question to confirm the results. QER-20-012 – 1 day from incident to identification of the issue; 4 days to perform the investigation and notification to Color Health which included rerunning the sample in question to confirm the results. QER-20-013 – 6 days from incident to identification of the issue; same day to perform the investigation and notification to Color Health The CDPH Branch Laboratory strives for improvement which can be seen by our median response time in Q1 2021 of 17hours (see Attachment D5821_1). There is no regulatory requirement for a laboratory to assess any particular process with a quality indicator (42 CFR 493.1701); the selection is left to the discretion of the Laboratory Director. The initial Quality Management Plan, drafted and approved by the previous Lab Director, was a best attempt at how to assess, monito.		3May2021			
	due to laboratory accincorrect plates used reported as unsatisfathis does not provide disposition of the specific. Based on the laboratory accinctly according to the second seco	poratory director's email ratory has processed 1, 2 patient samples as of	er, nd on		laboratory testing: preanalytical, analytical and post Finding established benchmarks for a peer compari volume, automated one test (new) laboratory was n The quality indicator for amended reports was initi reported tests; no target metric was assigned in Nov December. The College of American Pathology (C. 11 indicators through their Q-TRACKS program at statistical median rate of 2.8 test result corrections phillable tests. Among results released in 2020 and ir branch laboratory had ~0.83 and ~0.24 per 10,000 t corrections which is lower than the median 2.8 rep CAP Q-TRACKS program. When CDPH Lab data target of performance, the lab conducts a document investigation to problem solve, determine root caus implement corrective measures to improve the perf	son for a large ot possible. ally set as a % of rember or AP) field tested ad determined a per 10,000 to 2021, CDPH est result orted by the exceed defined ted ee and				
D5821		eported patient test resu	ılts	D5821	Based on our performance to industry standard, the not determine a quality issue with amended reports Quality Indicator Monitoring Guidance. College of Pathology, 2011 (see Attachment D5821_2).	e laboratory did				
	are detected, the lab	oratory must do the								

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following:

STATEMENT OF DEFICIENC ES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:		(X2) MULTIPLE CONSTRUCTION A. BUILDING					(X3) DATE SURVEY COMPLETED				
CPH88			39	B. WIN	G				-		04/22/2021		2021
NAME OF PR	ROVIDER OR SUPPL ER		STREET ADDR	RESS, CITY	, STATE	, ZIP COD	E				1		
	RANCH LABORATOR	Υ	28454 L	IVINGS	TON A	VE							
			VALEN	CIA, CA	91355	5							
(X4) D PREFIX TAG	SUMMARY STATEMENT OF DEFICIENC ES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX OR LSC DENTIFYING NFORMATION) TAG					PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)						(X5) COMPLETION DATE	
D5821	Continued From page	ie 31		D58	321 Co	ntinued fro	om page 3	1					
	(k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report. This Standard is not met as evidenced by: Based interviews with laboratory staff on 02/07/2021 and 02/08/2021, review of policies and procedures (P/P), quality control (QC) and quality assurance (QA) records, review of patient test records covering the period from 11/14/2020 to 11/20/2020, for 38 out of 38 patient test records reviewed, it was determined that the laboratory failed to ensure it promptly notified and issued amended reports to the individual using the test results.				Through the partnership and oversight by the California Dept of Public Health and the Testing Task Force, the laboratory has put in place procedures to align with the contractual agreements for preanalytical and postanalytical test order management, specimen collection and result reporting processes. The Laboratory has a Prescribing Order from the California Department of Public Health issued by Dr. Erica Pan, the Acting State Health Officer, to perform SARS-CoV-2 testing specifically on samples collected from participants at California COVID-19 testing collection sites. All results are released per the agreement between the State of California and the CDPH Branch Laboratory-related service agreements. There are two 'users' of the Covid testing conducted at this laboratory: Color Genomics and OptumServe; the ordering clinician is Dr. Pan. All placed electronic orders and samples obtained at California Dept of Public Health approved collection sites route through the COLOR database and portal. Results obtained at CDPH Branch Laboratory are transmitted electronically to COLOR for creation of the patient report and release of results to Optum Serve, the patient and CalREDIE through their online portal. Dr Pan receives aggregated test results on a daily basis via the CDPH Branch Laboratory daily update that includes the number of samples received, the number of samples received, the precentage positive, negative, unsatisfactory, invalid and presumptive positive over a 30 day sliding window. See D5805. As the contractual relationship with COLOR Genomics was being finalized shortly before the laboratory started testing, the focus for initial start-up was the routine report templates. The Laboratory Director had not formally approved CA-RPT-SOP-003 (Issuing								
	Findings included: 1. Executive Order N-52-20 provided temporary regulatory relief permitting a provider to disclose COVID-19 test results to a patient via the Internet or other electronic means, prior to reviewing patient test results.				Th we Te: Dr we bei rea CC sur 20-	port templa e 3 inciden ek period i sting Task . Erica Pan re notified ing aware o unalyzing d DLOR (the mmarized i -010, COLC curs on the	ces noted n late Nov Force, Ca, , and Cali of the am of the prob ata, result 'user') wa in the tabl OR's posti same day	in this obvember as lifornia D fornia Of ended resolem, solving and ps notified e below. It ing of the ras notified as notified	oservation and early Dept of Pufice of He sults and ting the prosting to . The time is noted amended cation. Re	occurred ecember. blic Healt alth and I the delay toblem, ro the Color eline for t that that report to sults were	d during a California th, including Human Se- from time etesting an portal wh he 3 event except for the portal e made	2- a ng rvices of d/or een s is	
	2. Based on interview with the laboratory sta on 02/07/2021 and 02/08/2021, there were several patient test results reported in error du			QER#		mediately a	N-52-20 o	# of Days	RCA and	COLOR	R portal as	Days to	LFS Stated
	to the following: a. Quality Exception	n Report (QER)-20-010) and			Issued	Problem	Post Issue	Results in LIMC	Notified to Amend	Report Issued to Portal	Resolve Post Aware	Delay in Reporting
		errors in barcode entry		20- 010	22	14Nov	17Nov	3	21Nov	21nov	25Nov	5	11
	. 5 5			20- 012	1	20Nov	25Nov	1	27Nov	28Nov	28Nov	3	8
	-	ent test reports were 1/14/2020. Corrected		20- 013	15	23Nov	28Nov	5	01Dec	01Dec	01Dec	3	8

