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Automated Chemistry Policy for the Determination of Hemolysis, Lipemia and Icterus - Royal Oak

Document Type: Policy

I. PURPOSE AND OBJECTIVE:

This policy describes how technologists should deal with serum or plasma samples that show evidence of hemolysis, lipemia or icterus. Hemolysis is the destruction of red blood cells with the liberation of hemoglobin and other red cell contents. Lipemia is defined as “Fat in the blood” and is caused by an increase in triglycerides. Icteric or icterus, refers to pigmentation of the tissues, membranes, and secretions with bile pigments, measured as bilirubin in the serum/plasma. The Abbott Architect chemistry system is currently used for determination of hemolysis (H), lipemia (L), and icterus (I) by spectrophotometry.

II. POLICY STATEMENT:

A. **Hemolysis**

1. Hemolysis may affect chemistry measurements in the following way:
   a. interfere with photometric measurements
   b. cause release of analytes from red cells, resulting in an increase in serum/plasma levels, e.g. K+, AST, LD
   c. dilute analytes that are present in low concentrations in the red cell, e.g, ionized calcium, Na+
2. **Hemolysis index less than 500**
   When the H index is between 50 mg/dL and 500 mg/dL, Instrument Manager (IM) automatically sends a comment regarding the effect of hemolysis on the analytes listed in the table. The comment appears in the comment line of the result field in the Laboratory Information System (LIS). Not all analytes are affected by hemolysis (up to 500 mg/dL) - results for these analytes will be reported without any comment.
3. **Hemolysis index greater than 500**
   a. A single order for either glucose or creatinine can be reported, regardless of the hemolysis level.
   b. A single order for Salicylate, ETOH, Phenobarbital, Phenytoin, Carbamazepine, Theophylline, Valproic Acid, Tobramycin, Digoxin, Amikacin, Vancomycin, Cortisol, or Gentamicin can be

reported up to the H index value specified in the table below, even if the hemolysis is due to in-vitro hemolysis.

4. **Hemolysis index > 500 due to in-vitro hemolysis**

   a. When IM determines that the H index is > 500, all results will hold in Instrument Manager and an Error Code will populate in Instrument Manager that indicates: "*Sample is hemolyzed. Please Request Redraw*." Cancel tests in the LIS and reject the results in IM. See table for exceptions.

Analyte	Hemolysis (mg/dL Hgb)	Comment Effect of Hemolysis on Test Result
Ammonia	**Cancel at 50**	
Iron	**Cancel at 100**	Variable at 50
PLAC	**Cancel at 50**	
LD	H index = or > 50	Increased
Potassium	H index = or > 50	Increased
Protein, Total	H index = or > 50	Increased
Direct Bilirubin	H index = or > 50	Decreased
Lactic Acid	**Cancel at 200**	Increased 100-199
AST	H index = or > 100	Increased
Magnesium	H index = or > 100	Increased
Phosphorus	H index = or > 100	Increased
Acetaminophen	**Cancel at 200**	
VB12	**Cancel at 200**	
Folate	**Cancel at 200**	
Amylase	H index = or > 250	Decreased
CK	H index = or > 250	Increased
T. Bilirubin	H index > 500	Decreased
Salicylate	**Cancel at 600**	
ETOH	**Cancel at 800**	
Phenobarbital	**Cancel at 800**	
Phenytoin	**Cancel at 800**	
Carbamazepine	**Cancel at 800**	
Theophylline	**Cancel at 800**	
Valproic Acid	**Cancel at 1000**	
Tobramycin	**Cancel at 1000**	
Digoxin	**Cancel at 1000**	
Amikacin	**Cancel at 1000**	
Vancomycin	**Cancel at 1150**	

