## Standards of Practice in Molecular Diagnostics

**PURPOSE/PRINCIPLE**

The Standards of Practice document contains administrative and technical requirements for accepting specimens for the purpose of obtaining information for the diagnosis, prevention and treatment of disease. These requirements are categorized as fundamental standards of practice. These core activities establish the infrastructure, competencies, and the dependability of services provided to the patient. The standards monitor the quality of specimens; the performance of test procedures, reagents, supplies, equipment, and personnel; review of test results; and documenting the validity of the test method to ensure accuracy and reproducibility. Collectively, these standards comprise the Quality Management System (QMS) that is designed to continuously analyze and improve services to achieve the best possible outcome for the patient.

**ABBREVIATIONS**

|  |  |
| --- | --- |
| * AMR: analytical measuring range
* CEUs: continuing education units
* DOB: date of birth
* F/T: freeze/thaw
* IC: Internal control
* LIS: laboratory information system
* LOD: Level of detection
 | * MRN: medical record number
* PM: preventative maintenance
* PPE: personal protective equipment
* PT: proficiency testing
* QC: Quality control
* RT: room temperature
* SOP: standard operating procedure
* TAT: turn-around-time
 |

**STANDARDS OF PRACTICE**

| **Quality Element** |  | **Standard of Practice** |
| --- | --- | --- |
| **Personnel** | 1 | Each employee must have the education, training and experience necessary to perform assigned tasks in the job description |
| **Training** | 2 | Training is provided as related to specific job requirements |
| **Competency** | 3 | Personnel competency is assessed upon initial training, at 6 months and annually thereafter. Evaluation of competence shall include but not limited to:

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| --- | --- |
| Step | Action |
| a | Direct observation employee’s performance of duties by designee |
| b | Observation of compliance with safety protocols |
| c | Periodic review of work for compliance with SOPs, turnaround times and workload volumes |
| d | Monitoring the recording and reporting of test results |
| e | Direct observation of performance of instrument maintenance and function checks |
| f | Assessment of knowledge and performance through proficiency testing |
| g | Assessment of problem solving skills |

 |
| **CEUs** | 4 | Continuing education shall be provided; minimum 12 CEUs are required annually |
| **Performance evaluation** | 5 | Each employee has an annual performance evaluation based on job description, objective measures and performance standards |
| **Records** | 6 | Personnel records are held for 5 years post termination |
| **Facilities and Safety** | 1 | Laboratory design, environment and resources shall be provided to support analytical systems, safety and security |
| **Workflow to prevent Nucleic acid contamination** | 2 | Measures are taken to prevent nucleic acid cross-contamination that include:

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| Step | Action |
| a | Separate rooms for pre-amplification and post amplification procedures |
| b | Unidirectional workflow from pre- to post-amplification processes when possible* May return to pre-amplification areas when closed systems are used providing that assay, PPE and discard procedures are followed
 |
| c | Preparation and storage of reagents in a dedicated work area that excludes nucleic acid or amplicon |
| d | Processing samples in a biosafety cabinet |
| e | Not exposing samples to post-amplification work areas prior to processing. |
| f | Dedicated equipment and PPE items for the pre- or post-amplification work areas |
| g | A decontamination plan to be implemented if amplicon contamination is identified by swipe testing |
| h | Template-free mastermix control to identify amplicon contamination |

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| **Airflow** | 3 | Negative and positive airflow shall be used for room containment and prevention of amplicon contamination |
| **Safety eLearning** | 4 | Training is provided for:* Emergency preparedness
* Chemical hygiene (“Right to Know”)
* Infection Prevention & Control
* General safety
* Hazardous/biohazardous materials and disposal
 |
| **Biosafety** | 5 | Work practices, biosafety equipment and procedures shall meet biosafety level 2 (BSL-2) criteria. Refer to policies:* MB 2.01 *Safe Work Practices*
* MB 2.02 *Biohazard Containment*
* MB 2.03 *Biohazardous Spills*
 |
| **Work areas** | 6 | Work areas shall be clean and well maintained |
| **Reagents and Supplies****Inventory Control** | 1 | Maintain inventory control records for reagents and commercial kits as follows:

