

Date: November 14, 2009
To: All Clinical Trials Coordinators and Researchers
Re: LABORATORY - CLINICAL TRIALS AND RESEARCH GUIDELINES FOR USE DURING PANDEMIC

Key Message:

The following guidelines will be utilized in response to the local/zone pandemic situation to optimize laboratory resources in respect to Clinical Trials and Research:

Laboratory Service Provided	Selective Prioritization	System Wide Prioritization
Quote and Operational Approval	Will continue as staffing levels permit	
Sample Collection	Will continue as staffing levels permit	
In-House Testing	Follow AHS Laboratory Services Essential Test Menus for Pandemic (H1N1) 2009	Follow AHS Laboratory Services Essential Test Menus for Pandemic (H1N1) 2009
Sample Shipment to Central Laboratory or Research Laboratory	Will continue as staffing levels permit	
Billing	Will be completed upon return to normal staffing levels	

Examples:

Current clinical trials that involve necessary health care for a patient	Collection and testing will be performed
Current clinical trials that require laboratory tests for continuation of the trial	Collection and testing will be performed
Drug levels relevant only to the study results	Collection will be performed and the samples stored for testing or shipping following return to normal staffing levels
New clinical trials	Start of the trial will be delayed until the activation level returns to de-escalation or recovery levels

- Please note every endeavour will be made to complete contract requirements to meet agreed upon obligations during the pandemic. Limitations in staffing levels may cause delays in service such that contract obligations are not fully met.
- If staffing levels can no longer maintain collections/testing, study related blood work (collection and testing) will be discontinued/delayed until levels return to normal. This is at the discretion of the Zone Emergency Operational Center (ZEOC) and the Laboratory Command Post Centre (LPCC).
- Please review pandemic information and make contingency plans for your clinical trials or research projects.
- Study Coordinators will be advised ASAP if there is any change to the level of laboratory service.

For additional questions contact:

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