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Beaumont Laboratory Clinical Pathology Royal Oak Effective Date:02/26/2020Supersedes:01/24/2020Related Documents:

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

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Purpose

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.

Hemolysis

Hemolysis may affect chemistry measurements in the following way:

- interfere with photometric measurements
- cause release of analytes from red cells, resulting in an increase in serum/plasma levels, e.g. K+, AST, LD
- dilute analytes that are present in low concentrations in the red cell, e.g, ionized calcium, Na+

Hemolysis index less than 500

When the H index is between 50 mg/dL and 500 mg/dL IM automatically sends a comment regarding the effect of hemolysis 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 hemolysis (up to 500 mg/dL) - results for these analytes will be reported without any comment.

Analyte	Hemolysis (mg/dL Hgb)	Comment – effect of hemolysis on test result	
Ammonia	Cancel at 50		
Iron	Cancel 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	H index = or > 100	Increased	
AST	H index = or > 100	Increased	
Magnesium	H index = or > 100	Increased	
Phosphorus	H index = or > 100	Increased	
Lactic Acid	Cancel at 200		
Acetaminophen	Cancel at 200		
Amylase	H index = or > 250	Decreased	
СК	H index = or > 250	Increased	
T. Bilirubin	H index >500	Decreased	

Hemolysis index greater than 500

A single order for either glucose or creatinine can be reported, regardless of the hemolysis level.

A single order for ETOH can be reported up to an H index of 800, even if the hemolysis is due to in-vitro hemolysis.

Hemolysis index > 500 due to in-vitro hemolysis

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.

For samples from NICU babies (any age) or neonates (less than 4 weeks old)

- Report results as though in-vivo hemolysis has been confirmed (see table page 3)
- i.e. any or all results listed in the table "Reportable tests for in-vivo hemolysis" can be resulted.

Considerations when in-vivo hemolysis is suspected:

In-vivo sample hemolysis may be due to patient pathophysiology or some type of cardiopulmonary 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.

In-vivo hemolysis assessment

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:

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.

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.

Was the sample obtained from a venipuncture or from a line (central, arterial)?	Venipuncture / Line
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)?	YES / NO

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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 (page 3 of 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):

- Write the patient's name and MRN on the board in both Core Lab and Stat Lab
- Complete the patient information form in the attached addendum and return to the chemistry manager or lead technologist.
- If the technologist/pathologist is unable to determine whether in-vivo hemolysis has occurred:
 - Release results according to the **Reportable Tests for In-Vivo Hemolysis** table

<u>Reporting results when in-vivo hemolysis has been confirmed or is strongly suspected:</u>

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 CAP.

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 Potassium Chloride CO2 Glucose BUN Creatinine Calcium T.Bilirubin [@] Magnesium Phosphorus Transferrin LD Haptoglobin Albumin	Radiometer ABL 825 Sodium Potassium Chloride CO2 Glucose Ionized calcium pH PCO2 PO2	[@] IM H v "Sa may	
Albumin CRP Ferritin			

[@]IM comment generated when H value >500: "Sample is hemolyzed. Result may be falsely decreased."

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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 SOFT.

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")

For analytes that <u>cannot</u> be reported, type "." in the LIS result field, and attach the following comment to the first analyte reported: **@CHVO** ("*Unable to report all results.*")

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 SOFT.

Attachment - for cases determined to have in-vivo hemolysis

To be completed and given to Chemistry manager or lead technologist

Patient Name:	MRN:
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Specimen ID(s):_____

Was the sample obtained from a venipuncture or from a line (central, arterial)?	Venipuncture / Line
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)?	YES / NO

Name/ID of Care Provider contacted:

Technologist:	Date:	

<u>Lipemia</u>

It is the policy of the Automated Chemistry Lab to "Airfuge" all patient samples, (**except samples for lipid testing**) with a lipemic index \geq 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.

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 <u>></u> 50	Decreased
Ammonia	L index =100-199	Result may be compromised
Calcium	L index <u>></u> 125	Decreased
Urea	L index ≥ 125	Decreased
All EXCEPT Lipid Panel	L index <u>> 200</u>	Airfuge sample; Report with comment @CH04

Add the comment @CH04 ("Sample pre-treated to minimize the effects of lipemia") to all samples that are airfuged.

