Guideline for Reporting Laboratory Test Results

CLP-025 (replaces C020)

Revised September, 2009

1. Purpose

The purpose of this Guideline is to establish reporting protocols which will enhance patient safety and at the same time prevent unnecessary telephone calls to clinicians outside of office hours.

For most clinical situations, the standard reporting mechanism used by OAML member laboratories meets the needs of patients and clinicians in the community. There are two circumstances which present exceptions to routine reporting guidelines and which may require expedited reporting processes.

These are:

a) Test results which deviate significantly from reference values and are apparently unexpected, based on the information available to the testing laboratory.
b) A clinician has requested expedited reporting to meet a special clinical need.

2. Background

The tables at the end of this Guideline contain test results that will be flagged by the laboratory for further evaluation. These values have been defined specifically for a community laboratory environment and are based on published literature as well as the experience of Ontario's community laboratories. The likelihood that these results are clinically significant and require immediate or prompt action will depend on a number of factors including:

- previous or concurrent test results known to the laboratory
- information provided by the ordering clinician
- the scope of practice of certain medical specialists

3. Definitions

a) Level I or "Critical" values

These are results that show a marked deviation from reference ranges, with no clear indication to the laboratory that these are expected deviations. Results of this nature may indicate a significant risk of a life-threatening event. Prompt medical intervention may be required. As such, these results are considered "critical" results and will be called to clinicians 24 hours a day, 7 days a week.

The final classification of a laboratory result as "critical" is based on its laboratory value(s), as well as the patient's analytical history and any available clinical information. For this reason, not all laboratory results falling into the critical range will be classified by the laboratory as true critical results for the purpose of immediate physician notification.

b) Level II or "Alert" values

These are results that deviate from their reference ranges less significantly than Level I values. If unexpected, these results suggest the possible need to re-evaluate the patient's clinical condition without waiting for routine report communication.

Level II values are communicated between 08:00 and 20:00 hours. They may be faxed or phoned. Such attempts by the laboratory to communicate directly with the clinician's office will cease once results have been delivered in the routine fashion (electronic, fax or hard copy).

Since the Level II values are not considered "critical", clinicians may provide direction in writing to the laboratory to communicate all Level II results electronically or directly to a clinical management system. In such cases, clinicians assume responsibility for receiving the results and taking the appropriate action.

4. Role & Responsibilities of the Ordering Clinician

Given that a critical result may have serious consequences for patient welfare, it is mandatory that such results be communicated as soon as they become available. When such results are found, the laboratory will initiate a telephone call to the ordering clinician. The ordering clinician, regardless of scope of practice, has a professional responsibility to provide the laboratory with contact information, which will allow direct communication of these results at all times.[1]

5. Exceptions to the Reporting Protocol

a) Specialists' practices

It is recognized there will be clinical situations in specialists' practices where critical results will commonly occur. Accordingly, specialists who do not wish to receive critical results within the scope of their practice may make a written request to the laboratory to be exempted from the reporting protocol. *Non-specialist physicians and other clinicians may not request blanket exemptions, but can be exempted on a case-by-case basis by so requesting on the individual requisition.*

b) Microbiology

When a preliminary report that is considered critical is successfully communicated by the laboratory, further preliminary and/or the final microbiology report will not be communicated as second critical values. It is the responsibility of the ordering physician to obtain additional information from the final report when away from the office or when this is required for confirmation of the appropriateness of treatment.

c) Recurrent Level I and Level II results

Experience shows that certain Level II and even Level I results can be expected recurrences. Those level I and II values marked with an asterisk (*) on the following tables will only be communicated within normal business hours when the result is recurrent within a period of four (4) months. Such results may be communicated electronically.

Exceptions to the recurrent rule:

(i) Hemoglobin

When a Level I or Level II hemoglobin value has fallen by 10 g/L or more from the previous result, it will be appropriately communicated, even if recurrent within 4 months.

---

[1]The Canadian Medical Protective Association. Information Letter, Responsibility for follow up of investigations.

Volume 23, Number 2, June 2008.