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| --- | --- | --- |
|  | Activity | Action |
| a | Reagents/kits arrive | a. Record in QC log book* Date of receipt
* Lot number(s)
* Quantity

b. Verify proper shipping conditions* Contact purchasing buyer if conditions not acceptable
* Document failure in *QC and Equipment Failure Log* and Inventory Log book
 |
| b | Reagents/Kits are received | Date and place “New Shipment” label on box  |
| c | QC is verified | Record date performed in QC log book; fill out and place “Ready for Use” label on box  |
| d | Placed in service | Record date in QC log book |
| e | QC fails | * Document failure in *QC and Equipment Failure Log* and Inventory Log and corrective action
* Notify section technical director or designee
* Notify manufacturer for further instruction or replacement
* Discard reagents after notification if no further testing will be performed
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| **New lot/shipment QC** | 2 | Verify QC on each new lot or new shipment of reagents/kits before or concurrent with use. Suitable materials for qualitative tests: * Positive/negative known patient samples tested on previous lot
* External QC materials tested on previous lot
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| **Reagent labeling** | 3 | Reagents, solutions, control materials and other supplies shall be labeled as appropriate

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| --- | --- | --- |
|  | Activity | Action |
|  a | Labeling criteria | Properly label reagents with following:* Identity
* Concentration as applicable
* Storage conditions
* Preparation date or date reconstituted
* Identity of the preparer
* Expiration date
* Date opened: Record new expiration date on reagent if applicable
 |
| b | Reagents with no manufacturer expiration date provided | Assignment of expiration date after preparation or aliquoting: |
| * 5% Extran: 1 yr, RT
* 70% alcohol: 1 yr, RT
* NFW: 1 yr, RT, 4 – 8⁰ C
 | * Process/Extraction Controls: 1 yr., -70⁰ C
 |
| c | Labeling Micro-centrifuge tubes (TE, NFW, UTM) | Each tube does not need to be labeled individually as long as the storage box/rack includes the identifying information and each tube is traceable to the storage box/rack. |

 |
| **Storage** | 4 | Store reagents according to manufacturer’s instructions; refer to individual assay procedures |
| **Freeze/Thaw cycles** | 5 | Store primers, probes and mastermix in small aliquots to minimize the number of freeze-thaw (F/T) cycles if applicable

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| Activity | Action |
| Establish number of F/T cycles | Monitor control results for identifying reagent deterioration |
| Manufacturer recommendations | Review if available |

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| **Kit components** | 6 | Never interchange kit components unless specified by manufacturer or verified by laboratory |
| **Expired reagents** | 7 | Do not use expired reagents/kits for testing patient samples or if the reagent quality has deteriorated or been contaminated * Out dated items may be used for training purposes, stored separately from working reagents and marked “Training or Research Only”
 |
| **Equipment/****Instrumentation****Function checks** | 1 | Function checks are performed annually and records maintained by the BioMed department to confirm the safety and proper identification of equipment for use. |
| **Defective equipment** | 2 | Remove defective equipment from service until repaired to meet acceptable criteria or disposal* Decontaminate equipment prior to service, repair or disposal
* Provide PPE for field service agents if necessary
 |
| **Service contracts** | 3 | Purchased service contracts for preventive maintenance (PM) shall have a description of the services performed for equipment covered in the contract