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AND PLAN C	F CORRECTION	IDENTIFICATION NUMBE	=K:	A. BUILDING	<u> </u>	COMPLETE	ΞD
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NAME OF PE	ROVIDER OR SUPPL ER		STREET ADD	RESS, CITY, ST	ATE, ZIP CODE		
CDPH BF	RANCH LABORATOR	Υ		LIVINGSTOI CIA, CA 91:			
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D5821	Continued From pag		D5821	Continued from page 32			
	reports were subsequently issued on 11/25/2020, 11 days after the issuance of the original report. There was no evidence submitted to show the amended reports were sent to each patient or to the authorized person who requested the test. ii. The following are the accession numbers of the 22 out of 22 patient test results, which were amended 11 days after the issuance of the original report, with no evidence to show that amended reports were sent to each patient or to the authorized person who requested the test.			ation, the CDPH scedures for ician, can make ent notification om the in the error to posted, the error to posted, the example of the california ited amended dering clinician, naying letter ted for each rts with is cited in this subsequent when the patient and sendorff, ly detected in patient and need for atient health cospitalization in the basis of respect to the y Director, Dr. of those with d or and the close contacts			
		n Report(QER)-20-012 easing the incorrect file	2		(3) Preventative Measure: Dr. Pan will be notified of all results issued in error. Submission of notification letters and results to Dr Pan occurs by email with request read receipt. The submission email, the original report, the amended report, the individual notification letter and the accompanying acknowledgment will be electronically stored in the individual event file within the Quality		
	was of 11/20/2020. A correct issued on 11/28/2020 of the original report, submitted to show the sent to the patient, or who requested the terminal was a submitted to show the sent to the patient, or who requested the terminal was a submitted to show the sent to the patient, or who requested the terminal was a submitted to show the sent to the patient.	est report, accession nu originally issued on ted report was subsequed, 8 days after the issua There was no evidence at an amended report of to the authorized persect.	uently ance e vas on		Management archived Amended Reports folder. CDPH Branch Laboratory and Color Health have t three times a week. A call between the Laboratory, and Optum Serve is held once a week. These forma communication channels, as well as real-time commemail and phone ensures prompt response to a requestreated reports or to be aware of upcoming corrected reports.	Color Health Il munication via uest to issue	

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CAPA-20-004 stated an incorrect assigned data

STATEMENT OF DEFICIENC ES AND PLAN OF CORRECTION		S (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:			PLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED	
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NAME OF PR	OVIDER OR SUPPL ER		STREET ADDR	RESS, CITY, ST	ATE, ZIP CODE		
CDPH BR	ANCH LABORATOR	Y		IVINGSTON			
(X4) D PREFIX TAG	(EACH DEFICIENCY MUS	TATEMENT OF DEFICIENC ES ST BE PRECEDED BY FULL RE ENTIFYING NFORMATION)		TAG CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)			
D5821	- 1 5	•		D5821	Continued from page 33		
	belonging to samples released to a differer i. A total of 15 pationiginally issued on 1 were subsequently is after the issuance of was no evidence subreports were sent to authorized person wiii. The following art the 15 out of 15 patie amended 8 days after report, with no evider reports were sent to authorized person wiii.	s in a different batch we	eports days re ed rs of ere ginal led		(4) Monitoring Mechanism: An amended reports audit is conducted every month, assessing the QERs associated with each event, the cause, the number of reports, the review of both origin and amended report. See FY2021 Audit Schedule and the Amended Report Audit Plan (see Attachments D5779_1 and D5779_2) is updated to include the review of submission of letter and acknowledgement of receipt from Dr. Erica Pan. In addition the verification of submission and subsequent acknowledgement receipt of amended reports to Dr. Pan has been added to the monthly Quality Management Review as a postanalytical quality assessment metric, with a target of 100% or no incidences of failu to submit. D5891 This particular finding 1 and 2 indicates that the laboratory failed to meet the CFR 493.1291 standard for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified the postanalytical system/phase of laboratory, more specifically called the Test Report. The standard states that patient specific data (results) are accurately and reliably sent from the point of dentry to final report destination, in a timely manner. There are 12 points (a-1) with multiple subparts that define the requirements. As has been stated previously, in preparation for the start of testin last fall, the laboratory had established 2 overarching policies and procedures, approved by the Laboratory Director, to directly address when and how to address identified problems that required corrective actions: The Quality Management Plan (QMI and the Quality Exception Reporting (QER) and CAPA plan. Each of the foundational Quality System Essentials (QSE) that support the laboratory's operations are supported by the Continuous Improvement and Occurrence Management QSE; its' purpose is capture and analyze information originating from quality exceptions (QE) that occur in ALL phases of laboratory testing. The Quality Management Plan (v2 01Mar2021) in Section 5.5.3 specifically addresses the postanalytical mechanisms to monitor, assess, and w		3May2021
	943,252 SARS-CoV- 03/25/2021, 6:43 p.m	• •			retained, but the extracted DNS is stored at least 1 r depending on testing volume and storage capacity.	HONTN	
D5891	POSTANAI YTIC SY	STEMS QUALITY		D5891			

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ASSESSMENT

	OF DEFICIENC ES F CORRECTION	(X1) PROVIDER/SUPPLIER/C IDENTIFICATION NUMBE		1 1	(X2) MULTIPLE CONSTRUCTION A. BUILDING		(X3) DATE SURVEY COMPLETED		
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NAME OF PR	OVIDER OR SUPPL ER		STREET ADDR	RESS, CITY, ST	ATE, ZIP CODE				
CDPH BR	ANCH LABORATOR	Y	28454 L	28454 LIVINGSTON AVE					
				CIA, CA 91					
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D5891	policies and procedu mechanism to monitor indicated, correct propostanalytic systems This Standard is not Based on interviews 02/07/2021 and 02/0 and procedures (P/P quality assurance (Q. patient test records of 11/14/2020 to 01/13/2 test records reviewed laboratory failed to expolicies and procedu mechanism to monitor indicated, correct proposition analytic systems specimens include an ongoing modocument quality issued. The laboratory faprovided the correct of specimens that were (See D5805).\ The laboratory fanotified and issued an indicated and issued as possible of the correct of the specimens that were (See D5805).\ The laboratory fanotified and issued as possible of the correct of the specimens that were (See D5805).\	establish and follow writeres for an ongoing or, assess and, when blems identified in the specified in §493.1291 met as evidenced by: with laboratory staff on 8/2021, review of policiely, quality control (QC) a A) records, random reviovering the period from 2021, for 20 out of 20 pad, it was determined that stablish and follow writtines for an ongoing	es nd ew of latient the en latient led to r ing: eport n of bV-2	D5891	The Quality Management Plan also provides param known as key quality indicators, to monitor activitic patient outcome that will affect many patients. These valuated by comparing the lab's performance again thresholds for performance and available published The type and number of monitored indicators are dalaboratory's scope of care. This laboratory perform SARS-CoV-2 RT-PCR and testing started in this lab of November, 2020. It takes a few months to establish thresholds and be able to track shifts and trends as documented and process improvements are initiate. There is no regulatory requirement for a laboratory particular process with a quality indicator (42 CFR selection is left to the discretion of the Laboratory Enitial Quality Management Plan, drafted and approprevious Lab Director, was a best attempt at how to and document quality activities during startup and possible indicators that would be selected for the thaboratory testing: preanalytical, analytical and post Finding established benchmarks for a peer compari volume, automated one test (new) laboratory was n quality indicator for amended reports was initially septorted tests; no target metric was assigned in Nov December. The College of American Pathology (C. 11 indicators through their Q-TRACKS program ar statistical median rate of 2.8 test result corrections pibillable tests. Among results released in 2020 and in branch laboratory had ~0.83 and ~0.24 per 10,000 to corrections which is lower than the median 2.8 repo CAP Q-TRACKS program. When CDPH Lab data target of performance, the lab conducts a document to problem solve, determine root cause and implem measures to improve the performance. Based on out to industry standard, the laboratory did not determ issue with amended reports. The laboratory acknowledges that it failed to detect observations made by LFS during its onsite visit on 08Feb. Following the receipt of the inspection repo 23Apr2021, the lab implemented its Continuous Im Occurrence Management Plan. Each of the observa investigated, root	es critical to be indicators are ist defined benchmarks. ependent on the sone test, oratory the first ship performance quality issues are d. to assess any 493.1701); the birector. The birector. The word by the assess, monitor indicated the rece phases of analytical. son for a large of possible. The et as a % of ember or AP) field tested in determined a ber 10,000 2021, CDPH est result by the exceed defined ed investigation ent corrective in a quality when the two specific 07Feb and ret dated provement and tions were rective action in the steps and e untestable due that our code the steps and the steps and a content of the steps and a content			
	_	e the accession number			These errors include lost, discarded or damaged spe laboratory accidents, scanning errors, or mishandlii specimen.				