(ii) Platelet Counts

Platelet counts of 10 $x10^9$ or less will be communicated as Level I values, even if recurrent within 4 months, unless written instructions to the contrary are received from a medical specialist and are approved by the Laboratory Director.

(iii) Urinalysis, Glucose and Ketones

When blood glucose analysis is requested simultaneously with urinalysis in a known adult diabetic (documented by previous diabetic glucose values or HbA1C measurements), the glucose values in blood will take precedence and Level I and Level II protocols for blood glucose will apply.

The combination of urine glucose >55 mmol/L AND urine ketones ≥4 mmol/L in any child (less than 12 years old), or these same results in adults or adolescents (12-18 years old) with no previous documentation of diabetes mellitus at the reporting laboratory, will be communicated in accordance with the Level I protocol, even if recurrent within 4 months. Urine glucose >55 mmol/L AND urine ketones ≥4 mmol/L in adults or adolescents (12-18 years old) who are clearly diabetic based on available laboratory data, but without accompanying (same requisition) serum glucose results, will NOT be considered Level I results.

Note: For patients suspected of being at immediate risk due to the possibility of undiagnosed diabetes mellitus and/or an accompanying significant metabolic derangement, it is strongly advised that clinicians utilize dipstick urinalysis in the office setting to make this determination. This will allow for immediate response to a situation that could conceivably deteriorate before a laboratory-processed result can be reported.

6. Expedited Reporting by Request of a Clinician

Limited exceptions to the routine standard of service for reporting results may be made (see "Urgent" and "ASAP" below). The ordering clinician is responsible for providing a mechanism that will ensure immediate receipt of such results. This may include a previously authorized system for electronic reporting and/or a 24-hour contact telephone number(s).

Please note that "STAT" testing with guaranteed reporting in less than 4 hours is NOT consistent with the mandate of Ontario's community laboratories. A community laboratory is not the appropriate venue for diagnosis of acute, potentially life-threatening conditions, such as myocardial infarction or sepsis. Such patients should be referred to acute care settings where both testing and clinical intervention is available.

There are two categories of expedited results:

a) Urgent

The following tests are available on an urgent basis from OAML member laboratories. Depending on geography, weather conditions and time of request, all of which may affect the delivery of specimens, urgent results will be available anywhere from 6 to 12 hours after the receipt of the specimen in the laboratory. When the clinical need requires a more rapid analysis, clinicians are advised to contact the Laboratory Director of the testing laboratory to ensure this need can be met by the laboratory, even if the test appears on the list below.

Amylase\Lipase	Urea	Chloride	INR
Creatinine	Malaria	Sodium	Potassium
Glucose	CBC	Calcium	Neonatal bilirubin

Other tests may be available on an urgent basis, but must be requested by communicating directly by telephone with the Medical Director or the Laboratory Director. This is required to ensure that the requested testing is logistically possible, and that the turnaround time will meet the clinical need.

b) ASAP (As Soon As Possible)

Clinicians may request a special communication of test results as soon as they are available. Test results requested ASAP will be communicated by FAX, other electronic means or, if specifically requested, by telephone. Turnaround time will depend upon the type of assay requested. Most tests will be communicated in less than 24 hours when ordered ASAP.

To ensure prompt communication of Urgent or ASAP results, clinicians' contact numbers must be provided. If this information has not been provided, results will be reported in routine fashion, unless they are actual Level I or Level II values.

7. INR Recommendation

The experience of laboratories suggests that communication of significantly abnormal INR results is facilitated when patients are instructed to visit community patient service centres Monday to Thursday, not Fridays or weekends. Informing laboratories of any anticipated absences of the requesting clinician will also significantly help the communication of INR results.

The requesting clinician has the option of ordering INR in accordance with the Urgent Protocol (see Urgent Section above) when absence from the office can be anticipated, or when clinical circumstances suggest that an adjustment to anticoagulant dosage may be required.