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| --- | --- |
| Activity | Action |
| Instrument PMs | Performed annually or at specified intervals by manufacturer  |
| Thermocycler temperature checks | Performed at lease annually or at specified intervals by manufacturer or BioMed |

 |
| **Daily maintenance** | 4 | Document daily/routine preventive maintenance that is not included in a service contract on appropriate log sheet |
| **Equipment/****Instrumentation****cont.****Performance verification** | 5 | Positive and negative controls along with previously tested low-positive and negative patient samples (2 or more) will be used to challenge the LOD and verify the sensitivity/performance with each of the following:* Installation of a new instrument or loaner
* Replacement of a critical instrument part or any major repair
* Relocation of an instrument
 |
| **Comparability of instruments/methods** | 6 | Instruments/methods that are different or are associated with a separate computers will be used to test for the same analytes simultaneously to compare functionality. * Acceptance criteria: appropriate targets are detected by both qualitative methods
 |
| **Review** | 7 | Daily/routine instrument maintenance and function checks shall be reviewed at least monthly |
| **Performance records** | 8 | Maintain performance records of calibrations, verifications and equipment repairs for the life of the equipment and two years thereafter |
| **Additional info** | 9 | Refer to ***Appendix A*** for individual equipment/instrument maintenance and frequencies. |
| **Standard Operating Procedure Manual**  | 1 | A standardized format shall be used for policies and procedures to ensure that documents are identified, reviewed, approved and retained. |
| **(SOPM)** | 2 | The electronic SOPM shall be available at the work bench |
| **Review/frequency** | 3 | Records of procedure review and approval by the laboratory director and section technical director will be maintained

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| If | Then |
| New or revised policy or procedure  | The laboratory director and section technical director will review and approve the policy/procedure before implementation  |
| Biennial review | The laboratory director or designee will review every 2 years |
| Review of electronic procedure | Include statement “reviewed by [name] on [date] in the record within share point |
| Change in directorship | The new laboratory director/section technical director will review the policy/procedure manual within a reasonable time making sure that procedures are complete and current  |

 |
| **Knowledge of contents** | 4 | Testing personnel shall review new or revised procedures to maintain competency and standardized work practices* Verify knowledge of procedure contents in MedTraining through email notification with electronic link to review
* Deviation from SOP may place laboratory services at risk
 |
| **Revision recommendations** | 5 | Submit recommendations for document revisions on the “Document Change Request Form” QP 6.20 |
| **Retired procedures** | 6 | Retain retired procedures for 2 years; document date of initial use and retirement date |
| ***Pre-Analytical Phase*****Sample Collection, Identification, and Handling** | 1 | Specific instructions for proper identification, collection and handling of samples are available on the [Laboratory Services](http://khan.childrensmn.org/Communities/Lab.asp) web page, Lab Test Directory |
| **Sample identification**  | 2 | Two of the following patient identifiers are required on submitted samples (Administrative policy 630.00) * Patient’s full first and last name
* Medical record number (MRN)
* Date of birth (DOB)
 |
| ***Pre-Analytical Phase cont.*****Test requisition** | 3 | The requisition for testing shall contain sufficient information to identify the patient and authorized requestor as well as pertinent clinical data such as but not limited to:

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| --- | --- |
| * Unique identification of the patient
 | * Sample source
 |
| * Gender
 | * Test requested
 |
| * Age, date of birth
 | * Date and time received in the laboratory
 |
| * Requesting physician
 | * Two forms of identification
 |
| * Date and time of collection
 |  ***Note:***name, DOB or MRN are required |

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| **Accession** | 4 | All samples received shall be accessioned in the laboratory information system (LIS) |
| **Sample rejection** | 5 | Follow criteria for acceptance and rejection for primary samples; refer to Specimen Rejection Criteria MB 1.02 and Laboratory Specimen Labeling 630.00

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| If  | Then |
| Sample does not meet acceptable criteria | Request new specimen |
| Sample does not meet acceptable criteria but is irreplaceable, i.e. CSF or surgical specimen | Consult with technical director or pathologist |
| Compromised sample is processed | The final report should indicate the problem and that caution is required when interpreting the result. |