STATEMENT OF DEFICIENC ES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/C IDENTIFICATION NUMBE			PLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED				
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NAME OF PR	OVIDER OR SUPPL ER		STREET ADDR	STREET ADDRESS, CITY, STATE, ZIP CODE						
CDPH BR	ANCH LABORATOR	Y		28454 LIVINGSTON AVE VALENCIA, CA 91355						
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D5891	Continued From pag	je 35		D5891	Continued from page 35					
	the 20 randomly reviewed patient test records covering the period from 11/14/2020 to 01/13/2021, wherein the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the postanalytic systems.				Although the reporting language does not change the test for the patient since retesting would be neconot accurately reflect the disposition of the sample. acknowledges that the reporting language should be the case of laboratory error. (1) Immediate Corrective Action: A request was not Genomics by the Laboratory Director on April 30, the language of the report to say, "Test could not be due to laboratory error." It is expected that the chareffect no later than 07May2021. (2) Patient Impact: Although the language used prinot accurately describe that a laboratory error occupatient was advised that no result was obtained, and was recommended. The language used on the repoil impact on patient care since the recommendation of (3) Preventative Measure: The Accessioning Superior accurately describe Measure: The Accessioning Superior accurately described that the characteristic described that the cha	essary, it does The laboratory e changed in made to Color 2021, to change e completed nge will be in reviously did rred, the d that retesting rt had no lid not change.				
D6076	03/25/2021, the labor 943,252 SARS-CoV-03/25/2021, 6:43 p.m LABORATORY DIRECFR(s): 493.1441 The laboratory must the qualification required this subpart and provand direction in accounties subpart. This Condition is not on the severity of the was determined that	have a director who me irements of §493.1443 rides overall management rdance with §493.1445 met as evidenced by: Experiments of the condition Laborator aplexity Testing, Labora	eets of ent of Based in, it	D6076	all selected "UNSAT" codes prior to release to ensu code has been selected. (4) Monitoring Mechanism: • As this occurrence has entered the CAPA preffectiveness check will be conducted for two days post implementation of the new report language to verify implementation. • Samples unable to be tested due to laborator reported on quality exception reports (QERs QERs by the Quality team during weekly schemeeting involves reviewing the incident will section or Manager (technical supervisor). To include confirming that the correct "UNSAT been applied in the event of a laboratory erreport from each incident will be viewed to a UNSAT6 code and correct report template is each incident will be viewed to a Cunsata confirming that the correct and the pept of Public Health, California Testing Ta California Health and Human Services, includent) that includes the number and type of U (Unsatisfactory specimens) received and train and shifts. UNSAT Code 6 indicates Laborat et unsatisfactory Samples are also tracked as a indicator and reported in monthly quality results.	ocess, an o consecutive template y error are s). Review of neduled n the laboratory 'his process will r'' code has or. One patient ensure correct s used. s (California askforce, uding Dr. Erica 'NSAT cked for trends tory Error. key quality				

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	OF DEFICIENC ES F CORRECTION	(X1) PROVIDER/SUPPLIER/C IDENTIFICATION NUMBE		, , -	LE CONSTRUCTION	(X3) DATE SUR COMPLETE	
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D5891	covering the period find 1/13/2021, wherein establish and follow was procedures for an on monitor, assess, and problems identified in 1/2 and problems iden	ewed patient test record from 11/14/2020 to the laboratory failed to written policies and going mechanism to when indicated, correct the postanalytic system or the postanalytic system	on , f eets of eent of Based in, it	D5891	Continued from page 35 Finding 1b: In reviewing LFS observation and the laboratory's sicause analysis and findings, the CDPH Branch Labochanging the notification procedures for amended r Dr. Pan, the ordering clinician, can make the detern the appropriateness of patient notification based on and the amount of time from the collection and orig There is no change in the laboratory process of com laboratory error to COLOR for creation of the amer Once posted, the patient has access to results. See E. (1) Corrective Action: Even though the California Health was already aware of these cited amended re Laboratory is supplying Dr. Pan, the ordering clinic and amended reports with an accompanying letter the amended report has been submitted for each aff The Original and Amended Reports with accompan notification letters for the 38 records cited in this obwell as the same documentation for subsequent inci attached (See Attachment C). (2) Patient Impact: With respect to the health of the community the Laboratory Director, Dr. Adam Ros determined the patient impact of those with initially results but later not detected results would likely respect/hological stress due to the incorrect diagnosis a quarantine or isolation. There would be minimal painpact as the decision on potential treatments or he would be made by the patient's medical provider on symptoms rather than a positive test result. With rehealth of the patient and community the Laboratory Adam Rosendorff, determined the patient impact of initially not detected results but later either detected presumptive positive did pose a risk to the patient a community due to the risk of viral transmission to cond delay in seeking medical attention. (3) Preventative Measure: Dr. Pan will be notified, hours of notification to COLOR of an amended report and results issued in error. Submission of notification results to Dr Pan occurs by email with request read submission email, the original report, the amended Report solder. (4) Monitoring Mechanism: An amended reports ac	pratory is reports so that mination as to previous result ginal report. Immunicating a nded report. Dept of Public stults, the cian, all original notifying her feeted sample. The provious as idences are the patient and sendorff, y detected stult in patient and need for attent health ospitalization in the basis of espect to the provious proviou	
	Findings included:				receipt of amended reports to Dr. Pan has been add monthly Quality Management Review as a postanal assessment metric, with a target of 100% or no incid to submit.	ed to the ytical quality	

