Beaumont HEALTH

Beaumont Laboratory
Clinical Pathology
Royal Oak

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AUTOVERIFICATION ON Abbott Chemistry Analyzer

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I. Purpose

The purpose of this document is to provide instructions for auto verification to be used at the bench while doing patient test resulting and to perform yearly validation on the auto verification process and LIS calculations.

II. Clinical Significance

Auto verification releases results from the Architect Chemistry instruments that are within reportable range, have acceptable LHI 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. LHI refers to serum indices: lipemia, hemolysis and icterus.

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. All analytes will be validated for auto verification pass and auto verification fail, at both high and low limits, once a year. Delta checks and special rules will be validated once a year. Some testing will be done following each of the LIS database updates.

B. 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.

C. Evaluate routine patient samples to verify LIS calculations. 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.

D. Autoverification documentation will be recorded on the Auto Verification Validation Worksheets. Calculation documentation will be recorded on the Calculation Verification Worksheet.

E. Any detected failure of auto verification in the LIS will be reported to the LIS department for correction/modification of the software.

V. Procedure

A. The Architect instrument runs tests.

B. Instrument Manager applies autoverification rules. Results are then sent to the LIS.
Note: See Autoverification Reportable Range and Delta Check Listing for analytes and limits.

1. **If all rules pass,** the patient results are released, autoposted and autoverified.
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, and results are posted by the operator.

1. **If IM flags a critical result,** Operator verifies, and reports result or rejects and reruns the test in Instrument Manager.
2. **If a result is outside of the reportable range,** the operator evaluates the result, and takes appropriate action.
3. **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.
4. **If an index reportable range fails H >500,** operator reviews results in Instrument Manager and cancels the tests in the LIS. Note: Refer to hemolysis interference policy.

D. SPECIAL rules violated cause results to stop posting in Instrument Manager.
Note: Operator intervention is required, such as failing autoverification. See 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. (Anion Gap, Globulin, A/G ratio, Chol/HDL Ratio, LDL, % Saturation)
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 hemolysis, lipemia, and icteric interference policies.
5. **If there is a test that requires additional handling to verify result,** perform additional task, evaluate and release results (Dilutions).
6. **If Lipemia index >200,** airfuge specimen and repeat all testing except Lipids. Comment: "Specimen is pre-treated to minimize the effect of lipemia" or *@CH04*
7. **If Creatinine <0.65 mg/dL and age <19 years,** Creatinine repeated with CrENZ.

E. Watch for results not transmitting to LIS. This can be monitored in the Status Display in IM.

VI. Calculations and Interpretations

A. Refer to the following table for reportable range limits, and delta checks

Test	Reportable Range	Delta Check		Test	Reportable Range	Delta Check	
ACE	8-52	50%	30 days	GLCSF	10-600	60%	32 days
Albumin	1.0-6.0	0.8	30 days	Glucose 17-116 yrs	55-450	100	30 days
ALP	30-800	50%	30 days	Glucose 0-23 months	55-180	100	30 days
ALT	6-350	50%	30 days	Glucose 2 - 16 years	55-300	100	30 days
Ammonia	10-119	50%	30 days	HDLC	20-120		
AMY	13-300	50%	30 days	Iron	30-300		
AST	10-600	50%	30 days	K	2.7-6.1	1.0	30 days
BILNE, Total		50%	32 days	Lactic Acid	0.4-3.9		
BILNE, Direct		50%	32 days	LD	30-800		
BILI, D	0.1-8.0	50%	30 days	LDL Direct	5-250		
BILI, T	0.1-20.0	50%	30 days	Lipase	10-300	50%	30 days
Calcium	6.5-11.0	0.8	30 days	Lp(a)	1.3-90.0		
Chol	100-500			Mag	1.0-5.0	30%	30 days
CK	30-1500	60%	30 days	Na	125-150	9	30 days
Chloride	85-120	10	30 days	Phos	2.0-7.0	50%	30 days
CO2	15-35	40%	30 days	PLACA	10-382		
Creatinine 0-16 yrs	0.30-2.8	50%	30 days	Protein, Total	4.5-10.0	1.5	30 days
Creatinine 17-116 yrs	0.30-7.5	50%	30 days	PRCSF	6-300		
GGT	7-1000	50%	30 days	Transferrin	155-330	100	30 days