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| **Aliquots** | 6 | All sample aliquots shall be traceable to the primary sample using appropriate identifiers |
|  | 7 | Prepare and handle aliquots in a manner to prevent cross-contamination of primary and aliquot samples |
| ***Analytical Phase*****Method verification and validation** | 1 | The laboratory will only use procedures that are validated and confirmed suitable for the intended use |
| **Method Verification****Performance specifications***Refer to MB 5.06 for additional information* | 2 | Method verification will be performed before a test method is used to report patient results. Verify performance specifications for:

|  |  |  |
| --- | --- | --- |
| Qualitative AssayPerformance specifications | FDA approved methods (unmodified) | Modified FDA-cleared or Laboratory developed |
| Accuracy | X | X |
| Precision | X | X |
| Reference range | X | X |
| Reportable range (AMR) | Not required | X |
| Analytical sensitivity (LOD) | Not required | X |
| Analytical specificity  | Not required | X |

 |
|  | 3 | Document method verification procedure and data |
| **Approval** | 4 | Document approval by section technical director and date of implementation |
| **Records** | 5 | Retain data for the period which the procedure is used by the laboratory and 2 years after the method is discontinued |
| **Ongoing Method validation after verification** | 6 | Ongoing method validation after verification for qualitative testing shall be monitored by:* Quality Control included in each run
* Proficiency testing
* Technical staff competency
* Correlation with clinical patient data; positivity rates
 |
| ***Analytical Phase*: QC****Target control** | 1 | Test external positive and negative controls that assess the entire assay process with each analytical run; test the same as patient samples |
| **Extraction control** | 2 | Include an extraction control with each extraction process; detection range defined |
| ***Analytical Phase*: QC****Internal control** | 3 | Include an internal control with each patient sample to detect sample inhibition |
| **Multiplex controls** | 4 | For multiplex assays, external controls for each target are rotated so that all targets are tested periodically. |
| **QC Processing/testing** | 5 | Process and test quality control materials in the same manner as patient samples unless specified by the manufacturer |
| **QC Results** | 6 | Interpret QC results according to manufacturer’s instructions |
|  | 7 | Record all QC results on appropriate form |
|  | 8 | Document all out-of-control results and corrective action on *QC and Equipment Failure Log*

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| --- | --- |
| If | Then |
| Results are out-of-control  | Do not report patient results until problem is resolved; repeat/re-evaluate patient results for clinical performance |
| Test remains out-of-control | Repeat test with new reagents; notify technical director |
| Problem remains unresolved | Perform alternate testing |

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| **Equivocal QC** | 9 | If assay negative control is positive or unresolved, investigate problem; refer to MB 3.01, Engineering Controls to Prevent Nucleic Acid Contamination |
| **QC Review** | 10 | Technical director or designee will review QC records at least monthly |
| **QC Records** | 11 | Maintain QC records for a minimum of 2 years |
| ***Post-Analytical Phase*****Patient Reports****HIPPA** | 1 | Report results only to authorized personnel in compliance with HIPPA regulations |
| **Critical values** | 2 | Notify provider of “critical values” immediately. Refer to policy *Critical Limits for Laboratory Test Values* for failed attempts; file safety report. |
| **Verbal results** | 3 | When giving verbal results, document person notified, date and time |
| **Turnaround time** | 4 | Results are available within the stated turnaround time published on [Laboratory Services](http://khan.childrensmn.org/Communities/Lab.asp) web page, Lab Test Directory; LIS provides a monthly TAT report  |
| **Testing personnel****Review criteria** | 5 | Staff technologists shall review patient results before filing in the LIS according to the following criteria:

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| --- | --- |
| Step | Action |
| a | Required QC materials have been processed |
| b | QC data is within acceptable performance |
| c | Specimen identification and associated results are accurately recorded |
| d | Critical and alert values are immediately communicated and documented |
| e | Reports are complete |

 |
| **Technical Specialist review** | 6 | Ongoing review of test results shall be performed by technical specialist or designee |
| **Correcting patient data** | 7 | Correct errors in a timely fashion. Refer to the protocols MB 1.03 and LIS 1.8 for *Correcting Patient Data*

