LifeLabs®
Medical Laboratory Services

Inside Diagnostics

REVISED COMMUNITY LABORATORY GUIDELINE FOR REPORTING LABORATORY TEST RESULTS 2009

LifeLabs, together with other members of The Ontario Association of Medical Laboratories (OAML), adopted a common protocol for the communication of Expedited and 'Critical' results in 2001.

This protocol was revised in 2003. The revision included a system to manage and downgrade certain recurrent alert and critical results which were not unexpected.

The 2009 revision recognizes the increasing use and availability of electronic delivery of LifeLabs laboratory results into Clinical Management Systems (CMS) or via iLablink. Potentially these make telephone communication of all expedited results and all other results except for 'Critical' values redundant, providing of course the clinician has a system in place to regularly check for these. It is clear many do and that we make a number of redundant often annoying calls which serve no useful clinical purpose.

We must continue to call "Critical" Values but clinicians will have the option to receive all ASAP, Urgent and Alert results electronically via the modalities noted above or to a verified fax machine.

You will receive a communication in the first part of 2009 to verify contact numbers including 'out of office' numbers and fax numbers. You will be given the option to opt for electronic communication of all but 'Critical' results providing you personally sign to certify that there is a system in place to regularly check these.

LifeLabs is happy to continue to call all results as we do currently. The choice is yours.

We encourage you to read the revised guideline when it is delivered to you. It will also be posted on the LifeLabs (www.lifelabs.com) and OAML websites (www.oaml.com).

Finally, you will see we recognize the values are not useful in some types of specialist practice including oncology and nephrology as well as some other areas. We are able to administer specific exceptions to our protocol and currently do so for a number of specialists. Clinicians who require such exceptions should communicate in writing in order to initiate the process.

The aim of the revision is to enhance patient safety, decrease unnecessary calls to clinicians, comply with regulatory requirements and heed risk management advice. This is clearly a difficult but important balance and one which is not easy to administer for both the laboratory and the clinicians we serve.

IN THIS ISSUE

C3, C4 : CHANGE IN SPECIMEN HANDLING REQUIREMENTS

Stability studies completed by LifeLabs have illustrated the stability of complement C3 and C4 at temperatures of 2-8C and -20C. As a result of these studies, the handling requirements for C3 and C4 have been updated to accept specimens stored at refrigerated temperatures (2-8C).

MEASUREMENT UNCERTAINTY AND CLINICAL DECISIONS: A DRY SUBJECT BUT AN IMPORTANT ONE

We are often asked to explain the difference in values obtained from two testing locations or data from two unique testing events.

All laboratory measurements contain a degree of uncertainty due to imprecision associated with pre-analytical, analytical or post-analytical variables. Possible sources of uncertainty in analyte measurement are listed in the following table.

Possible Sources of Uncertainty in Diagnostic Measurements

Pre-Analytical	Analytical	Post-Analytical
Patient pathologies (e.g. jaundice)	Calibration traceability	Non-standardized units
Patient preparation or state (e.g. diet, fasting, stress)	Calibration preparation	Inappropriate significant figures in reporting
Medications	Reagent preparation	
Therapies (ie radiation, or antibody based therapies)	Equipment performance	
Poor collection technique	Temperature and humidity fluctuations	
Specimen handling and transportation	Assay specificity	
Specimen storage		
Biological variation		

Establishing the traceability of an analytical procedure to a reference method and calibration material is receiving increased attention as the desire to adopt uniform clinical decision points for diagnosis and treatment based on analytical results. There are still relatively few analytes that have defined traceability reference methods and calibrators however, so physicians need to be aware of the potential impact of method differences on patient results. From a practical perspective many but not all of the sources of measurement uncertainty can be controlled. It still makes sense to utilize the same laboratory using the same method and equipment platform when assay results for an analyte have to be compared over a period of time. This is true of INR but also of other assays such as creatinine. Standardized calibration of all kits for quanitation of creatinine to the reference method, isotope dilution mass spectrometry (IDMS), is moving closer but has not yet been completed, by some manufacturers and significant differences in values between method may still be observed.

The laboratory defines measurement of uncertainty for each analyte based on observed performance (% CV) of routine quality control (QC) materials of the same matrix and at relevant clinical decision points. The analytical performance goals for each analyte are defined by clinical need and by our regulators. Using a group of basic statistical tools, observed QC performance, identification and control of the root causes for false positive or negative data, the laboratory can confirm the method is "fit for purpose" and describe the level of confidence one should have in the result reported.

Example: Serum Creatinine

Method	Jaffe kinetic	
Traceability:	HPLC certified reference method IDMS commutable	
Calibrator Uncertainty:	0.85%	
Biological Variation:	5.3% within subject	
Precision Goal		
	< 75 umol/L = 4.0%	> 74 umol/L = 3.0%
Precision Observed:		
	58 umol/L = 2.8%	582 umol/L = 1.4%
Measurement Uncertainty		
	100 umol/L = ± 2.8 umol/L	500 umol/L = ±7.0 umol/L

Here you can see that the actual uncertainty depends on the concentration of the analyte.

