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Dearborn Laboratory Auto Technical Auto-Validation Of Abbott Architect Results

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

A. Auto-validation is the automatic release of results from clinical automated instruments via Instrument Manager (IM). Auto-validation of laboratory results is the process of interaction between IM and a Laboratory Information System (LIS). Both need to be present and have the capabilities necessary to perform the functions.

B. Results eligible for release to the medical record without human review are produced by the analyzer and must pass through a user defined algorithm in the IM. If all criteria are met, the results are released by the IM to the LIS and automatically posted to the patient record. The IM validation must be completed and signed by the Medical Director prior to implementation of any Auto-validation.

II. GENERAL NOTES:

A. Result that fails to verify and/or a result that exceeds the instrument range will not be released until reviewed by the technical staff in IM.

B. When Quality Control (QC) is being run on an instrument (Abbott Architect analyzer), that instrument should be disconnected (“taken off line”) from the automation line until all QC are within acceptable ranges. No results should be auto-filed if QC is not within acceptable ranges.

C. The delta check time limit is set in IM.

D. All 8 architect instruments on the a3600 automation line have a designated naming convention by Abbott. These instrument names are mapped to the LIS method codes for result filing.

Additionally, every instrument is given a designated number on the automation line.

E. Specimens that are front-loaded must be “scanned” frequently to see which tests may still be pending and need attention.

F. STAT pending logs can be viewed on the Turn-Around-Time (TAT) board within the department.

G. For detailed instructions about how to report patient testing that has been held for review, refer to the Abbott Instrument Manager Operating Guide.

H. Manually program and front load questionable specimens by sample cup location on the analyzer to avoid auto release. (Turn bar code label around so it will not be read).

III. RELEASING RESULTS:

A. **If a specimen is held for technical staff review in IM, because of predefined auto- validation criteria, the technologist should do the following:**

1. If an analyte is out of instrument range (technical range), follow the procedure for the instrument (i.e. dilution).
2. If an analyte exceeds critical values, follow the procedure for calling critical values.
3. If an analyte exceeds the delta value, review the result and repeat/investigate specimen validity as necessary to assure valid results.

B. **Auto-validation with Serum Indices:**

1. Each specimen will be assessed for Hemolysis, Icterus, and Lipemia (HIL). The serum will be given a value from for each parameter (lipemia, icterus, and hemolysis). Based on rules built in IM, when an HIL value exceeds certain preset criteria, the results for that specimen will not autovalidate. Results that do not autovalidate will go to the IM Specimen Management Workspace for the technical staff to assess the specimen and review the results before releasing. If prompted by IM, redraw the order and add a follow-up per the Acceptable Specimen Criteria policy (Dearborn Laboratory Auto Technical Determination of Hemolysis, Lipemia and Icterus For Chemistry).

C. **Abnormal Results Due to Preanalytical Handling (Outreach Specimens):**

1. In order to prevent the release of abnormal results that are most likely due to pre-analytical specimen handling, follow the following protocol:
    a. If the result is held for review because of decreased glucose, increased K, PHOS, or TLD (not due to hemolysis) and the following conditions exists:
        i. Specimen **highlighted** as **unspun,** has fibrin clot or cells, or possible delay in centrifugation.
            a. Attach the CH10 canned comment from the drop down to the following scenarios which expands to: “Specimen arrived insufficiently centrifuged. Prolonged contact of serum to cells may falsely decrease Glucose and/or falsely increase Potassium, LD, and Phosphorus results.”

b. Report Glucose when <50 mg/dL, no gray top tube is available, and the specimen is >4 hours old and attach the CH10 canned comment.

c. Report any value below the normal range for Glucose and attach the CH10 canned comment. If the potassium is >6 mmol/L, report the result as ">6 mmol/L" and attach the CH10 canned comment.

d. Report any value above the normal range for the Potassium, LD, and Phosphorus result and attach the CH10 canned comment.

D. **Elevated Potassium due to possible K_2EDTA contamination:**

1. Retrieve specimen primary tube to verify it was not drawn in a K_2 EDTA anticoagulant tube.
2. If Potassium (K) is >10 mmol/L and calcium is <2 mg/dL or similar results, and sample is not in a K_2 EDTA tube, the specimen was probably transferred from the EDTA tube to a chemistry tube. Results should not be reported and the specimen should be recollected.
3. Specimens also need to have any tests that were run on the possibly contaminated tube, cancelled and have the charges credited.
4. Enter a Safety event report (RL Solution) or ask the Medical Technologist Lead to enter a report. For instructions on how to enter an RL Solution, refer to the procedure called "Safety Event Reporting- RL Solutions" in PolicyStat.

E. **Results due to possible IV contamination of inpatient specimens:**

1. Check with caregiver to find out if patient has an IV and if the specimen may be contaminated.
2. After specimen has been reran to verify result, report ALL results and attach the CH07 comment "Possible IV contamination, suggest recollection."

F. **Linearity :**

1. **If the result is outside of the instrument linearity,** the result will have the appropriate < or > sign sent from the Instrument. Operator evaluates high and low linearity for acceptability and takes appropriate action.

G. SPECIAL rules violated cause results to stop posting in Instrument Manager.
Note: Operator intervention is required, such as failing auto verification.

1. **If there is an instrument flag generated automatic re-run,** the results will be in Instrument Manager for the operator to review for release or resolution.
2. **If there is an absurd value for a calculated test,** the operator must resolve the problem analyte, repeat testing, calculate results and report (% Free PSA).
3. **If there is an instrument exception,** the operator must resolve and repeat testing (Clotted, QNS samples).
4. **If there is an index result that requires a comment regarding the integrity of the**

specimen, a comment auto-populates in IM. The operator must enter into the comment field the appropriate comment for lipemia when the sample is pre-treated. Refer to the policy for Dearborn Laboratory Auto Technical Determination of Hemolysis, Lipemia and Icterus For Chemistry).. **If there is a test that requires additional handling to verify result,** perform additional task, evaluate and release results (Dilutions).

5. **If Lipemia index >200,** airfuge specimen and repeat all testing except Lipids. Comment: "Specimen is pre-treated to minimize the effect of lipemia."
6. **If PSA is ordered on a female patient** the operator must cancel the test with the comment, "Test not indicated for this patient." Add a Follow-up flag with the comment PSA not performed on female patients.
    a. Client Services will contact the account. If an error was made and the patient is deemed a male at birth patient, Client Services will resolve the Follow-up and if indicated order the correct test and correct the gender.
7. If PSA is ordered on a male patient under 50 years old the Instrument Manager will suppress the order and route the specimen to the Input/Output module lane.
    a. The tech will then deliver the specimen to Specimen Processing for proper test cancellation ("Cancel code 158- Unable to Perform Assay –enter in comments PSA <50") and a send out order will be placed for the PSA to be sent to RO for testing to be performed at Mayo Clinic Laboratory.

Attachments

Test Instrument ID and Connection Name.pdf

Approval Signatures

Step Description	Approver	Date
Medical Director	Jeremy Powers: Chief, Pathology	10/18/2023
Policy and Forms Steering Committee Approval (if needed)	Michelle Alexander: Medical Technologist Lead	10/16/2023
	Kimberly Geck: Dir, Lab Operations B	10/12/2023
	Stephanie Mullins: Supv, Laboratory	10/12/2023

Michelle Alexander: Medical Technologist Lead	10/11/2023

Applicability

Dearborn