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| --- | --- |
| Step | Action |
| a | Promptly notify the patient’s physician or nurse of reporting error |
| b | Promptly issue a corrected report that is identified as a corrected report |
| c | Maintain the information in the original report as well as the corrected report |
| d | Document in report, the person notified, date and time  |

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| ***Post-Analytical Phase*** **Referral Testing** | 1 | Include the name of the reference laboratory actually performing the testing on patient reports |
| **Referral test reporting** | 2 | Report the exact results and information directly related to the interpretation of the results as issued by the testing laboratory |
| **Scan report** | 3 | Scan original report from testing laboratory into the patient’s chart |
| ***Post-Analytical Phase*** | 1 | Records are stored in a manner that maintains their integrity and facilitates their retrieval |
| **Records****Record Retention****Correction of Laboratory Records (QC, temp logs, etc.)** | 2 | The laboratory shall retain the following records for at least the specified period of time:

|  |  |  |
| --- | --- | --- |
| Record | Length of time | Location |
| Test requisitions | 2 years | Stored in Sunquest OER |
| Test reports | 2 years | * Stored in Sunquest and Cerner archived electronic records
* Worksheets, QC and identity of personnel performing testing will also be retained for 2 years
 |
| Retired procedures | 2 years | * Stored in molecular office and online: G drive in Lab Procedures folder (Controlled access) and SharePoint document control system
* Records must include date in use and retirement
 |
| Instrument Preventive maintenance | Life of instrument and 2 years after discontinued | Includes service and repair records, certifications; located in Service Manuals, rm B422 |
| Routine maintenance records  | 2 years | Includes temperature monitoring, daily/weekly cleaning, etc.; stored in Service Manuals, rm B422 |
| Verification/Validation studies  | Period of time assay is in use and 2 years thereafter | Test performance specifications and validation documentation, stored in Molecular office |
| Personnel | 5 years | Stored in Laboratory manager’s office |
| QC records | 2 years | Recorded on instrument logs, Sunquest worksheets, QC forms, and in the Inventory QC Log Book, rm B422 and rm B423 |
| Proficiency Test results | 2 years | Stored in Molecular office, rm B454 |
| Inventory Control for supplies | 2 years | Includes the recording of reagent/kit lot numbers, controls used and results, date of receipt, date placed into service, Inventory Manuals, rm B422 |
|  Safety Reports, Occupational injuries | 5 years | Report to the Office of Patient Safety or Risk using online reporting located on the Children’s Intranet |

 |
| 3 | When a correction is required, erroneous entries must be left visible (no white out or erasing) or accessible. Erroneous results must be crossed out, initialed, and dated when a correction is made.  |
| ***Post-Analytical Phase*** **Confidentiality** | 1 | All patient identified information and test results will be considered health related confidential information |
| **Online HIPPA training** | 2 | All employees are required to complete online confidentiality training annually |
| **Quality Assessment and Improvement** | 1 | The laboratory will participate in an external proficiency program/alternate performance assessment to verify the reliability and accuracy of test results at least twice per year |
| **Proficiency Testing (PT)** | 2 | Refer to policy MB 5.04 *Performing Proficiency Testing* |
|  | 3 | PT results will be investigated if the score is less than 100 percent |
|  | 4 | PT samples can be used for competency testing after the final submission date to the regulatory testing program |
| **Error correction** | 5 | When errors in patient reports are detected or PT samples fail, the laboratory shall prompt an investigation to determine the underlying cause of the problem  |
| **Process improvement** | 6 | Any changes that may be required to SOPs resulting from error corrective action will be documented and implemented as required |

**References**

1. Daly, J., Section 14. Quality Assurance, Quality Control, Laboratory Records and Water Quality. InLynne S. Garcia (ed) *Clinical Microbiology Procedures Handbook,* Third edition2010, American Society for Microbiology, Washington, D.C.
2. Garcia, Lynne S., *Clinical Laboratory Management,* 2004, ASM Press, Washington, D.C., pg. 369 - 385, 745 – 752.
3. NCCLS publication GP26A, *A Quality System Model for Health Care; Approved Guideline* [ISBN

