

**Accession of Maternal Specimens  
for Prenatal Screening  
Tracking No. CP003  
Version 4.2**

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**I. Title**

Accession of Maternal Specimens for Prenatal Screening (PNS).

**II. PRINCIPLE**

Maternal samples for Prenatal Screening are picked up daily from the post office or sent by courier service to the State contract laboratories. Each specimen is assigned a unique accession number which consists of a total of 13 digits: three digits for the Julian date, two digits for the check-sum, three digits for the sequence number, a forward slash (/), the letter A for first trimester specimen and the letter P for second trimester specimen, four digits for the year, and two-digits for the laboratory code. The second trimester specimens are analyzed for 4 analytes: alpha-fetoprotein (AFP), human chorionic gonadotropin (hCG), unconjugated estriol (uE3), and inhibin A (INH). The first trimester specimens are analyzed for two analytes: PAPP-A and HG1. Information on the test request form (TRF) that accompanied each specimen determines if the specimen should be entered into the State Screening Information System (SIS) as first trimester (A) or second trimester (P) specimen. The SIS computer system will take into consideration gestational age data to determine a final trimester assignment for the specimen. However, once an accession number is assigned to a specimen, the accession number remains the same regardless of SIS's final assignment of first or second trimester.

**III. Specimen Collection and Type**

1. A blood specimen is collected from women who are between 10-13 weeks 6 days (first trimester) or at 15-20 weeks (second trimester) of pregnancy.
2. The collection tube is a Becton Dickinson (BD) 3.5 ml serum separator tube (SST) containing separator gel and are provided by the State PNS program.
3. Serum which is collected in the specified collection tube is an acceptable sample. Serum which is collected by any other tube other than BD SST is not acceptable for use in the PNS program. However, specimen collected in a red top tube is adequate only for 2<sup>nd</sup> trimester screening. Please refer to section VII, Procedures, for more details.
4. Blood specimen for first trimester screening that arrived in the laboratory without prior centrifugation (that is, the gel separator is located at the bottom of the collection tube) is an **INADEQUATE** specimen. The instability of PAPP-A during transit from collection to laboratory makes it essential that first trimester specimens are centrifuged and the serum separated from the clot by the gel separator soon after collection.

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5. Blood specimen for second trimester that arrived in the laboratory without prior centrifugation is acceptable due to a longer period of stability for AFP, HCG, uE3 and Inhibin while in transit.

#### **IV. Equipment and Supplies**

1. SATO Barcode Printer
2. Barcode labels
3. Centrifuge capable of delivering 1000-1300 x g for 10-15 min.
4. Plastic tubes, 10 x 13 mm, polypropylene
5. Disposable plastic pipettes

#### **V. Reagents - NA**

#### **VI. Calibration and Quality Control- NA**

#### **VII. Procedures**

##### A. Determine Adequacy of Specimens According to the Following Criteria:

1. Judge the specimen adequate if it meets the following criteria.

- a. Quantity

Volume – Adequacy in volume (at least 0.5 ml of serum) is performed at the assay station.

- b. Quality:

- 1) The specimen is collected using a Becton Dickinson (BD) serum separator tube (SST), Cat # 367983), 3.5 mL draw, provided by the State PNS program.
- 2) Hemolysis – This is determined at the assay station. A specimen is considered adequate if the color of the serum portion is **not** darker than the serum portion of the tube in the color standard for PNS assays.

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c. Identification:

The tube is labeled with the same TRF form number, patient's name, and blood collection date (BCD) as entered on the accompanying TRF.

2. Judge the specimen **inadequate** if:

- a. There is no blood in the collection tube.
- b. Collection tube is not a BD red top blood collection tube or a BD SST tube provided by the PNS Program. Specimen collected for 1<sup>st</sup> trimester screening using BD red top tube is **inadequate**.
- c. Collection tube is broken or leaking.
- d. Separator gel in collection tube is not located between serum and blood clot after centrifugation, either in the laboratory or collection site prior to shipping. For a 2<sup>nd</sup> trimester specimen, an improperly centrifuge specimen at the collection site can be re-centrifuge at the laboratory and if gel is properly set between serum and blood clot, specimen is adequate.
- e. Collection tube is identified as first trimester specimen and arrived not centrifuged (gel separator is located at the bottom of collection tube).
- f. Serum is hemolyzed (that is, color of the serum in the collection tube is darker than the sample picture of hemolyzed serum provided by GDLB)
- g. Patient's name and identifying information are not on the tube.