Cortisol	**Cancel at 1500**	
Gentamicin	**Cancel at 2000**	

5. **For samples from Neonatal Intensive Care Unit (NICU) babies (any age) or neonates (less than 4 weeks old)**
    a. Report results as though in-vivo hemolysis has been confirmed
    b. Any or all results listed in the table "Reportable tests for in-vivo hemolysis" can be resulted.
6. **Considerations when in-vivo hemolysis is suspected:**
In-vivo sample hemolysis may be due to patient pathophysiology or some type of cardio-pulmonary device or procedure that is damaging the patient's red cells. When in-vitro hemolysis has occurred, a careful redraw may provide an acceptable sample for testing. However, when hemolysis is originating in-vivo, redrawing the specimen does not improve the quality of the sample. Interferences or result abnormalities may vary according to whether the hemolysis has occurred in-vitro or in-vivo. In many hemolyzed samples it is not possible to determine the type of hemolysis either by visual inspection or from chemistry test results. Because the incidence of in-vitro versus in-vivo hemolysis varies with patient location, the information outlined below should be obtained by the technologist from the nursing unit to help determine whether in-vivo hemolysis is likely:
    a. 2nd Hemolyzed sample from an *In-patient*-Once a **2nd hemolyzed sample with a hemolysis index >500 mg/dL** is received on a given patient, the possibility of in-vivo hemolysis should be considered.
        i. Was the sample obtained from a venipuncture or from a line (central, arterial)?
        ii. Does the patient have a left ventricular assist device (LVAD – e.g. Impella device) or are they being treated by ECMO (extracorporeal membrane oxygenation) or CRRT (continuous renal replacement therapy)?
    b. 3rd Hemolyzed sample from *Emergency Center*-Once a **3rd hemolyzed sample with hemolysis >500mg/dL** is received on a given patient, the possibility of in-vivo hemolysis should be considered.
        i. Was the sample obtained from a venipuncture or from a line (central, arterial)?
    c. Based on the information obtained, the technologist will make the best judgment as to which type of hemolysis has occurred. If necessary, the pathologist on-call for Chemistry can be contacted for advice. If the most likely explanation is in-vivo hemolysis, test results can be reported out as indicated in the "Reportable Tests for in-vivo Hemolysis" table located in this procedure. If the H-index is very high (e.g. > 500) and the potassium is within the reference range or just slightly increased, hemolysis is most likely to be occurring in-vivo. If the potassium is > 10 mmol/L, hemolysis is likely to be in-vitro. A potassium result of > 10 mmol/L has been deemed by Beaumont clinical staff to be most likely incompatible with life. Samples obtained by venipuncture are more likely to result in in-vitro hemolysis, however, line draws can occasionally cause this problem.

        After obtaining the relevant information (see above):
        i. Write the patient's name and Medical Record Number (MRN) on the board in both Core Lab and Stat Lab
        ii. Complete the patient information form in the In Vivo Hemolysis Specimen Reporting Form

(Attachment) and return to the Chemistry manager or lead technologist.

iii. If the technologist/pathologist is unable to determine whether in-vivo hemolysis has occurred:

a. Release results according to the **Reportable Tests for In-Vivo Hemolysis** table

7. **Reporting results when in-vivo hemolysis has been confirmed or is strongly suspected:**

a. Manufacturer's specifications for hemolysis interference on the Laboratory's chemistry analyzers usually do not extend to the levels encountered in significant in-vivo hemolysis. However, in cases of in-vivo hemolysis, the Laboratory will report out at least some chemistry test results for patient care purposes. Acceptability was based on a combination of in-house studies and information from Abbott and the Collete of American Pathologists (CAP).

b. The following tests will be reported when **marked in-vivo hemolysis (i.e. H index > 500) has been identified**:

Reportable Tests for In-Vivo Hemolysis	
Abbott Analyzer	**Radiometer ABL 825**
Sodium	Sodium
Potassium	Potassium
Chloride	Chloride
CO2	CO2
Glucose	Glucose
BUN	Ionized calcium
Creatinine	pH
Calcium	PCO2
Total Bilirubin@	PO2
Magnesium	
Phosphorus	
Transferrin	
LD	
Haptoglobin	
Albumin	
CRP	
Ferritin	
@IM comment generated when H value >500: "Sample is hemolyzed. Result may be falsely decreased."	

