Quality Assurance of Clinical Laboratory Practice Program	
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Subject: OAML PROTOCOL FOR REPORTING LABORATORY TEST RESULTS (revised June 2003)	

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

A. When results deviate significantly from reference values

B. When the physician requests expedited reporting to meet a special clinical need.

A. REPORTING WHEN RESULTS DEVIATE SIGNIFICANTLY FROM REFERENCE VALUES

OAML laboratories have agreed to a defined schedule of test results that must be communicated directly to physicians based upon the two result categories described below. These reporting limits have been defined specifically for a community laboratory environment and are based on published literature as well as laboratory experience.

Level I A result that will cause the patient to suffer a life-threatening event if not communicated and treated immediately. These results show marked deviation from reference ranges suggesting that, if unexpected, a patient's life is in danger and prompt medical action may be required. These results must be called as soon as results are available, 24 hours per day.

Level II A result that deviates significantly from the reference range and, if unexpected, suggests the need to re-evaluate the clinical situation prior to the arrival of a report by routine channels. These results are called between 08:00 and 20:00 hours.

Laboratories have an obligation to attempt to communicate these abnormal results. The ordering physician has a professional responsibility to provide the laboratory with contact information, which will allow direct communication of these results to the physician (or a delegate providing coverage during absences).

There will be situations when a markedly abnormal result is not unexpected. Certain **level I** values may be frequently expected in certain types of specialist practice. Under these circumstances an exception to a calling protocol may be made when a physician communicates this on the laboratory requisition or in writing to the laboratory. Specific exceptions to calling guidelines may be made on written requests to the laboratory director.

NB: Blanket exception to calling is considered medically unacceptable by the College of Physicians and Surgeons of Ontario and cannot be honoured by OAML member laboratories.

Recurrent Level I and Level II results

Experience shows that certain Level I and Level II results are frequently recurrent and the recurrence is not unexpected. Level I and II values marked with an asterisk * will not be communicated outside normal office hours, when recurrent up to four months after the previous Level I or II value for the same analyte. Such results may be communicated by fax.

The following exceptions will apply:

When a hemoglobin value has fallen by 10 G/L or more from the previous Level I result it will be communicated in accordance with the Level I Protocol.

Platelet counts of 10 $x10^9$ or less will be communicated as Level I values even when recurrent.

A physician requiring immediate communication of known recurrent Level I or II values marked with an asterisk may over-ride these rules by requesting the analysis be handled as Urgent as described below.

*Urinalysis Level I Glucose **and** Ketones*

When blood glucose analysis is requested simultaneously with urinalysis in an adult known diabetic (documented by previous diabetic glucose values or Hb A_1C measurements) the glucose values in blood will take precedence and the Level I and Level II protocol for Glucose will apply. The combination of Glucose >55 mmol/L and Ketones > 1.5mmol/L will be considered a Level I result in children (less than 12 years old) and adults with no documentation of diabetes mellitus in the reporting laboratory.

INR

The Level II value for INR is 4.5. Results between 3.6 and 4.4 will be communicated during office hours and may be delivered by fax. The requesting physician has the option of ordering INR (Prothrombin time) in accordance with the Urgent Protocol (see page 3), when absence from the office can be anticipated, or the clinical circumstances suggest that an adjustment to anticoagulant dosage may be required.

B. EXPEDITED REPORTING UPON REQUEST OF THE PHYSICIAN

Exceptions to the routine standard of service may be made, independent of the test result, upon request by the physician. The ordering physician has the responsibility to provide information, including 24-hour contact numbers, which allows prompt reporting. Please note that “STAT” testing with guaranteed reporting in less than 4 hours is not consistent with the mandate of community laboratories. In a situation where patients require such prompt evaluation they should be referred to a facility where both testing and clinical intervention can be delivered.

There are two categories of expedited results:

1. Urgent Protocol

The following list of tests is available on an urgent basis from OAML Laboratories. Depending on geography and weather conditions, results will be available within a period of 6 to greater than 12 hours.

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

Other tests may be available on an urgent basis, but must be requested by direct communication with the Medical Director or Laboratory Director of the testing laboratory. This is required to ensure that the requested testing is logistically possible and that the turn around time will meet clinical need. OAML laboratories have agreed to add the following tests, if approved by Laboratory Director or Medical Director:

Therapeutic drugs including acetaminophen, carbamazepine, digoxin, lithium, phenobarbital, phenytoin, salicylate, theophylline and valproic acid.

hCG or pregnancy test, when ectopic pregnancy is suspected or an urgent X-ray is required.

2. ASAP (As Soon As Possible)

Physicians may request a special communication of test results as soon as these are available. Test results requested ASAP, will be delivered by Fax to the physician's office or, as required, by telephone. Turn around time will depend upon the type of assay requested. However, routine tests will be communicated in less than 24 hours. To ensure prompt communication, contact numbers must be provided. If these are not available, the results will be reported in a routine fashion unless the results are Level I or Level II values.

Chemistry: Summary of Critical Results

Assay	Level I	Level II
Acetaminophen	> 660 µmol/L (> 4 hours post ingestion)	
Amylase*	*> 10 X Upper Limit of Normal (U/L)	*> 3X Upper Limit of Normal (U/L)
Bilirubin	Paediatric Levels (µmol/L)[1] Neonates 24-48 hours >260 Neonates 49-72 hours >310 Neonates > 72 hours >340	
Calcium*	*< 1.65 mmol/L *> 3.25 mmol/L	
CO_2	< 10 mmol/L > 40 mmol/L	
Carbamazepine	> 63 µmol/L	
Carboxyhemoglobin	> 0.50	> 0.35
Cholinesterase, RBC	< 0.50 X Lower Limit of Normal (U/L)	
Cholinesterase, Serum	< 0.50 X Lower Limit of Normal (U/L)	
CK-MB	Elevated Relative Index (%) (Defined as the ratio of CK-MB to total serum CK. Note: This cut off point is method dependent)	
Creatinine*		*> 650 µmol/L
Digoxin	> 3.5 nmol/L (> 6 hours post dose)	
Ethanol		> 33 mmol/L
Ethosuximide		> 1000 µmol/L

* Will not be communicated outside office hours when recurrent up to four months after the previous level I or level II value for the same analyte.