8. Neonatal Bilirubin

Neonates are often seen in clinicians' offices outside the hospital setting. Cases of suspected hyperbilirubinemia often require rapid clinical treatment decisions. While community laboratories can provide "Urgent" testing for neonatal bilirubin, the stated turnaround time (6-12 hours after receipt of the specimen in the laboratory; see section 6(a)) may not adequately serve clinicians' needs in many cases. Furthermore, should the detected level of bilirubin be such that immediate treatment needs to be initiated, further time will be lost in travel to an appropriate treatment centre. For this reason, blood samples for suspected neonatal hyperbilirubinemia are best drawn and tested in an acute care setting, where treatment can begin without delay, when required.

9. Summary of Level I/Critical and Level II/Alert Results

Chemistry:

Assay	Level I / Criticals	Level II / Alerts
Acetaminophen	>660 umol/L (>4 hours post ingestion)	
*Amylase	>10X Upper Limit of Normal (U/L)	>3X Upper Limit of Normal (U/L)
Bilirubin	Paediatric Levels (umol/L):[2] Neonates 24-48 hours >260 Neonates 49-72 hours >310 Neonates >72 hours >340	
Calcium	<1.65 mmol/L >3.25 mmol/L	
Calcium, Ionized (corrected for pH)	<0.80 mmol/L >1.60 mmol/L	

*Will not be communicated outside office hours when recurrent up to four months (see Section 5C)

[2] Subcommittee on Hyperbilirubinemia, Academy of Pediatrics. Management of Hyperbilirubinemia in Newborn Infant 35 or More Weeks of Gestation, Clinical Practice Guideline. *Pediatrics* July 2004; Vol.114: 297-316.

Chemistry (cont'd):

Assay	Level I / Criticals	Level II / Alerts
Carbamazepine	>63 umol/L	
Carboxyhemoglobin	>0.50 (Proportion of hemoglobin saturation)	>0.35 (Proportion of hemoglobin saturation)
Cholinesterase (acetyl), RBC	<0.50X Lower Limit of Normal (U/L)	
Cholinesterase (acetyl), Serum	<0.50X Lower Limit of Normal (U/L)	
CK-2(CK-MB) Note: It is not appropriate to order CK-2 in addition to CK total when monitoring potential statin myotoxicity.	Elevated Relative Index (%) (Defined as the ratio of CK-2 to total serum CK.) Note: This cut-off point is method dependent.	
CO_2	<10 mmol/L >40 mmol/L	
*Creatinine		>650 umol/L
Digoxin	>3.5 nmol/L (>6 hours post dose)	
Ethanol (plasma)		>33 mmol/L
Ethosuximide	>1000 umol/L	
Glucose	Children (<12 years): <2.0 or >20.0 mmol/L Adults/Adolescents (12-18 years): >30.0 mmol/L (valid for grey-tops, properly centrifuged SST tubes or serum aliquots)	Adults/Adolescents (12-18 years): >20.0 mmol/L (valid for grey tops, properly centrifuged SST tubes or serum aliquots)
Glucose and Ketones (urinalysis)	Adults/Adolescents (12-18 years) not known to be diabetic; Children (<12 years): Glucose >55 mmol/L **AND** Ketones ≥4 mmol/L Blood glucose result will take precedence over urine results in adults and adolescents only.	

*Will not be communicated outside office hours when recurrent up to four months (see Section 5C)

Chemistry (cont'd):

Assay	Level I / Criticals	Level II / Alerts
Iron		>55 umol/L (if age <10 years)
Isopropanol	All positives	
Lead		>3.0 umol/L
*Lipase	>10X Upper Limit of Normal (U/L)	>3X Upper Limit of Normal (U/L)
Lithium	>2.5 mmol/L	>2.0 mmol/L
*Magnesium		<0.40 mmol/L
Methanol	All positives	
Phenobarbital	>250 umol/L	
Phenytoin	>130 umol/L	
Potassium	<2.5 mmol/L >6.6 mmol/L **If haemolysed or if the time to separation has been delayed, the result is no longer meaningful and will not be considered a Level II result.**	<2.8 mmol/L >6.2 mmol/L **If haemolysed or if the time to separation has been delayed, the result is no longer meaningful and will not be considered a Level II result.**
Primidone	>110 umol/L Phenobarbital is an active metabolite of primidone and will also be reported.	>70 umol/L Phenobarbital is an active metabolite of primidone and will also be reported.
Salicylate	>3.0 mmol/L	>2.2 mmol/L
Sodium	<120 mmol/L >160 mmol/L	
Theophylline	>220 umol/L	>110 umol/L

