ADM 108 ADM 108 - Quality Control Policy

Copy of version 5.0 (approved and current)

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Organization Howard University Hospital

Comments for version 5.0
processed revision to include a recall section in the Quality Control ADMIN 108 policy

Approval and Periodic Review Signatures

Type	Description	Date	Version	Performed By	Notes
Approval	Lab Director	7/12/2023	5.0	Ali Mousa Ramadan MD	
Approval	Quality Assurance Manager	6/26/2023	5.0	Lydia Seifu	
Approval	Lab Director	6/15/2022	4.0	Ali Mousa Ramadan MD	
Approval	Laboratory Operations Manager	6/15/2022	4.0	Wendell McMillan (108860)	
Approval Captured outside MediaLab	Lab Director	6/15/2022	4.0	Wendell R. McMillan II	Recorded on 6/15/2022 by Wendell McMillan (108860) when document added to MediaLab (previous system of record: Paper Copy)
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Approvals and periodic reviews that occurred before this document was added to the MediaLab Document Control system may not be listed.

Version History

Version	Status	Type	Date Added	Date Effective	Date Retired
5.0	Approved and Current	Major revision	6/26/2023	7/12/2023	Indefinite
4.0	Retired	First version in Document Control	6/15/2022	6/15/2022	7/12/2023

HOWARD UNIVERSITY HOSPITAL
DEPARTMENT OF PATHOLOGY AND LABORATORY MEDICINE

STANDARD OPERATING POLICY AND PROCEDURE MANUAL

POLICY: QUALITY CONTROL POLICY
No. ADMIN/108/2004/4

STATEMENT OF POLICY:
This policy establishes the guidelines for monitoring and evaluating the quality of the testing process for each testing process for each test method to ensure accuracy and reliability of patient testing results and reporting.

SCOPE:
The policy applies to all areas of the Department involved in patient testing and resulting including point of care testing sites.

POLICY:
- The standard operating Procedure Manual of each laboratory must clearly describe its Quality Control Program. Specification should include but not limited to the following information:
    - Use of controls
    - Calibrations
    - Setting tolerance limits
    - Linearity
    - Corrective actions
    - Goals
    - Levels of accountability
    - Review procedures
    - Records and documentation
- Statistical analyses are performed on qualitative tests on a monthly basis. The analyses are to include means, standard deviation and coefficient of variation.
- New reagents and controls must be evaluated for accuracy by means of parallel testing with previously used reagents and controls, or other methods.
- External and/or Internal Audits must be performed on all reportable tests (Reference Policy: ADMIN/109- Proficiency Testing and Alternative Assessment Policy).
- Comparability verification of results throughout the clinically appropriate ranges are performed bi-annually for tests performed using different methodologies or instruments. Acceptable tolerances between results produced by different methods, or different instruments must be defined.
- All reagents and solutions used in the laboratory and point of care testing sites are properly labeled. Labels should include:
    - The identity of the material and its strength
    - The date it was received in the laboratory

- Date prepared or opened
- The initials of the person who prepared or opened the reagent
- Expiration date
- Storage requirements
- Cautionary information
- Expired reagents and supplies are discarded immediately **except** for expired reagents that are used for teaching: they must be clearly labeled "EXPIRED" and stored in a separate area away from reagents being used for patient testing.

PREVENTATIVE MAINTENANCE:
The Quality Control Program includes provisions for preventative maintenance of instruments by periodic testing and inspection of instrument, as appropriate to assure proper instrument function. Preventative maintenance schedules are in accordance with all applicable regulatory requirements and manufacturer's recommendations.

- All non-certified thermometers must be checked against the laboratory's NBS certified thermometer before being placed in service and annually thereafter.
- Volumetric equipment including pipettes and dilutors must be periodically evaluated for accuracy. Damaged, etched or chipped glassware must be discarded.
- Temperatures of all refrigerators and freezers in use in the laboratory must be monitored at least once per day and the appropriate documentation made.
- Incubators and water baths are monitored daily or more frequently and defined by laboratory requirements.

NOTIFICATIONS FROM VENDORS/RECALL:
The Laboratory manages all notifications from vendors of defects or issues with reagents, supplies, instruments, equipment, or software that may affect patient care/client services.

Notifications can take the form of product recalls, market withdrawals, or software patches and upgrades. The Laboratory must take timely action to ensure there is no effect on testing results or laboratory services. Laboratory Managers must document vendor notifications and appropriate actions taken.

RECORD REVIEW:
All quality control records are reviewed at least monthly by the laboratory director and/or assistant laboratory manager.

RECORD RETENTION:

Quality control records other than Blood Bank are maintained for a minimum of 2 years. Blood Bank records are maintained for a minimum of 5 years. Preventative maintenance and repair records are maintained for 2 years. Compliance is audited by the laboratory QA officer.