[1] *Management of Hyperbilirubinemia in the Healthy Term Newborn*, Provisional Committee for Quality Improvement and Subcommittee on Hyperbilirubinemia, *American Academy of Pediatrics*, vol. 94 (4), 199, p 558-565.

Chemistry: Summary of Critical Results

Assay	Level I	Level II
Glucose	Children < 2.0 mmol/L All ages >30.0 mmol/L Children Age defined as < 6 months. If patient age is less than 6 months, glucose results less than 2.0 will be communicated as a critical value.	All ages < 2.0 mmol/L All ages > 20.0 mmol/L Children Age defined as < 6 months. If patient age is less than 6 months, glucose results less than 2.0 will be communicated as a critical value.
Urinalysis (blood glucose takes precedence for adult diabetics)	Glucose > 55 mmol/L **and** Ketones > 1.5 mmol/L	
Ionized Calcium*		*< 0.80 mmol/L *> 1.60 mmol/L
Iron		> 55 µmol/L (if age < 10 years)
Isopropanol	All positives	
Lead		> 3.0 µmol/L
Lipase*	* >10 X Upper Limit of Normal (U/L)	* > 3 X Upper Limit of Normal (U/L)
Lithium	> 2.5 mmol/L	> 2.0 mmol/L
Methanol	All positives	
Magnesium* Phenobarbital	 > 250 µmol/L	*< 0.40 mmol/L > 200 µmol/L
Phenytoin	> 130 µmol/L	
Potassium	< 2.5 mmol/L > 6.6 mmol/L (non hemolyzed)	< 2.8 mmol/L > 6.2 mmol/L
Primidone	> 180 µmol/L Reflex to phenobarbital if primidone > 70	> 70 µmol/L Reflex to phenobarbital if primidone > 70
Procainamide		> 50 µmol/L

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Chemistry: Summary of Critical Results

Assay	Level I	Level II
Quinidine	> 30 µmol/L	
Sodium	< 120 mmol/L > 160 mmol/L	
Salicylate	> 3.0 mmol/L	> 2.2 mmol/L
Theophylline	> 220 µmol/L	>110 µmol/L
Tricyclic Antidepressants Amitriptyline Clomipramine/ Desmethylclomipramine Desipramine Doxepine/Desmethyldoxepine Imipramine/Desipramine Maprotiline Nortriptyline Trimipramine		 > 1.8 µmol/L > 1.8 µmol/L > 1.8 µmol/L > 1.8 µmol/L > 1.8 µmol/L > 1.8 µmol/L > 1.8 µmol/L > 1.8 µmol/L
Urea*		* > 35.0 mmol/L
Gentamicin	Trough > 2.0 mg/L (> 8 hours post dose)	
Amikacin	Trough > 10.0 mg/L (> 8 hours post dose)	
Tobramycin	Trough > 2.0 mg/L (> 8 hours post dose)	
Netilmicin	Trough > 2.0 mg/L (> 8 hours post dose)	
Valproic Acid	> 1400 µmol/L	> 1000 µmol/L
Benzodiazepines		> 7.0 µmol/L

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Microbiology: Summary of Critical Results

Reportable Result	Level I	Level II
Sterile Site Specimens: Positive gram stain and/or culture (See exception below)	X	
Sterile Site Specimens : Culture positive for Coagulase Negative Staphylococcus (Exception: cerebrospinal fluid isolates are considered Level I):	(X)	X
Enteric Specimens: *E coli* 0157, *Vibrio cholerae, Shigella dysenteriae*	X	
Enteric specimens: *Salmonella typhi* and *paratyphi*, *Shigella* "non-dysenteriae" species		X
Wound Swabs: Group A *Streptococcus*		X
Ocular Specimens: Culture positive for *Neisseria gonorrhoeae* or *Pseudomonas aeruginosa*	X	
Blood smears positive for Malaria parasites	X	
Any specimens positive for systemic Fungi		X
First time isolates of VRE and MRSA Any specimens positive for uncommon or unusual organisms i.e. *Brucella* sp., presumptive *Clostridium botulinum* etc.	X	X X

Hematology: Summary of Critical Results

Assay	Level I	Level II
Hemoglobin*	*< 60 g/L	*< 80 g/L *> 200 g/L
Platelet Count (x 10^9/L) *	*< 20 x 10^9 / L	*< 50 x 10^9 /L
Total WBC (x 10^9/L) *	*< 0.5 x 10^9 / L	* < 1.0 x 10^9 / L *> 150 x 10^9 / L
Abs Neutrophil (x 10^9/L) *	*< 0.5 x 10^9 / L *> 40 x 10^9 / L	*< 1.0 x 10^9 / L *> 30 x 10^9 / L
INR (Prothrombin Time)	> 6.0	> 4.5
PTT	> 80 seconds	> 40 seconds
Morphology	All positive malaria smears and Positive intracellular bacteria in WBC	
Fibrin Degradation Product		> 0.25 mg/L
Urinalysis (Blood glucose takes precedence in adult diabetics)	Glucose > 55mmol/L **and** Ketones > 1.5 mmol/L	

* Will not be communicated outside office hours when recurrent up to four months after the previous level I or level II value for the same analyte.