21 Audit Schedule _January - July

| MONTH | AREA | SYSTEM/PROCESS | REPORT OWNER |
|----------|---|---|---|
| | | | Operations Director, |
| | | On site walkthrough review of compliance with technical | Wet Lab Managers, |
| January | Extraction | Procedures, Safety, Reagents, Instrumentation and Workflow | Extraction Supervisors |
| | | Available and Signed Personnel Training Records for Regulatory | Operations Director Wet Lab Managers |
| | All Technical | Compliance | Supervisors |
| | 7th recimieat | Сотриалос | Supervisors |
| | | | |
| | Testing Processes for Proficiency Testing Regulatory Compliance | | |
| February | All Technical | (Complete Attestations Fall 2020 | Quality Manager |
| | | End to End Sample Tracer Audit for preanalytical, analytical and post | |
| | | analytical processes covering sample receipt, equipment | |
| | All Areas | qualification, maintenance GDP documentation, QC personnel | ODC Discolar Maddah |
| | | qualification, training, competency documents, result reporting and | OPS Director, Wet Lab |
| | | corrected reports. | Managers, Supervisors OPS Director, Wet Lab |
| | All Areas | Reagent Labeling Compliance | Managers, Supervisors |
| | 711711643 | Equipment Maintenance Logs: GDP compliance and regulatory | OPS Director, Wet Lab |
| | All Areas | compliance | Managers, Supervisors |
| | | | , i |
| | | Document Control: | Lab Director, OPS |
| | | Director Approval of Documents | Director, Wet Lab |
| March | All Areas | Employee Review of Documents | Managers, Supervisors |
| | | | Operations Director, |
| | Pre/Post | On site walkthrough review of compliance with technical | Wet Lab Managers, |
| | PCR W-F/Day | Procedures, Safety, Instrumentation and Workflow | PCR Supervisors |
| | | End to End Sample Tracer Audit for preanalytical, analytical and post analytical processes covering sample receipt, equipment | |
| | | qualification, maintenance GDP documentation, QC personnel | |
| | | qualification, training, competency documents, result reporting and | OPS Director, Wet Lab |
| | All Areas | corrected reports. | Managers, Supervisors |
| | Result | Corrected Reports: Review all instances and verify that original and | Lab Director, Quality |
| | Reporting | amended versions are retained and available to the lab | Manager |
| | Specimen | | Lab Director, Quality |
| | Acceptability | Delayed Receipt Cancellation Report (LIMC Function) Request to IT | Manager |
| | All Areas | Peagent Labeling Compliance | OPS Director, Wet Lab |
| | All Al Eds | Reagent Labeling Compliance Equipment Maintenance Logs: GDP compliance and regulatory | Managers, Supervisors OPS Director, Wet Lab |
| | All Areas | compliance | Managers, Supervisors |
| | , , cus | | managers, supervisors |
| | | | OPS Director, OPS |
| | Accessioning | | Managers, Accession |
| April | | Specimen Receipt/Manifest Date/Time Stamp Audit | Supervisors |
| | | | OPS Director, Wet Lab |
| | Extraction | On site walkthrough review of compliance with technical | Managers, Extraction |
| | W-F/Night | Procedures, Safety, Reagents, Instrumentation and Workflow | Supervisors |

