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Beaumont

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Area	Laboratory-Blood Bank
Applicability	All Beaumont Hospitals

Blood Bank Autoverification Policy

Document Type: Policy

I. PURPOSE AND OBJECTIVE:

It is the department policy that all normal results with valid test grading/interpretation from the Blood Bank analyzers will be auto-verified in the Blood Bank and Laboratory Information Systems.

II. POLICY STATEMENT:

The blood bank laboratory initiated auto-verification on 07/21/24. It is the policy of Corewell Health to provide auto-verification guidelines for Blood Type, Antibody Screen, Antigen Testing, Cord Blood Evaluations and Gel Crossmatch testing performed on the Blood Bank analyzers.

III. DEFINITIONS:

A. **MTS**: Micro Typing System

B. **BBIS:** Blood Bank Information System, currently SafeTrace Tx, which is web based software utilized by blood bank staff for blood product inventory management as well as to receive patient orders from LIS and send results back to LIS/HIS for posting in the patient electronic health record (EHR).

C. **LIS**: Laboratory Information System, currently the EPIC Beaker module within the HIS where laboratory staff orders, enters, and results laboratory tests. Only laboratory staff have access to Epic Beaker.

D. **HIS:** Hospital Information System, the hospital-wide EPIC computer system specifically where nursing staff and clinicians view laboratory results, among other items in the EHR.

E. **Middleware:** Device that allows two-way communication between the instrument and the BBIS. The instrument can both download orders from the BBIS and upload results to the BBIS.

F. **Bi-directional Interface**: Device that allows two-way communication between the BBIS and the LIS where orders/results are sent between the LIS and the BBIS.

IV. AUTO VERIFICATION CRITERIA:

A. Autoverification criteria is based on current valid blood and antigen typing reaction grading, valid result interpretations in accordance with logic tables within the BBIS and clinically significant results. Values outside of those limits will require technologist intervention.

B. When all of the following criteria evaluate as "True", then the BBIS system will auto-verify results.

C. A blood group (ABO), Rh (Rh), blood type (ABORh) or patient antigen result will not be autoverified in the BBIS if the system detects a difference between previously reported result and the result from the current sample. The results will be held in the Interface Manager.

D. Any sample with instrument flags will stop auto-verification so that the tech can review the instrument results and sample to properly identify the best course of action for resulting the patient.

V. QUALITY CONTROL:

A. Validation of auto-verification will be performed initially and whenever there is a change to the system that could affect the auto-verification logic. This is done by using selected patient samples including samples that have been previously tested and are expected to either pass or fail the criteria stated above.

B. If multiple sites use the same BBIS and server, only one site needs to perform the auto-verification validation. If there are any site specific rules, those rules must be validated per site. All labs must retain a copy of the auto-verification validation.

C. Evaluation will be performed on routine patient samples to document auto verification of samples that passed criteria and lack of auto-verification for samples, which failed the criteria. If unable to fulfill auto verification testing criteria with routine specimens, order a test patient for the particular analyte and wet test using QC or dry test on the instrument and instrument manager.

D. This is a zero tolerance system for errors in the software application. Any detected failure of the software system to detect appropriate samples for auto-verification will be immediately reported to Haemonetics or the Corewell Health Digital Services group as applicable for correction/ modification of the software.

E. Auto verification documentation will be recorded on the Auto Verification Validation Worksheet attached.

VI. Procedure

A. The Ortho Vision Analyzer runs tests

1. All sample results are reviewed by the instrument software based on user defined criteria set for each test profile.
2. Results that meet that criteria are set to Auto accept and are sent to the BBIS.

3. Any results that fail the criteria will be held by instrument for manual review of the results and confirmation of interpretation before sending result to the BBIS.
    a. Graded reactions must be of specific strengths to be considered valid.
    b. All mixed field results are held for review.
    c. Any potential ABO/Rh discrepant results (missing/weak reverse reactions) are held for mandatory review.
    d. Any positive crossmatch or screening cell result are held for mandatory review.
    e. Any sample results with instrument flags will stop autoverification so that the tech can review the instrument results and sample to properly identify the best course of action for resulting the patient.
4. All tests must be interpreted based on the Blood Bank procedures, not necessarily how the ORTHO VISION™ interprets them.

B. The instrument middleware applies autoverification rules as listed in the attachment *Blood Bank Autoverification Criteria*. Result that meets that criteria are set to Auto accept and are sent to the BBIS.

C. All normal results from the analyzers with valid grading and no evidence of discrepancy with historical data in the BBIS will be auto-verified in the BBIS instrument middleware and automatically interfaced to the BBIS.
    1. If all rules pass, the patient results are released, autoposted and autoverified in BBIS and in Beaker LIS.
    2. If a rule fails, autoverification in the BBIS stopped and results are posted in the Interface Manager.

D. Results sent to the Interface Manager in the BBIS must be manually resulted/interpreted in accordance with steps outlined in the SafetraceTx (Blood Bank) Application procedure.

Attachments

Blood Bank Autoverification Criteria rev. (06/25/2024)

Blood Bank Autoverification Validation Worksheet rev. (09/30/2024)

Approval Signatures

Step Description	Approver	Date

	Jeremy Powers: Chief, Pathology	10/23/2024
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Applicability

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