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(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENC ES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY A. BUILDING AND PLAN OF CORRECTION IDENTIFICATION NUMBER: COMPLETED **CPH889339** B. WING 04/22/2021 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLER CDPH BRANCH LABORATORY 28454 LIVINGSTON AVE VALENCIA, CA 91355 (X5) COMPLETION SUMMARY STATEMENT OF DEFICIENC ES PROVIDER'S PLAN OF CORRECTION (X4) D (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY **PREFIX PREFIX** (EACH CORRECTIVE ACTION SHOULD BE DATE OR LSC DENTIFYING NFORMATION) CROSS-REFERENCED TO THE APPROPRIATE TAG TAG DEFICIENCY) D6076 D6076 D6076 Continued From page 36 03May2021 1. The Laboratory Director failed to ensure The current full-time, on-site Laboratory Director (effective quality assurance activities were established and 27Jan2021) is actively involved in the day-to-day operations maintained by the laboratory to assure the quality of the laboratory. The Quality Management Review process is now, as of Feb 2021, a monthly review, not a quarterly of services provided, and to identify failures in review. All laboratories have events that deviate from quality as they occur (See D6094). prescribed workflow and processes; it is the reason for continuous improvement and occurrence management. The Laboratory Director is actively overseeing enhancements to 2. The Laboratory Director failed to ensure the both Training/Orientation (CA-PER-SOP-001) and laboratory staff demonstrated competency prior to Competency (CA-PER-SOP-002 policies and procedures as evidenced by 412 / 412 (100%) of employees involved in the reporting patient test results (See D6102). testing process have documented training and a successful roll-out of 6-month competency assessment. D6094 LABORATORY DIRECTOR RESPONSIBILITIES D6094 03May2021 CFR(s): 493.1445(e)(5) D6094 1 and 2: This finding states that the Laboratory Director failed to ensure quality assurance activities were The laboratory director must ensure that the established and maintained by the laboratory to assure the quality assessment programs are established and quality of services, and to identify failures as they occur in maintained to assure the quality of laboratory both the analytical and post analytical phases of testing.. services provided and to identify failures in quality A Quality Management Plan (QMP, See Attachment A) as they occur. covering all the quality related processes of the 3 phases of laboratory testing (pre-analytical, analytical and postanalytical) as well as the associated activities that support This Standard is not met as evidenced by: those processes has been signed and in effect since Based on interviews conducted with the 01Nov2020 (Shantelle Lucas, Lab Director), and most recently 4/11/2021 (Adam Rosendorff, Laboratory Director). laboratory staff on 02/07/2021 and 02/08/2021, It has undergone numerous improvements during that and review of test records covering the period period, focusing on accurate result reporting, improved from 12/07/2020 to 01/13/2021, for 30 out of 30 training and competency documentation, enhanced audit schedules, improved QER and CAPA reporting, timely patient test records patient test records reviewed, reporting (turnaround time) and document management. it was determined that the Laboratory Director The QMP is built on 9 core quality essentials- sets of failed to ensure quality assurance activities were coordinated activities that support the three phases of the laboratory workflow. Internal audits and external inspection/ established and maintained by the laboratory to audits ensure quality is maintained in all areas of the assure the quality of services provided, and to laboratory and problems identified and remedied before identify failures in quality as they occur. they have a chance to impact patient testing. In addition, daily, weekly, and monthly reviews focus on a comprehensive list of key performance indicators that are Findings included: shared with all stakeholders. The QMP specifically addresses processes to monitor, The Laboratory Director failed to establish capture and document non-conforming events as QERs, and follow written policies and procedures for an how to assess risk to determine if more in-depth actions in ongoing mechanism to monitor, assess, and the forms of Root Cause Analysis (RCA) or CAPA. There is weekly documented review of all QERs and CAPAs to when indicated, correct problems identified in the monitor progress, detect trends and initiate process analytic systems (See D5791). improvements, as appropriate. The Laboratory Director failed to establish

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	OF DEFICIENC ES CORRECTION	` '	1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:		(X2) MULTIPLE CONSTRUCTION A. BUILDING		(X3) DATE SURVEY COMPLETED		
		СРН88933	19	B. WING		04/22	2/2021		
NAME OF PR	OVIDER OR SUPPLIER		STREET ADDR	STREET ADDRESS, CITY, STATE, ZIP CODE					
	ANCH LABORATOR	v	28454	28454 LIVINGSTON AVE					
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D6076	OR LSC DENTIFYING NFORMATION)		d and uality in the rior to ITIES and and y quality 21, od f 30 ewed, or were y to	D6076	Continued from page 36 There is no regulatory requirement for a laboratory particular process with a quality indicator (42 CFR selection is left to the discretion of the Laboratory I initial Quality Management Plan, drafted and appr previous Lab Director, was a best attempt at how to monitor and document quality activities during sta indicated the possible indicators that would be sele three phases of laboratory testing: preanalytical, ampostanalytical. During the first two months of operation, analytical monitors of TAT, positivity rate, sample failure we daily and submitted to key stakeholders, including Regular monitoring of QC failure rates, audits of pl and review of customer complaints among other it reviewed at monthly and quarterly quality manager Currently, Patient look backs are conducted in the instrument failure or other analytic problem is ider are reviewed for evidence of erroneous results (QC month, heatmap analysis, curve analysis). In additiveviewing positivity rates, and error rates daily to n unusual trends that would indicate a systemic analy PostAnalytical quality monitors included review of amended reports as a percentage of total testing. A results are sent to COLOR for generation of the am and upload to their result portal immediately upon need for such action, even before a QER is initiated recently implemented a post-analytic QA process to accuracy of data released from VBL through patien (CA-RPT-SOP-004) The audit process was implemented in Q1 2021. Re and external audits (CA-QM-FM-018) are conduct for compliance with all phases of laboratory workfl support processes. A detailed Audit Schedule incluend to end patient audits, amended results audits, amintenance documentation, Good Documentation adherence to SOPs, employee qualification and traidocumentation and good laboratory practice, reage compliance, Director timely review and approval o	493.1701); the Director. The oved by the oxesess, retrup and cted for the alytical and l quality re monitored Dr. Erica Pan. ate heatmaps, ems are ment reviews. event that an otified. Batches review by on we are nonitor for any tric issue. I the number of the number o			
	Findings included: 1. The Laboratory Director failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems (See D5791).				and opportunities for re-training, where approprial conducted. When non-conforming practices or not is observed, the exception enters the QER/CAPA process is now, a monthly review, not a quarterly review. Management includes Key Performance Indicators and targeted and data to include summary information from the	te, are n-compliance process. s of Feb 2021, a nt review quality metrics			
	The Laboratory Director failed to establish		ish						

