Beaumont	Origination	3/1/2023	Document Contact	Jessica Czinder: Mgr, Division Laboratory
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Point of Care Autoverification Policy

Document Type: Policy

Status (Active) PolicyStat ID (12926586

I. PURPOSE AND OBJECTIVE:

- A. The purpose of this document is to provide technical staff with guidelines for autoverification rules between Telcor QML and the Laboratory Information System (LIS). Results in QML autoverify unless a rule is in place to hold the result in a QML exception queue for review. The QML server collects sample results from the Point of Care (POC) interfaced instruments and POC applications (ABL80, ABL90, Hemochron, HemoCue, i-STAT, Liat, Nova StatStrip, Piccolo, MTE (manual test entry), and WebMRE), evaluates results against autoverification rules, and uploads the compiled data to the LIS.
- B. This document is only applicable to areas that are approved for testing under one of the laboratory's Clinical Laboratory Improvement Amendments (CLIA) certificates.

II. POLICY STATEMENT:

A. This document provides the elements to comply with CAP checklist requirement GEN.43876 Current Autoverfication Rules.

III. CLINICAL SIGNIFICANCE:

A. Autoverification releases results from POC instruments and applications that are within reportable range, have acceptable lipemia, hemolysis and icterus values, do not have instrument flags associated with them, or violate "special" rules.

IV. AUTOVERIFICATION CRITERIA:

A. When all of the criteria in the Telcor QML Autoverification Rules attachment are met, QML will

automatically send results to the LIS and the QML Result Repository.

- B. Results that do not meet the criteria will be sent to either the QML Results Exceptions or Interface Exceptions queues. These queues are monitored by POC staff and issues are reviewed and resolved on a case-by-case basis.
- C. Quality control (QC) must be completed as indicated by the manufacturer and/or Individualized Quality Control Plan (IQCP) prior to testing patient samples.
 - 1. ABL80, ABL90, CoaguChek, Hemochron, HemoCue, i-STAT, Liat, Nova StatStrip, and Piccolo instruments have QC lock-out that is enabled to restrict instrument access until QC is performed and is acceptable.
 - 2. Manually entered test (manual test entry (MTE) and WebMRE) QC is reviewed by POC staff. If QC is not performed, documented, or repeated, in the event of a QC failure, POC staff follow up with the test area's management team. Patient results will be reviewed during the time period where QC compliance was not met.

V. QUALITY ASSURANCE:

- A. Validation of autoverification is performed initially, before testing is placed in use, annually thereafter, and whenever there is a change to the system that could affect the autoverification logic.
- B. Validation is completed by using patient samples. A patient sample is followed from instrument result to QML to the LIS. All results in all 3 systems must match and follow the rules on the Telcor QML Autoverification Rules attachment. Documentation will be reviewed and approved by any POC staff member.
 - 1. Any applicable calculation verification studies will be performed and reviewed during autoverification performance studies.
 - 2. For Royal Oak staff, please see Formulas for Manual Calculation Royal Oak for more information.
- C. Documentation will be saved on the POC SharePoint page for all sites to access.
- D. Any detected failure of the software system will be immediately reviewed in QML by POC staff. Should autoverification need to be suspended at any time, Telcor will be contacted and the instruments affected will be removed from use, if necessary, until the issue is resolved.

VI. REFERENCES:

A. Lab General Checklist, College of American Pathologists, Northfield, IL, current version.

Attachments

QML Configuration Detail - Interface Exceptions.pdf

QML Configuration Detail - Interface Profile - EPIC.pdf

QML Configuration Summary - Device Flag.pdf

Telcor QML Autoverification Rules.pdf

Approval Signatures

Step Description	Approver	Date
CLIA Medical Directors	Muhammad Arshad: Physician	3/1/2023
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CLIA Medical Directors	John Pui: Chief, Pathology	2/2/2023
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Applicability

Dearborn, Farmington Hills, Grosse Pointe, Royal Oak, Taylor, Trenton, Troy, Wayne