Should you have a question related to performance of a method, please do not hesitate to call a member of the Medical Scientific team at LifeLabs. ■

CHRISTMAS IS COMING!

Taking time to provide advice to patients who require regular, elective testing in anticipation of holidays such as Christmas will usually pay off in facilitating ease of management and possibly patient safety.

When possible it is advisable for patients to schedule visits for tests giving sufficient time for delivery of results and communication of any 'Alert' or 'Critical' values prior to the office closing for the holiday.

We serve a very large number of patients for tests such as INR so it is inevitable that some of these, on a daily basis, will generate results which indicate a need for a change in therapy. From experience, communication may be more difficult during the holiday period.

We suggest that patients requiring elective testing be advised to visit our Patient Service Centres no later than Monday, December 22, prior to the Christmas holiday.

Please note that all LifeLabs Patient Service Centres will be closed December 25, 26 and January 1.

We extend best wishes to all for the holiday season. ■

ATTENTION TO PRE-ANALYTICAL QUALITY WHEN COLLECTING A BLOOD SAMPLE: THINGS TO KEEP IN MIND

The quality of a lab test result is only as good as the specimen used to generate it. Pre-analytical issues have been established as the primary cause of the majority of analytical and clinically significant "errors". Being aware of and controlling each part of the specimen collection and processing procedure will help to ensure the highest quality of the sample.

In terms of quality improvement this is literally 'going for the low hanging fruit.'

For specific instructions on proper patient preparation and collection of specimens by analyte, please refer to the LifeLabs website (www.lifelabs.com) under "Laboratory Services".

Step of Procedure	Source of Information for Proper Procedure	Potential Issues	Tests Impacted
Patient Preparation	LifeLabs website, under "Laboratory Services"	Not fasting	• Glucose and lipids increased in non-fasting state. • Presence of lipemia in sample renders the sample unacceptable for analysis for some tests (e.g. ALT, Uric acid, Albumin).
Patient Preparation	LifeLabs website, under "Laboratory Services"	Posture	• Plasma volume is affected by patient posture during collection. Significant decrease in proteins and protein-bound substances in recumbent posture compared to erect posture. • Secretion of hormones such as catecholamines, aldosterone, renin and antidiuretic hormone affected directly by posture.
Time of Collection	LifeLabs website, under "Laboratory Services"	Diurnal variation	• Many hormones, including corticotropin, cortisol, TSH, renin, aldosterone and growth hormone, exhibit diurnal variation.
Type of tube used to collect	LifeLabs website, under "Laboratory Services" and Client Specimen requirement Chart (QRA; 14 December 2007)	Sample collected in wrong type of vacutainer tube	• Calcium significantly decreased by EDTA. • PTH significantly increased in EDTA tubes.
Order of draw	Client Guide: Order of Draw and Fill Line Level Chart (QRA; January 2008)	Carry over contamination of anticoagulant between vacutainer types	• Potassium artificially increased and calcium artificially decreased in a sample collected in an SST tube following Potassium EDTA (lavender) tube.
Phlebotomy	CLSI document H3-A6 Vol. 27, No. 26	Prolonged use of tourniquet	• Artifactual hemo-concentration, leads to increased proteins and protein-bound substances.
Phlebotomy	CLSI document H3-A6 Vol. 27, No. 26	Fist clenching	• Potassium significantly increased.
Phlebotomy	Client Guide: Order of Draw and Fill Line Level Chart (QRA; January 2008) and Inside Diagnostics (Summer 2008)	Underfilled tube	• Falsely prolonged coagulation results. • Falsely low WBC, high MCV and hematocrit, and morphologic changes to white and red blood cells. • May not have enough blood to isolate bacteria for blood cultures.
Phlebotomy	Client Guide: Order of Draw and Fill Line Level Chart (QRA; January 2008) and Client Specimen Requirement Chart (QRA; 14 December 2007)	Inadequate inversion of tubes after collection	• Plastic vacutainers are coated with "glass particles" to activate clot formation. Gentle inversion (4-6 times as per specific analyte instructions is imperative). • Formation of clots in EDTA (lavender) tubes impacting CBC analysis or potassium (SST tube).
Clotting process	Client Specimen Requirement Chart (QRA; 14 December 2007)	Inadequate time allowed for clotting	• Formation of clots in serum after centrifugation interferes with analytical processing.
Centrifugation	Client Specimen Requirement Chart (QRA; 14 December 2007)	Delay in separation of serum/plasma from red blood cells	• Ammonia levels rise rapidly. • Progressive decrease in glucose result. • Potassium will significantly increase. • Analytes in high intracellular concentration (e.g., magnesium LDH, AST, ALT, and Ferritin) will increase.
Labelling of tube	Client Guide: Order of Draw and Fill Line Level Chart (QRA; January 2008) and Dear Client Letter (October 2007)	Inadequate information, leading to isidentification of sample	• All tests.
Storage of sample prior to analysis	LifeLabs website, under "Laboratory Services" and Client Specimen Requirement Chart (QRA; 14 December 2007)	Incorrect storage temperature and/or excessive storage time to maintain stability of analyte	• All tests will be affected if samples are not stored at the right temperature and for the defined stability period.