 6238-387-6]. NCCLS, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA. (October 1999)

1. CLSI publication MM3-A2 Vol. 26 No. 8, *Molecular Diagnostic Methods for Infectious Diseases; Approved Guideline* – Second edition[ISBN 1-56238-596-8]. CLSI, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898 USA.
2. Anderson, Nancy L., et al, “Quality Systems in the Clinical Microbiology Laboratory”, CumiTech 3B, 2005, ASM Press, Washington D.C.
3. *Clinical Laboratory Standards of Practice*, State of New York Department of Health, Wadsworth Center, Albany, NY, 2008
4. Persing, David H, Tenover FC, Tanf YW, Nolte FS, Hayden RT, Van Belken A, *Molecular Microbiology, Diagnostic Principles and Practice,* Second Edition, 2011,ASM Press, Washington DC

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| Historical Record |  |
|   | **Version** | **Written/Revised by:** | **Effective Date:** | **Summary of Revisions** |
| 1.0 | P. Ackerman | 2/6/82 | Initial Version |
| 1.1 | P. Ackerman | 9/17/99  |  |
| 1.2 | P. Ackerman | 9/17/01 |  |
|  | 1.3 | P. Ackerman | 9/3/03 |  |
|  | 1.4 | P. Ackerman | 8/26/05 |  |
|  | 1.5 | P. Ackerman | 9/20/05 |  |
|  | 1.6 | P. Ackerman | 12/20/06 | Modified Thermometer section to include digital thermometers. Updated susceptibility weekly validation. |
|  | 1.7 | P. Ackerman | 7/6/07 | Added notification if patient results were affected by deficiencies. Title change from dept. supervisor to technical specialist. Revised antisera and reagent QC; eliminated daily QC for bacitracin, optochin and XV strips, Changed monthly QC for antisera to 6 months, trichrome stain changed from daily to weekly. Added Vitek 2 under Equipment section. Updated  ProbeTec environmental culture to weekly rotation from monthly. |
|  | 1.8 | P. Ackerman | 9/20/07 | Added ASR information, #8 in QC parameters and General Information. Added EasyQ to equipment. Changed the policy name from *Quality Control Guidelines* to *Quality Systems.* |
|  | 1.9 | P. Ackerman | 6/9/09 | Removed information that was Microbiology specific; added easyMag and SmartCycler to equipment section. Added new sections for Safety, Specimen Collection, Records, and Facility design. Modified method performance. |
|  | 10 | P. Ackerman | 9/1/11 | Reformatted procedure, Changed version designation to whole number, renamed document from Standards of Practice to Quality Management Standards of Practice; Added Quality assessment and confidentiality segments |
|  | 11 | P. Ackerman | 9/22/12 | Reagent labeling: Added Reagents with no expiration dfate provided by manufacturer |
|  | 12 | P. Ackerman | 9.20.14 | Removed EasyQ information Appendix A; added Focus Simplexa |
|  | 13 | P. Ackerman | 7.9.15 | Added GenMark eSensor to Appendix A, added technical director |
|  | 14 | P. Ackerman | 6.1.2016 | Reformatted for CMS upload; replaced logo |
|  | 15 | P. Ackerman | 3.23.17 | Removed SmartCycler from Appendix 1; updated Simplexa name: DiaSorin Liaison; added BD MAX |
|  | 16 | J. Laramie | 5.3.18 | -Updated storage location of validation materials and smart temps monitoring of room temps-Biennial review: 05.02.2018 JL |
|  | 17 | J. Laramie | 6.29.19 | -Removed BD Max-Rephrased instrument comparison testing – more inclusive  |
|  | 18 | J. Laramie | 4.13.20 | -Added correction of laboratory records  |