c. When IM determines that the H index is > 500, all results will hold in Instrument Manager and an Error Code will populate in Instrument Manager that indicates:
"Sample is hemolyzed. Please Request Redraw." This comment will not populate in the LIS.

d. For all analytes that will be reported (see table above) **add the comment CHVT** ("*Sample is markedly hemolyzed. Suggest clinical correlation to assess whether due to in-vitro or in-vivo*

hemolysis")

e. For all analytes that cannot be reported, **add the comment CHVO** ("*Unable to report all results*.")

f. For analytes that are affected by hemolysis, but we have deemed the result to be acceptable, a comment will be automatically added in IM and will populate in the LIS.

B. **Lipemia**

1. It is the policy of the Automated Chemistry Lab to "Airfuge" all patient samples, (except samples for lipid testing) with a lipemic index ≥ 200. The Beckman Airfuge is an air-driven ultracentrifuge that makes it possible to clear blood samples of chylomicrons (lipid particles between 80-500nm in diameter) that impair the accuracy of spectrophotometric analyses. Once the low-density chylomicrons are removed from the sample, the sample can be processed without the interference of lipids.

2. **Lipemia index less than 200**
When the L index is between 50 and 200 IM automatically sends a comment regarding the effect of lipemia on the analytes listed below. The comment appears in the comment line of the result field in the LIS. Not all analytes are affected by lipemia up to 200; results for these analytes will be reported without a comment.

Analyte	Lipemia Index	Comment
Magnesium	L index ≥ 50	Decreased
Ammonia	L index =100-199	Result may be compromised
Calcium	L index ≥ 125	Decreased
Urea	L index ≥ 125	Decreased
All EXCEPT Cholesterol, HDL Cholesterol, Direct LDL Cholesterol and Triglyceride	L index ≥ 200	Airfuge sample; Report with comment "Sample pre-treated to minimize the effects of lipemia"

3. Add the comment ("Sample pre-treated to minimize the effects of lipemia") in IM to all samples that are airfuged.

C. **Icterus**
When an icteric index is greater than 2.5, IM automatically sends a comment regarding the effect of icteria on the analytes listed below. The comment appears in the comment line of the result field in the LIS. Not all analytes are affected by icteria; results for these analytes will be reported without a comment.

Analyte	Icterus Index	IM Comments or Action
Iron	I index ≥ 2.5	Result may be compromised
Total Protein	I index ≥ 10	Decreased
Ammonia	I index ≥ 20 or	Program Auto Dilution 1:1.85. Manually dilute x2 and program

	Absorbance error	with dilution if needed to resolve
Phosphorus	I index ≥ 25	Increased
Creatinine	I index ≥ 30	Decreased

III. REFERENCES:

1. College of American Pathologists 2018 Interfering Substances Survey (IFS)
2. In-house hemolysis interference study
3. Abbott package inserts

Attachments

In Vivo Hemolysis Specimen Reporting Form.pdf

Approval Signatures

Step Description	Approver	Date
Medical Director	Ann Marie Blenc: System Med Dir, Hematopath	2/17/2022
Policy and Forms Steering Committee Approval (if needed)	Colette Kessler: Mgr Laboratory [RC]	2/9/2022
Policy and Forms Steering Committee Approval (if needed)	Gail Juleff: Project Mgr Policy	2/9/2022
Lab Chemistry Best Practice Committee	Qian Sun: Tech Dir, Clin Chemistry, Path	2/8/2022
Lab Chemistry Best Practice Committee	Elizabeth Sykes: System Med Dir, Chemistry	2/7/2022
	Colette Kessler: Mgr Laboratory [RC]	2/7/2022

Applicability

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