*Will not be communicated outside office hours when recurrent up to four months (see Section 5C)

Chemistry (cont'd):

Assay	Level I / Criticals	Level II / Alerts
Tricyclic Antidepressants Amitriptyline Clomipramine/ Desmethylclomipramine Desipramine Doxepine/ Desmethyldoxepine Imipramine/Desipramine Maprotiline Nortriptyline Trimipramine		>1.8 umol/L
*Urea		>35.0 mmol/L
Gentamicin	Trough >2.0 mg/L (>8 hours post dose for multiple daily dosing)	
Tobramycin	Trough >2.0 mg/L (>8 hours post dose for multiple daily dosing)	
Valproic Acid	>1400 umol/L	>1000 umol/L

*Will not be communicated outside office hours when recurrent up to four months (see Section 5C)

Microbiology: (see Section 5b)

Reportable Result	Level I Criticals	Level II Alerts
Sterile Site including cerebrospinal fluid Any positive direct examination (e.g. gram stain, KOH) and/or culture Note: Only the preliminary positive result will be communicated as critical. Any subsequent information must be requested by the ordering physician (see Section 5).	✓	
Blood culture: Any positive culture Note 1: Coagulase negative staphylococci when present in only one of the paired culture bottles will be regarded as a contaminant and will not be reported by this protocol. Note 2: Only the preliminary positive result will be communicated as critical. Any subsequent information must be requested by the ordering physician (see Section 5).	✓	
Enteric Specimens: *Escherichia coli* 0157:H7, *Vibrio cholerae, Shigella Dysenteriae type I, Salmonella typhi, Salmonella paratyphi A and B*	✓	
Enteric Specimens: *Shigella* "non-dysenteriae" species, *Clostridium difficile* toxins, *Salmonella spp* other than *typhi* and *paratyphi, Campylobacter spp, Yersinia enterocolitica, Yersinia pseudotuberculosis*		✓
Wound Swabs: Group A *Streptococcus*	✓	
Ocular Specimens: Culture positive for *Neisseria gonorrhoeae, Neisseria meningitidis, Pseudomonas aeruginosa*	✓	
Blood smears positive for malarial parasites	✓	
Any specimens positive for dimorphic fungi, e.g. *Blastomyces, Histoplasma, Coccidioides*		✓
First-time isolates of vancomycin-resistant enterococci (VRE) or methicillin-resistant *Staphylococcus aureus* (MRSA) from clinically infected sites, but not from screening sites.		✓
Highly aggressive organisms or positive results for recognized agents of bioterrorism, e.g. *Bacillus anthracis, Brucella spp, Yersinia pestis, Francisella tularensis, Burkholderia mallei, Burkholderia pseudomallei,* presumptive *Clostridium botulinum, etc.*	✓	
Any specimen positive for uncommon or unusual organisms that may portend an adverse clinical outcome e.g. *Corynebacterium diphtheriae, etc.*	✓	

Hematology:

Assay	Level I / Criticals	Level II / Alerts
*Hemoglobin	< 60 g/L See Section 5 c) (i)	<80 g/L >200 g/L See Section 5 c) (i)
*Platelet Count	<20 x 10^9 / L See Section 5 c) (ii)	<50 x 10^9 /L See Section 5 c) (ii)
Lymphocyte Count (absolute)	>250 X 10^9 / L	
Neutrophil Count (absolute)	<0.5 x 10^9 / L >100 X 10^9 / L	<1.0 x 10^9 / L >50 x 10^9 / L
INR (International normalized ratio)	>6.0	>4.5
APTT (activated partial thromboplastin time)	>100 seconds	>80 seconds
Morphology	All positive malaria smears and positive intracellular bacteria in WBC	

*Will not be communicated outside office hours when recurrent up to four months (see Section 5c)

9. References

Subcommittee on Hyperbilirubinemia, Academy of Pediatrics. Management of Hyperbilirubinemia in Newborn Infant 35 or More Weeks of Gestation, Clinical Practice Guideline. *Pediatrics* July 2004; Vol.114: 297-316.