B. Verification of Critical Information

A specimen is considered having inconsistent identification if it falls in any of the following categories: a) Name on the tube does not match name on the TFR b) Form number on the tube does not match form number on the TRF c) Blood collection date on the tube does not match the collection date on the TRF.

For a list of how to handle PNS specimens to determine adequacy and contact

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the PDC coordinators, see Quick Reference Chart for Management of PNS Samples attached at the end of the protocol. The Quick Reference Chart cannot list every situation you may encounter. **It is the responsibility of the NAPS Laboratory to look at all information on the tube and TRF** to determine if the specimen has positive identification.

1. Confirm that the PNS form number on the tube is identical to the respective TRF number.
  - a. If the numbers are identical, match blood collection date (BCD) and patient's name.
  - b. If the numbers are not identical, call the specimen inadequate. Refer to the Quick Reference Chart for Management of Expanded PNS Samples and take the following steps:
    - 1) Apply the accession label to the TRF and tube.
    - 2) Record reason and adequacy code on the TRF and enter TRF.
    - 3) FAX TRF to the coordinator as specified in attached Reference Chart.
    - 4) Enter specimen onto the Log of Expanded PNS Inadequate/Inconsistent Specimens.
2. Confirm that blood collection date on tube matches blood collection date on form.
  - a. If collection dates match, continue to confirm name.
  - b. If collection dates do not match, specimen becomes a headline case for the coordinator. Refer to the Quick Reference Chart for Management of Expanded PNS Samples and take the following additional steps:
    - 1) Apply accession labels to TRF and tube.
    - 2) Write the BCD from the tube on the TRF.
    - 3) Enter TRF and leave the collection date field blank.
    - 4) FAX TRF to the coordinator as specified in attached Reference Chart.
    - 5) Enter specimen onto the Log of Expanded PNS Inadequate/Inconsistent Specimens.

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3. Confirm patient's name on tube matches name on TRF.
  - a. The name on the tube matches the name on the TRF. Proceed to test, specimen is adequate.
  - b. If there is no name on the tube or TRF, call the specimen inadequate. Refer to the Quick Reference Chart for Management of Expanded PNS Samples and take the following steps:
    - 1) Apply accession labels to TRF and tube.
    - 2) Write reason and inadequacy code on TRF and enter TRF.
    - 3) FAX TRF to the coordinator as specified in attached Reference Chart.
    - 4) Enter specimen onto the Log of Expanded PNS Inadequate/Inconsistent Specimens.
  - c. If the patient's name on tube does not match name on TRF, call specimen inadequate. Refer to the Quick Reference Chart for Management of Expanded PNS Samples and take the following steps:
    - 1) Apply accession labels to TRF and tube.
    - 2) Write reason for inadequacy code on TRF and enter TRF.
    - 3) FAX TRF to the coordinator as specified in attached Reference Chart.
    - 4) Enter specimen onto the Log of Expanded PNS Inadequate/Inconsistent Specimens.
- C. Processing Specimens Collected in a Non - Standard Tube
  1. Specimen collected in a BD SST, not 3.5 mL draw. Specimen is adequate. (Is inadequate for 1<sup>st</sup> trimester if centrifuged upon receipt.)
    - a. Centrifuge specimen.
    - b. Pipette the serum into a 13 x 10 mm polypropylene plastic tube.
    - c. Attach to the plastic tube a label that has all the information on the blood collection tube.
    - d. Enter specimen onto the Log of PNS Inadequate/Inconsistent

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- e. FAX TRF to GDSP.
2. Specimen collected in a BD red top tube. Specimen is adequate for 2<sup>nd</sup> trimester screening only.
  - a. Centrifuge specimen.
  - b. Pipette off the serum into a 13 x 10 mm polypropylene plastic tube.
  - c. Attach to the plastic tube a label that has all the information on the blood collection tube.
  - d. Enter specimen onto the Log of PNS Inadequate/Inconsistent Specimens.
  - e. FAX TRF to GDSP.
3. Specimen collected in blood collection tube that is not a BD SST or red top for 2<sup>nd</sup> trimester screening
  - a. Call the specimen inadequate.
  - b. Enter TRF with inadequacy code O for Other.
  - c. Enter specimen onto the Log of Expanded PNS Inadequate/Inconsistent Specimens.
  - d. FAX TRF to GDSP.