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STATEMENT OF DEFICIENC ES AND PLAN OF CORRECTION

(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:

(X2) MULTIPLE CONSTRUCTION

A. BUILDING

CPH889339

B. WING

O4/22/2021

NAME OF PROVIDER OR SUPPLIER

CDPH BRANCH LABORATORY

28454 LIVINGSTON AVE VALENCIA, CA 91355

CDPH BK	ANCH LABORATORY	VALENCIA			
(X4) D PREFIX TAG	SUMMARY STATEMENT OF DEFICIENC ES (EACH DEFICIENCY MUST BE PRECEDED BY FULL RE OR LSC DENTIFYING NFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D6076	 The Laboratory Director failed to ensure quality assurance activities were established maintained by the laboratory to assure the quof services provided, and to identify failures quality as they occur (See D6094). The Laboratory Director failed to ensure laboratory staff demonstrated competency pureporting patient test results (See D6102). LABORATORY DIRECTOR RESPONSIBILITY 	uality in the ior to	D6076	(1) Assessment of Client feedback (2) Findings from internal audits (3) Findings from external audits (4) PT performance (5) Key Quality/Performance Indicator (KPI) a. Cancelled and Unsatisfactory Specimens b. Instrument Downtime c. Repeat Testing d. Compliance with Maintenance Documentation and GDP e. QC Failures f. TAT g. Positivity Rate h. Corrected Reports i. Safety Events	
	CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established maintained to assure the quality of laborator services provided and to identify failures in coast they occur. This Standard is not met as evidenced by: Based on interviews conducted with the laboratory staff on 02/07/2021 and 02/08/20 and review of test records covering the period from 12/07/2020 to 01/13/2021, for 30 out of patient test records patient test records review it was determined that the Laboratory Direct failed to ensure quality assurance activities we established and maintained by the laborator assure the quality of services provided, and identify failures in quality as they occur.	nee need and orry quality 021, riod of 30 iewed, ctor s were ory to	D6094	j. Completed Competencies with the 3-month window 1. Equipment/Method Performance Comparisons 2. Staff Suggestions 3. Monitoring and resolution of complaints 4. Performance of Suppliers 5. Review of QERs and CAPAs 6. Suitability of procedures and sample requirement 7. *Verify EUA/IFU current version & impact/ applicability of modifications 8. *Updated or New method validations 9. Personnel Changes in Volume and Compliance Recommendations for Improvement 10. Follow-up actions from previous meetings (1) Corrective Actions: All laboratories have events that deviate from prescribed workflow and processes; it is the reason for continuous improvement and occurrence management. When these occur, the laboratory follows its QER and CAPA processes. Each of the findings observed in the 23Apr2021 Inspection Report findings from the LFS inspection on 07Feb and 08 Feb have been or are being addressed with corrective actions already in implementation phase. See D5779 for analytical and D5787 for post analytical process corrective actions. (2) Patient Impact: See D5779 and D5787.	
	Findings included: 1. The Laboratory Director failed to establiand follow written policies and procedures foongoing mechanism to monitor, assess, and when indicated, correct problems identified in analytic systems (See D5791). 2. The Laboratory Director failed to establiand follow written policies and procedures for	or an the			

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	OF DEFICIENC ES F CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:			PLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED	
		СРН88933	39	B. WING		04/2	2/2021
NAME OF PR	OVIDER OR SUPPLIER		STREET ADD	RESS, CITY, ST	ATE, ZIP CODE	.1	
CDPH BR	ANCH LABORATOR	Y		28454 LIVINGSTON AVE VALENCIA, CA 91355			
(X4) D PREFIX TAG	(EACH DEFICIENCY MUS	TATEMENT OF DEFICIENC ES T BE PRECEDED BY FULL RE ENTIFYING NFORMATION)		ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTI (EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPRO DEFICIENCY)	D BE	(X5) COMPLETION DATE
D6076	1. The Laboratory Equality assurance acmaintained by the lab of services provided, quality as they occur 2. The Laboratory D laboratory staff demoreporting patient test LABORATORY DIRECFR(s): 493.1445(e) The laboratory direct quality assessment pmaintained to assure services provided an as they occur. This Standard is not Based on interviews laboratory staff on 02 and review of test recfrom 12/07/2020 to 0 patient test records pit was determined that failed to ensure quality established and main assure the quality of identify failures in quality of identify failures in quality and follow written poongoing mechanism	prirector failed to ensure tivities were established for and to identify failures (See D6094). For an and to identify failures (See D6094). For an	d and uality in the rior to ITIES and and y quality 21, but f 30 ewed, or were y to to ish or an I	D6076	Continued from page 36 (3) Preventative Actions: Through the course of Claboratory operations situations and scenarios occhappened in the past are identified. We are a youn, and all possible errors or gaps in processes cannot here are the solutions to these newly identified items are relaboratory management and the laboratory director appropriate mitigation and incorporation into SOP appropriate. The current Laboratory Director partiregular meetings with technical, general and operat supervisors to discuss improvement and regulatory review and approval of policy, plan, process, and pradvance of implementation is reiterated regularly. staff and supervisors are encouraged to make requeupdates withing 12 hours (1 shift) of identifying a reliaboratory director particimeetings with the Quality team where any issue with control (QER, Audit Process, or Gemba (walkthrout observation) is discussed and documented with me The quality and laboratory groups update the SOPs for approval by the laboratory director prior to imp For Amended Reports: Submission of notification I results to Dr Pan occurs by email with request read submission email, the original report, the amended individual notification letter and the accompanying acknowledgment will be electronically stored in the event file within the Quality Management archived Reports folder. See D5779 for analytical and D5787 analytical process prevenative actions. (4) Monitoring Mechanism: During any of the audif any uncontrolled document is discovered or therchange in policy, process, plan or procedure, or use document, that has not been pre-approved by the Laboratory director perform biennial review of its S they encompass the best practices being applied wit laboratory director perform biennial review of its S they encompass the best practices being applied wit laboratory workflow. During the monthly amended report audit, assessm QERs associated with each event, the cause, the nut the review of both original and amended report. The Audit Schedule and the Amended Repo	ar that have not glaboratory be anticipated. viewed with r for rs, as cipates in ional initiatives. His rocedures in The laboratory sts for SOP teeded change, pates in regular th document ggh) eting minutes. and submit it elementation. etters and receipt. The report, the report, the report, the report of a controlled aboratory informance and as part of the aff and OPs to ensure thin the	
	_	Director failed to establi icies and procedures fo			Quality Management Review as a POST Analytical assessment metric, with a target of 100% or no incident		

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failure to submit.