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| a Department of icHealth | Technical | Personnel: Complete Competency documentation for employees | OPS Director, Wet Lab |
| | Employees | trained in September (include compliance with GDP) | Managers, Supervisors |
| | | End to End Sample Tracer Audit for preanalytical, analytical and post | ···aiiaga:a) aapa: iiaa:a |
| | | | |
| | | analytical processes covering sample receipt, equipment | |
| | All Areas | qualification, maintenance GDP documentation, QC personnel | |
| | | qualification, training, competency documents, result reporting and | OPS Director, Wet Lab |
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| | Reporting | amended versions are retained and available to the lab | Manager |
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| | Acceptability | Delayed Receipt Cancellation Report (LIMC Function) Request to IT | Manager |
| | receptability | Belayed necespt editional neport (2.1116 i director) nequest to in | OPS Director, Wet Lab |
| | All Areas | Reagent Labeling Compliance | |
| | All Aleas | Reagent Labeling Compliance | Managers, Supervisors |
| | | | OPS Director, Wet Lab |
| | All Areas | Equipment Maintenance Logs: GDP and Regulatory Compliance | Managers, Supervisors |
| | | | |
| | | | OPS Director, OPS |
| | Accessioning | On site walkthrough review of compliance with technical | Managers, Accession |
| May | W-F/Nights | Procedures, Safety, Reagents, Instrumentation and Workflow | Supervisors |
| | - | Safety Compliance: Personnel Training Documentation LMS/Media | OPS Director, OPS & |
| | All Areas | Lab; HSO walkthroughs, Fire Extinguishers, Showers, Eye Wash Logs | Wet Lab Managers |
| | All | | IT Director, OPS |
| | Employees | Information Management: LIMC User Security Access and Rights | Director, HR |
| | Litipioyees | Information Management. Livic oser Security Access and Nights | |
| | T | Demond Complete Computers Demonder to Computer to | Operations Director |
| | Technical | Personnel: Complete Competency Documentation for employees | Wet Lab Managers |
| | Employees | trained in October (incl compliance with GDP) | Supervisors |
| | | End to End Sample Tracer Audit for preanalytical, analytical and post | |
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| | Specimen Acceptability | Deleved Bessint Consultation Bonest (LIMC Function) Besweet to IT | Lab Director, Quality |
| <u> </u> | Acceptability | | N / a · a a · a · a · a |
| ĺ | | Delayed Receipt Cancellation Report (LIMC Function) Request to IT | Manager |
| 1 | | | OPS Directors, Wet Lab |
| | All Areas | Reagent Labeling Compliance | OPS Directors, Wet Lab Managers, Supervisors |
| | All Areas | Reagent Labeling Compliance | OPS Directors, Wet Lab Managers, Supervisors OPS Directors, Wet Lab |
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| | All Areas | Reagent Labeling Compliance | OPS Directors, Wet Lab Managers, Supervisors OPS Directors, Wet Lab Managers, Supervisors Operations Director |
| Jun | All Areas All technical | Reagent Labeling Compliance Equipment Maintenance Logs: GDP and Regulatory Compliance Type A/B Equipment Maintenance Review (Pipettes, centrifuges, | OPS Directors, Wet Lab Managers, Supervisors OPS Directors, Wet Lab Managers, Supervisors Operations Director Wet Lab Managers |
| Jun | All Areas | Reagent Labeling Compliance Equipment Maintenance Logs: GDP and Regulatory Compliance | OPS Directors, Wet Lab Managers, Supervisors OPS Directors, Wet Lab Managers, Supervisors Operations Director Wet Lab Managers Supervisors |
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| cHealth | Reporting | amended versions are retained and available to the lab. | Manager |
| | Specimen | | Lab Director, Quality |
| | Acceptability | Delayed Receipt Cancellation Report (LIMC Function) Request to IT | Manager |
| | | | OPS Directors, Wet Lab |
| | All Areas | Reagent Labeling Compliance | Managers, Supervisors |
| | | | OPS Directors, Wet Lab |
| | All Areas | Equipment Maintenance Logs: GDP ad Regulatory Compliance | Managers, Supervisors |
| | | | OPS Director, OPS |
| | Accessioning | On site walkthrough review of compliance with technical Procedures, | Managers, Accession |
| | S-T/Nights | Safety, Reagents, Instrumentation and Workflow | Supervisors |
| | | | |
| | | | OPS Director, Wet Lab |
| JUL | Software | Automated Temperature Monitoring Audit | Managers, Supervisors |
| | Extraction | | OPS Director, Wet Lab |
| | S-W/Day | On site walkthrough review of compliance with technical | Managers, Extraction |
| İ | | Procedures, Safety, Reagents, Instrumentation and Workflow | Supervisors |
| | Technical | Personnel: Complete Competency Documentation for employees | OPS Director, Wet Lab |
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| | | | OPS Directors, Wet Lab |
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| | | | |
| | | | |

Pre-Scheduled Audits for 1st half of 2021 approved as written. Additional audits may be added to the schedule based on review of non-conforming events and continuous improvement actions. Audit Schedule is reviewed and updated every 6 months.

Reviewed and Approved:

| | | Signature | Date |
|---------------------|---------------------|--------------------------------------|-------------------|
| Quality Manager | Tricia Walker-Hill | Docusigned by: Thicia Walkerstillby: | 01 March 2021 1 |
| Laboratory Director | Dr. Adam Rosendorff | D88BA82DA(ME422 92C7B7F64A564C9 | 01 March 2021 1 |





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Adam Rosendorff Adam.Rosendorff@PERKINELMER.COM

PerkinElmer, Inc.

Security Level: Email, Account Authentication

(Optional)

Signature

Signature Adoption: Drawn on Device Using IP Address: 104.129.199.16

Electronic Record and Signature Disclosure:

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Tricia WalkerHill Tricia.WalkerHill@PERKINELMER.COM

QA Manager PerkinElmer, Inc.

Security Level: Email, Account Authentication

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Electronic Record and Signature Disclosure:

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In Person Signer Events

Editor Delivery Events

Agent Delivery Events

Intermediary Delivery Events

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Tricia Walkerfill D88BA82DA31F422

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| Payment Events | Status | Timostamns |