D. Processing Incorrectly Addressed Samples (mis-sent specimens to your laboratory)

Access and test specimen per protocol. If specimen is inadequate, follow protocol for handling an inadequate specimen.

E. Processing Specimens Found Inadequate at the Assay Station

The analyst at the assay station may call a specimen inadequate based on hemolysis and serum volume. When a specimen is made inadequate at the assay station, follow the steps below.

1. Retrieve the TRF from the data entry station.

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2. Write adequacy code on the TRF and enter TRF or change status if TRF was entered into SIS.
3. Enter specimen onto the Log of Expanded PNS Inadequate/Inconsistent Specimens.

F. Printing and Assigning Barcode Accession Labels.

1. Print barcode labels using the SATO barcode generator. Barcode labels are printed in duplicate.
2. Follow the instructions for printing barcode labels as specified in the PNS Assay protocol.
3. Assign an accession number to each specimen.
4. Place the right bar code label on the TRF.
5. Place the left bar code label on the tube. Do not cover the PNS form number.
6. Deliver all adequate samples including specimens in process of resolution by a coordinator, refer to Quick Reference Chart, to the assay station.
7. Store specimens in the refrigerator (2-8 degrees Celsius) if testing will not be done on the same day of receipt and accession. Keep the cap tightly sealed.

G. Storage of Specimens After Completion of Testing

1. After unloading specimens from the AutoDELFIA, cap each tube tightly.
2. Keep specimens in the refrigerator until specimens are removed from the Local and GDLB Repeat lists.
3. Store specimens in the freezer for thirty days.
4. Discard specimens after thirty days from completion of testing unless instructed by GDLB to ship specimens to another location. Retain a log of the specimens discarded.

H. Data Entry

1. Enter TRF including substitute TRFs on the same day of accession. Follow the instruction for data entry provided to you by GDSP.

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2. Enter specimens onto the Log of Expanded PNS Inadequate/Inconsistent Specimens as required.
3. Enter adequacy changes as soon as resolution is received from the coordinator. Data entry of adequacy changes must be completed before results can be released to SIS for risk calculation. This holds specimens with unknown adequacy status in lab control until coordinator resolution is completed. It also assures that clinicians will be informed of inadequate cases in a timely manner so that patients can be redrawn.

**VIII. Calculations- NA**

**IX. Reporting Results- NA**

**X. Procedure Notes- NA**

**XI. Method Limitations- NA**

**XII. References**

1. Receipt and Accession of Maternal Serum Specimens for Prenatal Screening Protocol, Version 3.4
2. Autodelphia PNS Assay Protocol
3. NAPS Laboratory Data Entry Manual, effective March 2009

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**Quick Reference Chart for Management of PNS Samples**

<b>Problem</b>	<b>FAX TRF?</b>	<b>Analyze Specimen?</b>	<b>Data Entry Action</b>
1. No information on tube or in package	NO	NO	DO NOT assign an accession number or data enter this specimen. Discard tube.
2. Specimen arrives with NO TRF (name and BCD on TRF label on tube )	No, create a substitute TRF **	NO	Enter substitute TRF. Specimen is inadequate, Adequacy Code is M for Mismatched/Unlabeled.
3. TRF form arrives without specimen	No, write reason on TRF before scanning **	NO	Enter information from TRF. Specimen is inadequate, Adequacy Code is N for No Blood.
4. Hemolyzed specimen with TRF	NO **	NO	Enter information from TRF. Specimen is inadequate, Adequacy Code is H for Hemolyzed
5. TRF# on tube does not match form # on TRF, but names match	No, write reason including the TRF# from tube on TRF before scanning, **	NO	Enter information from TRF. Specimen is inadequate, Adequacy Code is M for Mismatched/Unlabeled.
6. TRF# on tube does not match TRF# on form, names do not match	For Specimen #1 - No, create a substitute TRF **	NO	Access as 2 different specimens. Specimen #1 is considered a tube without TRF – Enter substitute TRF. Specimen is inadequate, Adequacy Code is M for Mismatched/Unlabeled