(X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENC ES (X1) PROVIDER/SUPPLIER/CLIA (X3) DATE SURVEY A. BUILDING AND PLAN OF CORRECTION IDENTIFICATION NUMBER: COMPLETED CPH889339 B. WING 04/22/2021 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER **CDPH BRANCH LABORATORY** 28454 LIVINGSTON AVE VALENCIA, CA 91355 (X5) COMPLETION SUMMARY STATEMENT OF DEFICIENC ES PROVIDER'S PLAN OF CORRECTION (X4) D (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY PREFIX **PREFIX** (EACH CORRECTIVE ACTION SHOULD BE DATE TAG OR LSC DENTIFYING NFORMATION) CROSS-REFERENCED TO THE APPROPRIATE TAG **DEFICIENCY**) D6076 D6076 Continued From page 36 Continued from page 36 1. The Laboratory Director failed to ensure quality assurance activities were established and Monitoring timely completion of QER and CAPA's has been added to the Quality Management Review with an expected maintained by the laboratory to assure the quality documented signature approval of the written corrective plan of services provided, and to identify failures in targeted for completion within 15 days. quality as they occur (See D6094). CDPH Branch Laboratory, under the direction of Dr. Adam Rosendorff, will continue to follow its continuous improvement 2. The Laboratory Director failed to ensure the and occurrence management, auditing, and quality management review processes to identify, assess, monitor and when identified, laboratory staff demonstrated competency prior to correct problems identified in any of the laboratory workflow or reporting patient test results (See D6102). ancillary processes. LABORATORY DIRECTOR RESPONSIBILITIES D6094 D6094 CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This Standard is not met as evidenced by: Based on interviews conducted with the laboratory staff on 02/07/2021 and 02/08/2021, and review of test records covering the period from 12/07/2020 to 01/13/2021, for 30 out of 30 patient test records patient test records reviewed, it was determined that the Laboratory Director failed to ensure quality assurance activities were established and maintained by the laboratory to assure the quality of services provided, and to identify failures in quality as they occur. Findings included: The Laboratory Director failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems (See D5791). The Laboratory Director failed to establish

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SUPPLIER/CLIA TION NUMBER: CPH889339 STREET ADD		COM	SURVEY PLETED			
	B. WING					
STREET ADD	B. WING 04/22/2021					
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VALEN	ICIA, CA 913	355				
BY FULL REGULATORY	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE			
Continued From page 37 ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the postanalytic systems (See D5891). LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12)						
re that prior to reconnel have erience, the type and and have mall testing report accurate to the the reconnect by: the re	53102	roster used for convenience in the laboratory was presented. Sthist time, the CDPH Branch Laboratory has developed audit procedures that specify what laboratory documents may be sh and the manner in which they are to be given to regulatory agencies. (1) Immediate Corrective Action: A current roster of techni (Extraction, PCR, and Data Analysis) and non-technical (Accessioning) staff is used to provide training documentation. The lists are very similar but do have a few differences (see Dindings 4 and 5). (2) Patient Impact: The unofficial roster is used by Manager Supervisors as a reference for staff on shifts or in areas with with they do not work directly. Inaccuracies in this roster may resinconvenience for laboratory staff; however, there is no impapatient care. (3) Preventative Measure: An inspection work instruction have a drafted by the CDPH Branch Laboratory. This draft has used as starting point for Quality team members, Supervisors Managers, and the Laboratory Director to have a group train session on conducting an efficient audit. Two training session mock inspection drills have been completed (see D5209, Attachment D5209_Audit and Inspection Training). Success challenges of these mock drills are being used to complete the Inspection Work Instruction. Techniques from this training used to efficiently meet requests from Laboratory Field Servic during an on-site visit in March 2021. (4) Monitoring Mechanism: Additional mock inspection dri will be held on all shifts. Team performance during any audit inspection is reviewed during post audit conference (as stipul in the work instruction). Areas of effectiveness as well as are improvement will be documented and enter the Continuous Improvement process (CAPA). Finding 3. The roster provided on 2/8/2021 was not an official one, the the following numbers as presented in the LFS findings vary slightly (see Finding 3). A review of our records found that 4	al . 5209 and aich it in c on geen gg and crees or ted fore, fore,			
	28454 VALEN EFICIENC ES BY FULL REGULATORY RMATION) Ssess, and dentified in the	28454 LIVINGSTON VALENCIA, CA 913 EFICIENC ES BY FULL REGULATORY RMATION) D6094 Seess, and dentified in the D70NSIBILITIES D6102 The that prior to resonnel have derience, the type and and have derience and latesting report accurate and latesting report accurate and the period from	D6094 Seess, and dentified in the			

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				(V2) MULTID	15.00	NETRUCTION			1		
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D6102	Continued From pag	e 38		D6102			Sun	Tue	We	d-Fri	Total
	i. Saturday to Tuesday (Day and Night Shift)						Day	Night	Day	Night	
	a. Accessioning b. Extraction				Α	ccessioning	34/34	43/43	46/46	37/37	
						Reformatter	36/36 (37 total)	46 / 46 (55 total)	38/38 (40 total)	48/48 (51 tota	1)
	c. PCR d. Data Analysis	CR			Extraction		36/36 (37 total)	41/41 (55 total)	38/38 (40 total)	48/48 (51 tota	
	•	riday (Day and Night St	niff)		ū	Chemagic RT-PCR Set-up	11/11	14/14	12/12	11/11	
	,	Wednesday to Friday (Day and Night Shift)			PCR	AJ PCR	11/11	14/14	12/12	11/11	48
	a. Accessioningb. Extraction					Analysis	7/7	5/5	6/6	3/3	21
	c. PCR					Total	89	117	104	102	412
	d. Data Analysis				Contin	nued from page 38	3			΄ Τ	1
	Laboratory Field Serv was determined that its written policies and 236 out of 426 (appro- laboratory staff to wo laboratory's documen	rsonnel records mailed vices office on 02/11/20/ the laboratory failed to find procedures by allowing the procedures by allowing the procedures by allowing the procedures of the total procedures that its new protocols had not be	21 , it follow ng otal the		time to capaci the ne what v were d Manag In add due to	the large numbe o meet the emerge ty, there was a del w document cont vas still needed. E lelayed. Subseque: gers regarding for ition, delays in pr limitations of the oad a large numb tion.	ency demands lay in entering rol system. The fforts to colle ntly, notificat ms that were roviding reconst	s for COVID- g training do- nis made it di- ct and docun ions to Super not complete ds upon aud ontrol system	-19 testing cumentation ifficult to tra- nent training visors and ed was delay it request was being able	n in ack ig yed.	
	training and competency protocols had not been completed as specified in its Quality Management Plan. i. Saturday to Tuesday (Day Shift) a. Accessioning				Data Analysis It is important to note that technologists in the Analysis group are the only staff who report patient results. 21/21 (100%) of the Data Analysts, as well as the Sign-Out Manager, had documented training prior to reporting patient results as documented on the Data Analysis (CA-PER-FM-015) initial training assessment form. Copies of this form, as well as a related but redundant form (see below) are provided in Attachment D5209_3a, D5209_3b and D52093z. These records were provided to LFS via email on February 8 as requested. Confirmation of the sent email is provided in Attachment D5209_3zb. Due to uncertainty about workflow ahead of the laboratory opening, two forms were created (prior to any employee onboarding) to capture training needed to extract and analyze data after completion of RT-PCR:						
		a.1. 1 out of 1 supervisor (resigned) a.2. 37 out of 37 accessioning staff- completed									
	b. Extraction				•	Data Extraction (Data Analysis (C.	A-PER-FM-0	15)			
	assessment	isors - no competency			data p never for mo the Da	tasks were separa rior to submitting implemented in to st analysts; howe ata Analysis form	g for analysis; his laboratory ver, four data (CA-PER-FM	however, thi . Both forms analysts init [-015] compl	s workflow were comp ially had on eted. The	was oleted oly	
	b.2. 17 out of 38 extra assessment	action staff- no compete	ency		maint imple	dant Data Extract ained with the the mented when sam cessary.	ought that the	workflow co	uld be	·	

