POLICY
Corewell Health East - Equipment and Instrument - Maintenance, Function and Downtime - Dearborn, Taylor, Trenton, Wayne

This Policy is Applicable to the following Corewell Health sites:
Corewell Health Dearborn Hospital, Corewell Health Taylor Hospital, Corewell Health Trenton Hospital, Corewell Health Wayne Hospital

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Functional Area:	Clinical Operations, Laboratory
Department Area:	Lab - General, Laboratory Policies

1. **Purpose**
   This document provides a process for staff to alert them of instrument and equipment issues in terms of any functionality and concerns - this includes a documented process for communication, verification, downtime, and follow up.

2. **Policy Statement**
   It is the policy of Corewell Health to verify and document the performance of all instruments and equipment prior to initial use, after major maintenance or service, and after relocation to ensure that they run according to expectations. Please see departmental instrument and equipment policies for more information as to operation procedures and troubleshooting guidelines.

3. **Downtime**
   A. In the event of a complete instrument and equipment downtime (i.e., laboratory experiences a complete loss of functionality), specimens would be routed to another Corewell Lab for completion based upon direction from senior management. Communication of this event and directives to the staff and hospital teams/leaders would be conducted via the laboratory leadership team.
   B. In the event of an individual instrument and equipment downtime (i.e., single laboratory instrument/ equipment is not functional):
      1. Information is communicated to the team members regarding the event - this may be done via email, log, and/or huddle.
      2. Alternate testing is established by leadership upon other instruments/equipment availability and need and communicated to the team (i.e., email, huddle and/or log).
      3. The attached “Equipment out of Service” form should be posted on the non-functioning unit which indicates status and can be written upon and erased using a dry-erase marker and wipe. This is in addition to any required communication tools (i.e., log).
         a. The sign should be printed on red paper, laminated (so that it is reusable), posted on the unit, and updated as needed.
         b. Any staff member who provides updates should initial/date as needed.

c. Once the instrument/equipment is resolved, the sign can be taken down and information removed.
d. Leadership should designate a spot where these red reusable signs may be kept for easy access in the department.

4. Procedure

A. Instrument/Equipment Performance Verification:
1. The performance of all instruments and equipment is verified prior to initial use, after major maintenance or service, and after relocation to ensure that they run according to expectation per manufacturer guidelines.
2. NOTE: Instrument/equipment performance verification (NOT to be confused with validation or verification of the test method performance specifications) includes processes to verify that the instruments and equipment perform according to expectations for the intended use and within defined tolerance limits.
3. If instruments or equipment are moved, the laboratory performs appropriate function checks to ensure that they were not adversely affected by the relocation process or changes due to the new environment. This does not apply to portable equipment used following the manufacturer's instructions.
4. For Evidence of Compliance, please refer to:
   a. Written instrument/equipment specific procedures that describe the proper functioning of instruments and equipment per manufacturer guidelines.
   b. Departmental records of appropriate function checks and/or maintenance charts and records.

5. Revisions

Corewell Health reserves the right to alter, amend, modify or eliminate this document at any time without prior written notice.

6. References

A. Clinical and Laboratory Standards Institute. Laboratory Instrument Implementation, Verification, and Maintenance; Approved Guideline. CLSI Document GP31-A. Clinical and Laboratory Standards Institute, Wayne, PA; 2009.

7. Policy Development and Approval

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8. Keywords:

Entities will reference associated information contained within this document as applicable
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