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	For Specimen #2 – No, write reason on TRF before scanning **		Specimen #2 is considered a TRF without a tube. Enter information from TRF. Specimen is inadequate, Adequacy Code is N for No blood.
7. TRF# is not on tube, name on TRF and tube match,	No, write reason on TRF before scanning **	NO	Enter information from TRF. Specimen is inadequate, Adequacy Code is M for Mismatched/Unlabeled
8. No name on tube, accompanied with TRF or other source of patient or clinical information	No, write reason on TRF before scanning **	NO	Enter information from TRF or substitute TRF. Specimen is inadequate, Adequacy Code is M for Mismatched/Unlabeled.
** FAX TRF to coordinator when the accession day is Friday			
<b>Problem</b>	<b>FAX TRF?</b>	<b>Analyze Specimen?</b>	<b>Data Entry Action</b>
9. Name on tube, no name on TRF, TRF# and BCD match	No, write name from tube on TRF before scanning **	NO	Enter information from TRF. Enter last name from tube with the addition “On Tube”. Specimen is inadequate, Adequacy Code is M for Mismatched/Unlabeled.
<b>10.</b> Different middle initials on tube and TRF	Yes, copy middle initial from tube onto TRF before faxing **	Yes	Enter TRF with middle initial from form. Fax the TRF and let the Coordinator investigate. Adequacy Code is C for Coordinator Resolution
11. Conflict between name on form and signature or label. If signature is missing or illegible, comparison is not required	No, write reason on TRF before scanning **	YES	Enter information from TRF. Adequacy Code is C for Coordinator Resolution
12. Different first name and different last name on TRF and tube, TRF# matches	No, write name from tube on TRF before scanning **	NO	Enter information from TRF. Specimen is inadequate, Adequacy Code is M for Mismatched/Unlabeled.
13. Same first name but different last names on TRF and tube, TRF# and BCD			

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<p>match</p> <p><b>a.</b> TRF name and tube name are different, tube last name matches maiden name</p> <p><b>b.</b> TRF has no maiden name and tube and TRF last name are different</p> <p><b>c.</b> Last name on form is hyphenated or is a 2 name last name and name on tube has either last name</p>	<p><b>a.</b> No</p> <p><b>b.</b> No, write reason on TRF before scanning **</p> <p><b>c.</b> Yes, write single last name from tube on TRF before FAXing</p>	<p>YES</p> <p>NO</p> <p>YES</p>	<p><b>a.</b> Enter information from TRF. Specimen is adequate</p> <p><b>b.</b> Enter information from TRF. Specimen is inadequate, Adequacy Code is M for Mismatched/Unlabeled</p> <p><b>c.</b> Enter information from TRF, Adequacy Code is C for Coordinator Resolution</p>
<p>** FAX TRF to coordinator when the accession day is Friday</p>			
<p><b>Problem</b></p>	<p><b>FAX TRF?</b></p>	<p><b>Analyze Specimen?</b></p>	<p><b>Data Entry Action</b></p>
<p><b>14.</b> Spelling of name is different on TRF and tube</p> <p><b>a.</b> Spelling difference is one letter different but name otherwise match</p> <p><b>b.</b> All other spelling difference</p>	<p>Yes, write name from tube on TRF before faxing to Coordinator **</p>	<p><b>a.</b> YES</p> <p><b>b.</b> NO</p>	<p>Enter name from TRF.</p> <p><b>a.</b> Fax the TRF and let the Coordinator investigate. Adequacy Code C for Coordinator Resolution</p> <p><b>b.</b> Adequacy Code is M for Mismatch</p>
<p><b>15.</b> First and last names are transposed, TRF# and BCD matched</p>	<p>Yes, write reason on TRF before faxing **</p>	<p>YES</p>	<p>Enter TRF. Adequacy Code is C for Coordinator resolution</p>
<p>16. First name is different on TRF and tube due to use of customary nickname or diminutive, e.g., Kim for Kimberly</p>	<p>NO</p>	<p>YES</p>	<p>Enter information from TRF. Specimen is adequate</p>
<p>17. BCD on tube does not match BCD on TRF</p>	<p>No, write BCD from tube onto TRF before scanning **</p>	<p>YES</p>	<p>Enter TRF and do not enter either BCD leaving the field blank. This will become a Headline case for the coordinator and coordinator will determine the correct BCD.</p>