, ,		(X1) PROVIDER/SUPPLIER/CI IDENTIFICATION NUMBE CPH88933	ER:	A. BUILDING	PLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED 04/22/2021		
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CDFH BK	ANCH LABORATOR	1		454 LIVINGSTON AVE LLENCIA, CA 91355				
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D6102	2 Continued From page 39			D6102				
	c. PCR c.1. 1 out of 1 supervisor- no competency assessment				PCR All PCR technologists (48/48; 100%), as well as all PCR Supervisors (4/4), had documented training prior to processing patient samples (Attachments D5209_3c – D5209_3g). A review of records did reveal a minor anomaly in the training record. For several individuals training in PCR, the training form was completed and signed for the RT-PCR Set-up on the Janus G3 (CA-PER-FM-012); however, the form for the RT-			
	c.2. 4 out of 13 PCR assessment	staff - no competency			PCR AJ thermocycler (CA-PER-FM-013) is not in record. A review of records indicates that technolog prepared the PCR batch on the RT-PCR Set-up an PCR plate to the AJ Thermocycler. Training on the	ogists d loaded the e RT-PCR		
	d. Data Analysis				Set-up, as well as data review, were completed by th These records indicate that the AJ thermocycler was started correctly. Since these are the tasks assessed for the individual being assessed performed the task con	as loaded and for training,		
	d.1. 1 out of 1 Sign o	ut manager (not indicat	ed)		the laboratory failed to properly document this as training.			
	d.2. 4 out of 4 data analysis staff- no competency assessment		ency		Extraction In the Extraction area, some staff currently perfor Reformatter automated liquid handling procedure chemagic automated nucleic acid extraction proce	e or the		
	ii. Saturday to Tuesda	ay (Night Shift)			therefore, the total number of training records for smaller than the total number of individuals in the detailed list is provided in Attachments D5209_31:	each is at area. A		
	a. Accessioning				Of the 183 staff members in Extraction: 173 have been trained to use the Reformatt	er liquid		
	a.1. 1 out of 1 superv assessment	visor- no competency			handler • 166 have been trained to use the chemagic nucleic acid extractor • Staff without current training for an instru permitted to operate that instrument			
	a.2. 1 out of 42 acces	ssioning staff - no			A review of records found that for the Reformatte	r·		
	competency assessn	nent			133 / 173 had completed training records a training	t the time of		
	b. Extraction				17 / 173 had an indication from the trainer was completed but a signature was not obta 23 / 173 were found to have inadequate docord training.	nined		
	b.1. 1 out of 1 superv	visor- no competency			of training			
	assessment				A review of records found that for the chemagic:	Aller Correct		
					 149 / 166 had completed training records at training 	tine time of		
	b.2. 42 out of 57 extraction staff- no competency assessmentc. PCR		ency		7 / 166 had an indication from the trainer ti was completed but a signature was not obta 10 / 166 were found to have inadequate doc of training	ined		
					(1) Immediate Corrective Action: Any task for which a training form was not captured was re-assessed for the individual or that individual was removed from that testing			
	c.1. 1 out 1 supervisor assessment	or- no competency			process until re-assessment could be completed. Analysis: Despite the redundancy between the Da and Data Analysis forms, for any missing Data Ex documentation, the analysts were assessed again b	traction		
	c.2. 7 out of 13 PCR	staff - no competency			Out Manager since this was part of laboratory pro Data Extraction form was retired on 10Apr2021 d with the Data Analysis form.	cedure. The		

STATEMENT	OF DEFICIENC ES	(X1) PROVIDER/SUPPLIER/CI	IΔ	(X2) MULTIP	LE CONSTRUCTION	(X3) DATE SUR	VFY		
	FCORRECTION	IDENTIFICATION NUMBE		A. BUILDING	·	COMPLETE			
		СРН88933	9	B. WING		04/22	2/2021		
NAME OF PR	OVIDER OR SUPPL ER		STREET ADDR	DDRESS, CITY, STATE, ZIP CODE					
CDPH BR	ANCH LABORATORY	Y	28454 L	4 LIVINGSTON AVE					
			VALEN	CIA, CA 913	555				
(X4) D PREFIX TAG	(EACH DEFICIENCY MUST	TATEMENT OF DEFICIENCES T BE PRECEDED BY FULL REI ENTIFYING NFORMATION)	I	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)				
D6102		Continued From page 40			Continued from page 40				
	assessment d. Data Analysis d.1 Sign out manager (not indicated) d.2. 2 out of 2 data analysis staff- no competency assessment				PCR: Although there is good evidence from the successful training run that the individuals lacking a signature for the AJ Thermocycler training form did complete training, the affected individuals were re-assessed when the omission was discovered. All staff, including the PCR Supervisors (see Attachment D5209_3z), were found to be adequately trained. Extraction: For the 23 / 173 (13%) that were identified in mid-December to have a missing training document for the Reformatter automated liquid handler: • 11 of these individuals were re-assessed by a Supervisor in				
	iii. Wednesday to Frida. Accessioning	esday to Friday (Day Shift)			December 2020 and found to be adequately t • 2 were removed from testing and re-assessed 2021 and found to be adequately trained • 10 of these individuals were reassessed in Jan				
	a.1. 1 out of 1 superv	isor- no competency			February (7) and March (1) and found to be trained.	adequately			
	assessment				For the 10 / 166 (6%) were found in a mid-December missing training document for the chemagic autom acid extractor: • 4 of these individuals were re-assessed by a second control of the				
	a.2. 47 out of 47 acce competency assessm	-			December 2020 and found to be adequately t of these individuals were reassessed in Februari March (1) and found to be adequately trained.	trained ruary (5) and			
	b. Extraction				All Extraction Supervisors were adequately trained Attachment D5209 $_3z$)	(see			
	b.1. 2 out of 2 superv assessment	isors- no competency			Accessioning: The accessioning process for this laboratory requires: Scanning of the barcode on the sample Batching into groups of 94 samples for testing Identifying unsatisfactory samples Although some accessioning staff performed heat inactivation				
		action staff- no compete	ency						
	assessment				prior to February 2021, most were trained in this pr February 2021 (see Attachments D5209_3q – D5209	9_3y).			
	c. PCR	-			Review of records showed that 47 / 160 training rec delayed; however, all have been completed. These d signatures were spread across the four shifts. Traini	elayed			
	c.1 2 out of 2 supervi	sor- no competency			accessioning staff for heat inactivation was docume appropriately by February 2021 for 158 / 160 of the staff. No staff were found to have deficiencies in tra Attachments D5209_3q – D5209_3y).	accessioning			
	c.2. 5 out of 15 PCR staff- no competency assessment d. Data analysis				Audit process: Paper copies of personnel files have to aide in timeliness of audit responses.				
					Training Process: The Personnel Orientation and Onboarding procedure (CA-PER-SOP-001 v2, 14Mar2021) has been updated to reflect and enhance current practice see Attachment D5209_1a.				
	d.1. 1 out of 1 Sign of	ut manager			A set schedule for a three-day orientation has been set. Training checklists (previously titled Training and Competency Assessment) have been updated to include all aspects of training				
	d.2. 2 out of 3 data a	nalysis staff- no compet	ency		(see D5209_1d). In addition, a roster with training is placed in each lab area so that any Supervisor can training status (see example in Attachment D5209_	easily see			

