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Area	Laboratory-Chemistry
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Auto/Calculation Verification Procedure

Document Type: Procedure

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I. PURPOSE AND OBJECTIVE:

The purpose of this document is to provide technical staff with procedures and guidance for auto verification and delta check rules between Abbott Architect, Instrument Manager (IM) and the Laboratory Information System (LIS). This procedure will also provide instructions for performing LIS calculation verification.

II. CLINICAL SIGNIFICANCE:

Auto verification is the process by which the IM middleware performs the initial review of test results transmitted from the Architect analyzers and releases results that are within reportable range, have acceptable hemolysis icterus and lipemia (HIL) values, do not exceed established delta checks, do not have instrument flags associated with them, or violate “special” rules. LIS rules are established to automatically perform calculations when required to complete results.

III. DEFINITIONS:

A. **HIL** refers to serum indices: hemolysis, icterus and lipemia.

B. **Special rules** refer to the list of analytes that stop posting in the LIS with actions required by the operator.

IV. QUALITY CONTROL:

A. Routine quality control (QC) results must be evaluated before release of patient results. If QC rules are violated, patient results will not be reported unless approved by supervisory staff.

B. All analytes will be validated for auto verification pass once. In addition, all analytes will be validated for auto verification fail, at both high and low limits, once. Delta checks and special rules will be validated once. Any changes that are made to an analyte must be validated for auto verification and Delta Checks.

C. Evaluate routine patient samples to document auto verified reportable range passed and failed samples. Each analyte must be ordered individually or all other analytes in the panel must be within reportable range with no delta checks or flags. 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 linearity material or dry test in IM.

D. Evaluate routine patient samples to verify LIS calculations at least once every 2 years. If unable to fulfill calculation verification with routine patients, order a test patient. Each calculation must be manually calculated and compared to the LIS reported result.

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

F. Any detected failure of auto verification in the IM will be reported to the IM administrator for correction/modification of the software.

V. PROCEDURE:

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A. The Architect instrument runs tests.

B. Instrument Manager applies auto verification rules. Results are then sent to the LIS.
Note: See Auto Verification Reportable Range and Delta Check Listing in attachments for analytes and limits.

1. **If all rules pass,** the patient results are released, auto posted and auto verified.
2. **If a rule fails,** auto verification is stopped, and patient results are held to be posted by tech.

C. Instrument Manager Specimen Management workspaces are reviewed by Medical Technologists for held results and results are posted by the operator.

D. SPECIAL rules violated cause results to stop posting in Instrument Manager.
Note: Operator intervention is required, such as failing auto verification. See attachments for Special Rules for specific analytes and actions.

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 (i.e% Free PSA, Anion Gap, Globulin).
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 and the results auto verify. Results in the IM will hold if the integrity requires operator intervention.

5. **If Lipemia index >200,** airfuge specimen and repeat all testing except Lipids. Comment: “Specimen is pre-treated to minimize the effect of lipemia.”

E. Validation of auto verification is performed anytime the IM database is altered. The procedure reviews patient samples that have been previously tested and either pass or fail the stated criteria. This is a zero-tolerance system for errors in the IM software application. Any detected failure of the software system to release or not to release sample results for auto verification is reported to the IM Administrator for review, correction, and/or modification of the IM software.

VI. CALCULATIONS AND INTERPRETATIONS:

A. The criteria used for auto verification and delta-checks of the Abbott ARCHITECT/Instrument Manager assays are listed in the attached worksheets. If the criteria are evaluated as ‘true’, then the IM will auto verify the specific assay.

1. 1 sample will pass each of the rules.
2. 1 sample will fail (less than) each of the rules.
3. 1 sample will fail (greater than) each of the rules.

B. **Special rules** violated cause IM and/ or LIS to hold results and may require additional handling to verify results:

1. Absurd Values for calculated tests.
2. Index results that require a comment regarding the specimen integrity.

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VII. REFERENCES:

1. Consultation with Technical Director for Automated Chemistry.
2. CLSI eCLIPSE - CLSI EP33 ED1:2016 Use of Delta Checks in the Medical Laboratory, 1st Edition [Internet]. [cited 2022 Mar 31]. Available from: https://clsi.edaptivedocs.biz/GetDoc.aspx?doc=CLSI%20EP33%20ED1:2016.
3. Schifman RB, Talbert M, Souers RJ. Arch Pathol Lab Med. 2017;141:813–23.
4. Park SH, Kim S-Y, Lee W, Chun S, Min W-K. Ann Lab Med. 2012;32:345–54.
5. Randell EW, Yenice S. Crit Rev Clin Lab Sci. 2019;56:75–97.
6. Strathmann FG, Baird GS, Hoffman NG. Clin Chim Acta Int J Clin Chem. 2011;412:1973–7.

Attachments

Abbott Chemistry Autoverification Worksheet Attachment A.pdf

Formulas for Manual Calculations Verification Worksheet _11_2022.pdf

Immunoassay Autoverification Worksheet Attachment B.pdf

Approval Signatures

Step Description	Approver	Date
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Applicability

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