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18. BCD is on tube but not on TRF or BCD on TRF but not on tube	No, write BCD from tube or "No BCD on tube" on TRF before scanning **	YES	Enter TRF and do not enter either BCD leaving the field blank. This will become a Headline case for the coordinator and coordinator will determine the correct BCD.
19. Different year for BCD on TRF and tube at beginning of year, but same month and day.	NO	YES	Enter the correct year, common problem early in a new year. Specimen is adequate
20. Clinician calls with additional information on patient that has matching name, TRF#, and BCD	Tell clinician to call coordinator	YES	Enter information from TRF. Based on information from clinician, coordinator will correct any errors on TRF.
21. Clinician writes important information about the patient on the form, specimen has matching name, TRF#, and BCD	Yes, circle clinician's comments before FAXing TRF to coordinator	YES	Enter TRF as it is filled out. DO NOT enter extra information into SIS.
** FAX TRF to coordinator when the accession day is Friday			
<b>Problem</b>	<b>FAX TRF?</b>	<b>Analyze Specimen?</b>	<b>Data Entry Action</b>
22. Clinician writes different trimester on form, i.e., writes First Trimester clearly on Second Trimester Form or vice versa, specimen has matching name, TRF#, and BCD	NO	YES, access specimen as trimester indicated by the clinician on the form	Enter as trimester written on the form. Enter TRF# if SIS allows. If not, enter all zeroes for form number.
23. TRF has invalid or illegible data, specimen has matching name, TRF#, and BCD	Yes, circle portions of concern before FAXing TRF	YES	Enter TRF as it is filled out, leave illegible fields blank.

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\*\* FAX TRF to coordinator when the accession day is Friday

**Appendix 1**

**LOG OF EXPANDED  
 PNS INADEQUATE/INCONSISTENT SPECIMENS**

DATE: \_\_\_\_\_ PERSON FILLING OUT FORM \_\_\_\_\_ LAB: \_\_\_\_\_

ACCESSION NUMBER	PNS-TRF FORM NUMBER	PATIENT LAST NAME IF DIFFERENT NAME ON TUBE USE LINE 2	COORDINATOR CONTACT		ADEQUACY CODE					DATA ENTRY DATE	INITIALS
			AGC CALLED	AGC FAXED	HG1	PAPP- A	AFP	HCG	UE3		
		1									
		2									
		1									
		2									
		1									
		2									
		1									
		2									
		1									
		2									

State of California  
Department of Public Health

Genetic Disease Laboratory Branch  
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**ADEQUACY CODES: H=Hemolyzed; N=No blood specimen; B=Broken tube; Q=Quantity insufficient; O=Other; C=Call coordinator to confirm match; M=Mismatched/ mislabeled**

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Prepared by: \_\_\_\_\_  
Renee Cullen, Supervising Chemist

Date: \_\_\_\_\_

Reviewed by: \_\_\_\_\_  
Thomson Ho, Ph. D., RS IV  
Acting Chief,

Date: \_\_\_\_\_

Approved by: \_\_\_\_\_  
Allen Wu, Ph.D., CLIA Lab Director

Date: \_\_\_\_\_



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**Technical Performance Verification**

**Procedure:** Accession of Maternal Specimens for Prenatal Screening  
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Employee's Signature <sup>1</sup>	Supervisor's Signature <sup>2</sup>	Completion Date of Training

1. Employee's Signature signifies that the employee feels he/she is confident in  
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- performing the procedure.
2. Supervisor’s Signature signifies that department supervisor is satisfied with the employee’s competence to perform the procedure.

**Procedure Review and Update Log**

**All procedures should be reviewed every 12 months. The Laboratory Director must also approve all new methods and procedural changes.**

**Procedure:** Accession of Maternal Specimens for Prenatal Screening  
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<b>Date</b>	<b>Supervisor’s signature</b>	<b>Procedure Version</b>	<b>Review</b>	<b>Update</b>	<b>Add-On</b>	<b>Laboratory Director’s signature</b>	<b>Date</b>
<b>8/13/13</b>		<b>V 4.2</b>		<b>X</b>			<b>8/13/13</b>

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