**Appendix A: Equipment Maintenance and Frequency**

1. Document instrument failures/problems in the *QC and Equipment Failure Log*.
2. Determine if instrument failure affected patient test results; note in log.
3. Describe corrective action taken.
4. Notify section technical director and/or designee

| Equipment | Step | Maintenance | Frequency |
| --- | --- | --- | --- |
| **Thermometers** | 1 | Check non-certified thermometers against NIST standard. Record in Service Manual. | Before placed into service |
|  | 2 | Digital thermometers: Place Traceable Certificate of Calibration in Service Manual.  | Replace upon expiration |
|  | 3 | Check for damage | Each day of use |
| **Temperature Monitoring System** | 1 | Vendor performs annual calibration of all temperature monitoring devices to a NIST standard; refer to Temperature Monitoring Procedure, TS 18.4 v3 | Annually |
| 2 | Calibration records are maintained by BioMed |  |
| 3 | Review temperature monitoring system for temperature variations and alerts | Daily |
| 4 | If a red alarm activates indicating an out-of-range temperature, document the reason for event and corrective action in SmarTemp | As needed |
| **Temperature dependent equipment and environment** | 1 | * Refrigerators – monitored by Smart Temp
* Freezers (–20°C) – monitored by Smart Temp
* Freezer (–70°C) – monitored by Smart Temp
* Room temperature – monitored by Smart Temp
 | * Continuous
* Continuous
* Continuous
* Continuous
 |
|  | 2 | Record temperature checks on Maintenance Log | Daily |
| **Microliter Pipettes** | 1 | Check for accuracy | Before placed into service and every 6 months thereafter |
|  | 2 | Use PSC pipette calibration system on 10µl pipettes and greater |
|  | 3 | Send automatic and low volume pipettes, <10µl to Gilson for calibration | Every 6 months |
| **Biological Safety Cabinets** | 1 | Certification of airflow rates and filter function | Annual |
|  | 2 | Clean and disinfect work surfaces with Bleach Sani-Cloth Wipes followed by water and 70% alcohol | Daily, between assays and if spills occur |
|  | 3 | UV work surface for 10 – 15 minutes | At the end of the workday |
| **Centrifuges** | 1 | Clean if soiling is present with Bleach Sani-Cloth wipes followed by water and 70% alcohol | As needed |
|  | 2 | Balance loads | Each use |
|  | 3 | RPMs checked by BioMed | Annual |
|  | 1 | Instrument under service contract. Preventive maintenance is performed by DiaSorin Field Application Specialist | Semi-annual |
|  | 2 | Test parameters and reagent lot information is recorded on the Segment Report | Each patient run |
| **DiaSorin**LIAISON® MDX(formerly Focus Simplexa) | 3 | Spectral Matrix/temperature accuracy checks performed using DiaSorin Liaison Calibration Panel by DiaSorin Field Application Specialist; Refer to “Certificate of Calibration” in Service Manual | Semi-annual |
|  | 4 | Decontaminate instrument with Sani-Wipe Bleach Clothes followed by water and 70% alcohol | As needed: contamination event |
| **GenMark eSensor XT-8 system** | 1 | XT-8 does not require routine maintenance |  |
| 2 | Instrument under service contract. Preventive maintenance is performed by GenMark-trained specialist | Annual |
|  | 3 | Test parameters and reagent lot information is recorded on the Run Report | Printed with each run |
|  | 4 | Decontaminate instrument with Sani-Wipe Bleach Clothes followed by water  | As needed: contamination event |
|  | 5 | Thermocycler temperature verification/accuracy is performed by BioMed | Semi-Annual |
| **NucliSens easyMag** | 1 | Perform routine maintenance | Each day of use; refer to easyMag maintenance log |
|  | 2 | Instrument under service contract. Preventive maintenance is performed by BioMerieux field service | Semi-annually |
|  | 3 | Test parameters and reagent lot information is recorded on the Run Report | Printed with each run |
|  | 4 | Clean instrument with 5% Extran followed by 70% alcohol | After final run |