Test	Reportable Range	Delta Check			Test	Reportable Range	Delta Check	
Trig	50-400				C3	80-200		
Urea	5-80	50%	30 days		C4	12-43		
Uric Acid	1.0 – 12.0	2.0	30 days		Cerulo	17-40		
A1AT	25.0-300				CRP	<0.4-33.6		
B2MG	0.25-16				hsCRP	0.2-3.0		
IgE	25-1000				Hapto	40-240		
Prealbumin	5.0-80.0				RF	<15		

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 (Anion gap, Globulin, A/G ratio, Chol/HDL ratio, LDL, %Saturation).
2. Index results that require a comment regarding the specimen integrity.

Special Rules	Action
Ammonia held in IM if H ≥ 50	Requires operator to cancel test
CK held in IM if H ≥ 50	Comment for Hemolysis populates
LD held in IM if H ≥ 50	Comment for Hemolysis populates
K held in IM if H ≥ 50	Comment for Hemolysis populates
Total Protein held in IM if H ≥ 50	Comment for Hemolysis populates
Iron held in IM if H ≥ 50	Comment for Hemolysis populates
Lactic held in IM if H 100-199	Comment for Hemolysis populates
ALT held in IM if H ≥ 100	Comment for Hemolysis populates
AST held in IM if H ≥ 100	Comment for Hemolysis populates
Magnesium held in IM if H ≥ 100	Comment for Hemolysis populates
Phosphorus held in IM if H ≥ 100	Comment for Hemolysis populates
Lactic Acid held in IM if H ≥ 200	Requires operator to cancel test
Acetaminophen held in IM if H ≥ 200	Requires operator to cancel test
Albumin held in IM if H ≥ 200	Comment for Hemolysis populates
Alk Phos held in IM if H ≥ 250	Comment for Hemolysis populates
Magnesium held in IM if L ≥ 50	Comment for Lipemia populates
Ammonia held in IM if L 100-199	Comment for Lipemia populates
Calcium held in IM if L ≥ 125	Comment for Lipemia populates
Urea held in IM if L ≥ 125	Comment for Lipemia populates
Iron held in IM if I ≥ 2.5	Comment for Icteria populates
Total Protein held in IM if I ≥ 10	Comment for Icteria populates
Ammonia held in IM if I ≥ 20	Sample repeated with autodilution
Phosphorous held in IM if I ≥ 25	Comment for Icteria populates
Creatinine held in IM if I ≥ 30	Comment for Icteria populates
TDM held in IM if value is < AMR	Requires operator to check for clots
All tests held in IM if H ≥ 500	Requires operator to verify sample has been centrifuged and cancel if true hemolysis.
All tests held in IM if L ≥ 200	Requires operator to airfuge and comment
% Saturation >100 is flagged as an absurd value	Comment automatically populates in LIS
DBILI > TBILI	Requires operator to resolve
K >7.0 and Calcium <5.0	Suspect EDTA Contamination
Globulin <0.1 is flagged as an absurd value	Requires operator to resolve
A/G ratio =0 or >5.0 is flagged as an absurd value	Requires operator to resolve
LDL Chol <15 is flagged as an absurd value	Requires direct LDL performed
Chol/HDL ratio <1.0 is flagged as an absurd value	Requires operator to resolve
LDL Chol stops auto-posting when LDL > Chol	Requires operator to resolve

VII. References

A. Consultation with Technical Director for Automated Chemistry.
B. Comparison table of delta checks from Ladenson, Whitehurst, Sher, Wheeler and Steiner, University of Pennsylvania, Peninsula General Hospital.
C. Clinical Chemistry, Vol. 21, No. 11 1975.
D. Clinical Chemistry, Vol. 34, No. 10, 1988.
E. Clinical Chemistry, Vol. 36, No. 12, 1990.
F. Department of Pathology Rhode Island Hospital delta check limits studies.

VIII. Authorized Approvers

Section Medical or Technical Director

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Document Control

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