REFERENCES:

1. Clinical and Laboratory Standards Institute Document H3-A6, Volume 27, No. 26. Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard – Fifth Edition.
2. Clinical and Laboratory Standards Institute Document H4-A4, Volume 19, No. 16. Procedures and Devices for the Collection of Diagnostic Blood Specimens by Skin Puncture; Approved Standard – Fourth Edition.

PRENATAL QUESTIONNAIRE

Immunohematology and blood banking is one area in the laboratory that highlights the importance of providing clinical information for the proper interpretation of laboratory results. Blood group discrepancies, positive direct coomb's tests, and red blood cell antibodies are a frequent occurrence in immunohematology. Good practice dictates that interpretations and follow up recommendations be provided to clinicians when abnormal findings are discovered. Although applicable to a wide variety of patient groups, availability of important clinical information is critical for interpreting results of tests ordered on the obstetric patient population.

Pregnancies and transfusions can trigger formation of alloantibodies. Some of the alloantibodies acquired during pregnancy may be significant and cause hemolytic disease of the newborn. Such antibodies require subsequent titer determinations at a frequency dictated by the stage of the pregnancy. Without knowing the stage of the pregnancy, let alone that the patient is pregnant, it is not possible for the laboratory to provide the most useful information to the requesting clinician. Similarly, without knowing that an Rh(D) negative patient has received an Rh(D) immunoglobulin injection, a passively acquired Anti D antibody from this injection, may be confused for active Rh(D) immunization. As a consequence, the patient may be wrongly denied future protective immunoglobulin injections, with the potential for grave consequences.

LifeLabs has developed a confidential prenatal questionnaire to collect the necessary clinical information. The patient (male or female) will not be asked any verbal questions. He/she will be asked to respond to the questions on a special form which must be attached to the OHIP requisition. The information recorded on this form will be entered in our laboratory information system and is accessible by our technologists. It will be used to generate the appropriate interpretative messages.

Patients presenting at our service centers will be given a copy of this form to fill out. Clinicians who draw their own blood samples should have received a letter, explaining this initiative, along with a copy of this form for their use. More copies can be obtained by photocopying or from our website through the following link (http://www.lifelabs.com/Lifelabs_ON/Health_Care/Specimen-Handling-and-Collection-Instructions.asp). Once the form is completed by the patient, including name and date of birth, it is imperative that it be attached to the OHIP requisition. ■

CREATININE REFERENCE INTERVAL CHANGE

On December 1, LifeLabs will implement a change in reference interval for serum creatinine measurements completed in the Ortho Vitros analyzer. This change in reference interval is necessary following the vendor's recalibration of the assay for traceability to the IDMS reference method. As a result, clients may expect to see approximately a 13% decrease in serum creatinine values upon implementation of the IDMS calibration process. The revised reference interval ranges for adult individuals are:

Males = 62-115 umol/L
Females = 45-97 umol/L

Please note, eGFR calculation is currently completed using the MDRD equation and is already corrected for bias to the IDMS calibration, as a result, minimal change to the eGFR can be expected.

Testing locations and patient results affected by this change will be identified by a note on the patient report highlighting the change in reference interval. ■

MEDICAL SCIENTIFIC STAFF PROFILE

Dr. Wahbi Hammouda, MDCM, FRCPC
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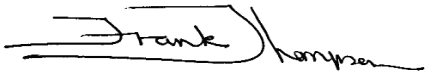
LifeLabs, Ontario

Dr. Hammouda obtained his medical degree from McGill University in 1980. He completed his residency training in hematology in 1985 and a research fellowship in Fibrinolysis in 1987, both at McGill University. He was an Assistant Professor of Medicine and an Assistant Professor of Oncology in the faculty of medicine, McGill University. In addition, he was a member of the Hematology Residency Training Committee, and Director of the Hemostasis Laboratory at the Sir Mortimer B. Davis Jewish General Hospital in Montreal. In February 2007, he moved to Toronto to assume the position of Director of Laboratory Hematology for Lifelabs, Ontario. In addition, he is a staff member in the Department of Clinical Pathology at Sunnybrook Health Sciences Centre, and a Lecturer in the Department of Laboratory Medicine and Pathobiology at the University of Toronto, and is active in the teaching of laboratory hematology to hematology and hematopathology residents. He has a special interest and expertise in the area of thrombosis and hemostasis. He is a fellow of the Royal College of Physicians and Surgeons of Canada, and a member of the International Society on Thrombosis and Haemostasis and of the American Society for Clinical Pathology. ■

ADIEU

This will be the last issue of Inside Diagnostics during my tenure as Medical Director, Ontario. I shall retire from LifeLabs at the end of January 2009. Dr. Douglas Tkachuk, currently at University Health Network, will become Medical Director as I depart.



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