Quality Management Program-Laboratory Services. Chemistry Broadsheet-Critical Values for Chemistry-General, 2006.

Salinas, M., Flores, E., Lugo, J., et al. Retrospective Study of Critical Values: Agreement and Improvement. *Science* 2007; Vol.39: 413-417.

The Canadian Medical Protective Association. Responsibility for follow up of investigations. Information Letter, June 2008; Vol.23: Number 2.

Acknowledgements

The OAML gratefully acknowledges the contributions of:

Frank Thompson MD, FRCPC
Former Medical Director, LifeLabs®, Ontario

Sheila Boss, PhD, FCACB
Laboratory Director and Scientific Director,
LifeLabs®, Ontario

Julius Kapala, PhD., RSM (CCM), SM (ASCP)
National Discipline Director, Microbiology
Gamma-Dynacare Medical Laboratories

Dr. Deborah Yamamura, MD, FRCPC
Director of Microbiology, LifeLabs®, Ontario
Medical Microbiologist/Infectious Diseases
Physician,
Hamilton Health Sciences, Hamilton

Dr. Wahbi Hammouda MDCM, FRCPC
Former Director of Laboratory Hematology,
LifeLabs®, Ontario
Head, Division of Haematopathology
St. Michael's Hospital, Toronto

Laboratory Guidelines in Support of Clinical Practice

The OAML, through its Quality Assurance Committee, co-ordinates the development, dissemination, implementation and review of Guidelines for Clinical Laboratory Practice.

Guidelines are reviewed every 5 years, or as the literature warrants. When consensus on the Guideline is achieved by the Committee, the Guideline is submitted to the OAML's Board of Directors for approval before distribution to clinicians.

The comments of end users are essential to the development of guidelines and will encourage adherence. You are strongly encouraged to submit your comments on this or any other OAML Guideline to:

Chair
Quality Assurance Committee
Ontario Association of Medical Laboratories
5160 Yonge Street, Suite 710
North York, Ontario
M2N 6L9

Tel: (416) 250-8555
Fax: (416) 250-8464
E-mail: oaml@oaml.com
Internet: www.oaml.com

Quality Assurance Committee Members

Doug Tkachuk MD FRCP(C)
Medical Director, LifeLabs®, Ontario

Philip Stuart MD, PhD, FRCP(C)
Medical Director, CML HealthCare Inc. Ontario

Joel Goodman PhD, FCACB
VP, Strategies and Innovation
Gamma-Dynacare Medical Laboratories

Janice Nolan MLT, CQA (ASQ)
Director, Quality & Regulatory Affairs
LifeLabs®, Ontario

Chair
Judy Ash M.PP.A.L., BSc, ART, CQMgr, CQA (ASQ)
Director, Programs & Member Services
Ontario Association of Medical Laboratories

No conflict of interest declared

Warning & Disclaimer

This Guideline was prepared to assist clinicians who order tests from community laboratories. Users must ensure that their own practices comply with all specific legislative, government policies or accreditation requirements that apply to their organizations. The Guideline is not meant to be construed as legal advice or be all inclusive on this topic. Given the complexity of legal requirements, users are reminded that whenever there is uncertainty regarding whether some aspect of a Guideline is appropriate for their practice or organization, further direction should be obtained from the Laboratory Director, their own professional association, college and/or legal counsel or appropriate government ministry.

ONTARIO ASSOCIATION OF MEDICAL LABORATORIES

WORKING TO KEEP OUR HEALTH CARE SYSTEM HEALTHY ™