<u>lcterus</u>

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	l index <u>></u> 2.5	Result may be compromised		
T Protein	l index <u>></u> 10	Decreased		
Ammonia	l index <u>></u> 20 or	Program Auto Dilution 1:1.85. Manually dilute x2		
	Absorbance error	and program with dilution if needed to resolve		
Phosphorus	l index <u>> 25</u>	Increased		
Creatinine	l index <u>></u> 30	Decreased		

Soft Lab Comments Defined

Code	Expanded Report Comment
@CH10	Sample is hemolyzed. Potassium may be falsely increased.
@CH21	Sample is hemolyzed. T Bili may be falsely increased.
@CH13	Sample is hemolyzed. AST may be falsely increased.
@CH14	Sample is hemolyzed. LD may be falsely increased.
@CH15	Sample is hemolyzed. CK may be falsely increased.
@CH38	Sample is hemolyzed. Phos may be falsely increased.
@CH37	Sample is hemolyzed. Uric Acid may be falsely increased.
@CH31	Sample appears lipemic. Lactic Acid may be falsely increased.
@CH32	Sample appears lipemic. Magnesium may be falsely increased.
@CH04	Sample pre-treated to minimize the effects of lipemia.
@CH27	Sample appears Icteric. Uric Acid may be variably affected.
@CH28	Sample appears Icteric. Lactic Acid may be variably affected.
@CH22	Sample appears Icteric. Creatinine may be falsely decreased.
@2HMT	Sample markedly hemolyzed.
@CHVO	Unable to report all results.
@CHVT	Sample is markedly hemolyzed. Suggest clinical correlation to assess whether due
	to in-vitro or in-vivo.

References

CAP 2018 Interfering Substances Survey (IFS) In- house hemolysis interference study Abbott package inserts

Authorized Reviewers

Section Medical or Technical Director

Document Control

Location of Master: Master electronic file stored on the Beaumont Laboratory server under S:/Document Control Library/CH/LOP/Masters

Master printed document stored in AutoChem General Policy and Procedure Manual-Core Lab Number of Controlled Copies posted for educational purposes: 0 Number of circulating Controlled Copies: 1

Location of circulating Controlled Copies: AutoChem General Policy and Procedure Manual-Stat Lab

Document History

Signature		Revision #		Related Document Reviewed/ Updated
Prepared by: Ann Oddi	6/8/04			
Approved by: Valerie Peterson MT, ASCP(SC)	06/8/04			
Reviewed by: (Signature)	Date	Revision #	Modification	Related Document Reviewed/ Updated
Valerie Peterson MT(ASCP) SC	10/1/07	r00	Into Document format	
REK	12/17/07	r01	Changed to Advia 2400 & DxC 800	
Raymond Karcher	12/4/08			
Raymond Karcher	12/4/09			
Dr, V. Kumar	8/28/10	r02	Included age of pediatric, added tables, added Total Bili and Glucose (Cartridge method). Included specimen can be analyzed on hemolyzed specimen only using the Glucose Modular method.	
Vivek Kumar, PhD	12/06/2010			
Vivek Kumar, PhD	09/08/2011	r03	SOFT revisions	
E. Sykes, MD	02/16/2012			
E Sykes, MD	02/14/2014			
Revised by: Amber M Macumber, MLS(ASCP) ^{cm} Robin Carey-Ballough MT(ASCP) Stephanie Barden, MLS(ASCP) ^{cm} Approved: Elizabeth Sykes, MD	11/17/2016	r04	Combine LHI to one policy. Update to automatic comments from Centralink. Update hemolysis procedure to include acceptable analytes for hemolysis; change cancellation to H index >500.Combine in vivo hemolysis procedure. Removed Lipemia comment when level is 245	
Revised by: Robin Carey-Ballough MT(ASCP) Approved: Kenneth Simkowski, PhD	01/25/2017 01/27/2017	r05	Remove BHBT cancellation at any level, add CRRT to in-vivo	
Revised by: Dina Mansour MLS(ASCP) ^{cm} Approved: Kenneth Simkowski, PhD	03/21/2017 03/29/17	r06	Added Toxicology Protocol under Hemolysis policy.	
Revised by: Robin Carey-Ballough MT(ASCP) Approved: Elizabeth Sykes, MD	08/22/2017	r07	Change "see comment" instruction to "." to satisfy compliance. Expand SOFT codes to define report comments.	
Peter Millward, MD	09/17/2018		New medical director	

AUTOMATED CHEMISTRY POLICY FOR THE DETERMINATION OF HEMOLYSIS

Peter Millward, MD	11/19/2018			
Kelly Walewski C(ASCP)cm Robin Carey-Ballough Qian Sun, PhD	01/10/2020 01/10/2020 01/16/2020	r08	Removed instrument specific information. Updated interference to Abbott Analyzers	
Robin Carey-Ballough	02/26/2020	r09	Update references, change Glucose and Creatinine single orders to reportable at any hemolysis level	
Qian Sun, PhD	03/03/2020			