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	OF DEFICIENC ES F CORRECTION	(X1) PROVIDER/SUPPLIER/CI IDENTIFICATION NUMBE			LE CONSTRUCTION (X3) DATE S COMPLE			
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CDPH BR	ANCH LABORATOR	Υ		28454 LIVINGSTON AVE VALENCIA, CA 91355				
(X4) D PREFIX TAG	SUMMARY STATEMENT OF DEFICIENC ES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC DENTIFYING NFORMATION)			ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOUL) CROSS-REFERENCED TO THE APPROFIDERICENCY)	(X5) COMPLETION DATE		
D6102	assessment iv. Wednesday to Fri a. Accessioning a.1. 1 out of 1 supervassessment a.2. 31 out of 37 accompetency assessment b. Extraction b.1. 1 out of 1 supervassessment b.2. 34 out of 46 extrassessment c. PCR c.1 0 out of 0 supervi c.2. 9 out of 14 PCR assessment d. Data analysis d.1. Sign out manage d.2. 3 out of 3 data a assessment 4. The following are	day (Night Shift) visor- no competency essioning staff- no nent visor- no competency faction staff- no compete isor (open position) staff- no competency	ency s of	D6102	Continued from page 41 (2) Patient Impact: Data Analysts: The only staff who review and releat Data Analysts and the Sign-Out Manager. Training 21/21 data analysts and the Sign-Out Manager were therefore, there was no impact on patient care. The failure to document training for Data Extraction (CFM-015) is minimal because: • There is complete overlap in the tasks betwee Extraction and Data Analysis • Data Analysis cannot be completed without Extraction PCR: Training for all PCR staff was adequately cap for one for four individuals. Since the data show the carried out correctly and the data were accepted by there is evidence that this omission did not impact Extraction: The limited number of instances of mis documentation identified are unlikely to impact pathe assay steps performed in extraction do NOT increview or analysis. Accessioning: Accessioning consists mainly of bare All unsatisfactory specimens are checked by a superejecting the sample. Upon assessment, no perform were identified, therefore, there is no impact on path Audit process: The ability to download records in bimpact on patient care. (3) Preventative Measure: A more formal training new technologists has been put in place - see. Since now has many performing employees there is more for new staff to observe procedures and work with supervisors. The redesigned training forms present Finding 1 help to facilitate this process. A summary PowerPoint was sent to all Managers a explaining the changes and the new and updated for 1, 2021 before the start of 6-month competency ass technical staff on April 21, 2021. Members of the Q met with each Supervisor performing 6-month con assessments before they began assessments and sev during assessments to ensure they understood the concess. Paper copies of all personnel records have been crefacilitate audit requests more quickly and efficiently the PCR area, all 18 staff trained from min 2020 to present indicates: • There continues to be no documentation is Data Analysts who are reviewing and releasi	grecords for e completed, is impact of the CA-PER- en Data Data		
	*	rom 12/07/2020 to the laboratory tested ar SARS-CoV-2 patient to			 completed In Extraction, of the 42 individuals trained in December or later, 42/42 were properly doct the Reformatter automatic liquid handler and delayed signature) were properly documented chemagic automated nucleic acid extraction 	umented for ad 41/42 (one ed for the		

	OF DEFICIENC ES	(X1) PROVIDER/SUPPLIER/C			PLE CONSTRUCTION	(X3) DATE SUR			
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		CPH88933	39	B. WING		04/22	2/2021		
NAME OF PR	ROVIDER OR SUPPL ER		STREET ADD	DDRESS, CITY, STATE, ZIP CODE					
CDPH BR	RANCH LABORATOR	Y		LIVINGSTON CIA, CA 913					
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D6102	results, but failed to e received appropriate and testing patient sa Accession Number 5. Based on the lab 03/25/2021, the labor	ensure all laboratory statraining prior to proces amples. poratory director's email ratory has processed 1 2 patient samples as o	on	D6102	Continued from page 42 An insufficient number of new hires in Accestarted since mid-December to assessed as new made. In addition to mock audit exercises, the mor audits conducted as part of the monthly aud assess whether personnel documentation is a complete. Finding 4 Of the 30 randomly selected samples: 5/5 Accessioning personnel have complete train documentation 5/5 Extraction personnel have complete train documentation. 1/5 had a delayed signature Reformatter training at the time she ran 10 / shown here; however, she was reassessed pri the remaining 11 / 21 samples. Upon reasses determined to be adequately trained and all ran were successful. 3/3 PCR personnel have complete training do 2/2 Data Analysts have complete training do 2/2 Data Analysts have complete training do See D5209 finding 6 for training documentation.) (1) Immediate Corrective Action: See finding 3 (2) Patient Impact: See finding 3 (3) Preventative Measure: See finding 3 (4) Monitoring Mechanism: See finding 3	attiveness; whires are attily tracer it schedule available and araining aning for 21 samples or to running sment she was samples she documentation			