Shared Health Diagnostic Services Guidelines

for

Clinical Trials and Research Studies

SH reserves the right to adjust charges at its discretion without notice. A copy of the current Guidelines will be available online for reference.

If any tests or services required are not listed in the following document, please contact the SH Research Support Office (RSO)

Version Date: January 2021

Initial Documentation, Activating Laboratory Component & Ongoing Requirements &

This is now part of the Shared Health Research and Innovation processes. Refer to website for additional information.

General Information

Laboratory Notification

When the 1st patient visit of a study is scheduled or expected, email the RSO.

If shipping of frozen samples is required on the day of collection, contact the RSO to make arrangements for this shipment.

Laboratory Hours of Operation

Laboratory dayshift is 0800h – 1615h

Any samples that are require shipping on day of collection, must be received in the laboratory by 1345h for processing, packaging and shipping, unless otherwise arranged during laboratory impact assessment.

Samples not requiring same day shipping must be received in the laboratory by 1500h to be processed on dayshift.

Specimen Collection / Phlebotomy

A maximum of 6 collections per study is allowed without prior authorization (3 morning or fasting collections and 3 afternoon collections)

For further information of specimen collection hours of availability, please contact the RSO. Only samples listed on the SH study requisition will be drawn for research purposes.

Monitor, Site Selection or Site Initiation Visits

To schedule an appointment or tour of the laboratory, contact the RSO at least 1 week prior to the intended visit.

Accessing Study Documentation

To arrange access or to request copies of any study documentation within the laboratory, contact the RSO.

Central Laboratory Supplies

Supplies required for processing specimens must be provided on the day of collection in a study kit which accompanies the samples or are provided at the time of specimen collection. This includes, but is not limited to, collection tubes, aliquot tubes and sample labels.

Sample Shipping/Pickup

Shipping supplies including boxes and pre-printed waybills/customs declarations must be provided prior to the shipment. Supplies will be accepted starting 3 business days prior to the scheduled shipment date.

Shipping supplies will not be stored within the laboratory space.

To arrange samples to be shipped and/or picked up in the laboratory, contact the RSO at least 1 week prior to the requested shipping/pickup date.

Laboratory Documentation

Copies of the following documentation will be forwarded to the appropriate site Clinical Research Offices and all current study coordinators yearly. If you require copies the documents at any other point in the year, please contact the RSO.

LABORATORY ACCREDITATION

SH laboratories are CAP or MANQAP accredited.

Current accreditation certificates can be could at online or by contacting the RSO.

LABORATORY DIRECTOR'S CV & MEDICAL LICENCE

The Chief Medical Officer for Shared Health Diagnostic Services is Dr. Amin Kabani and he is responsible for all Manitoba's public laboratory services. A copy of Dr. Kabani's CV and Medical License may be made available by contacting the RSO.

LABORATORY TEST REFERENCE RANGES

The Reference Ranges for Biochemistry and Hematology are updated yearly. If you require the reference values for a test that is not listed, you can access our Lab Information Manual online at or contact the RSO.

TDG/IATA CERTIFICATIONS

Copies of Staff's TDG & IATA Certifications for any staff involved with the shipping / handling of specimens may be made available by contacting the RSO.

FREEZERS & FREEZER TEMPERATURE LOGS

Copies of all freezer logs (-70°C and -20°C) used for storage of research specimens are kept on file. In the event that a monitor requires either the logs and/or freezer discs, please notify the RSO.

CENTRIFUGE SPEED AND TEMPERATURE CHECKS

Every 6 months, all Laboratory centrifuges are checked for speed accuracy and for temperature, if applicable. Clinical Engineering handles equipment repairs as required.

Definitions

Participant

Subject who is enrolled in a research study or clinical trial run in a SH facility

Local Testing

Any testing which is done within a SH facility, regardless of the need to refer testing to a referral laboratory within SH

Local Testing Requisition

A study specific requisitions which is created by the RSO. This requisition lists the testing required for a particular visit.

Central Laboratory

A laboratory which will be completing testing for a particular project and is contracted by the study sponsor. Samples going to this facility must be processed and sent out according to specifications set out by the Central Laboratory. These requirements will be listed on the SH Central Laboratory Requisition.

SH Central Laboratory Requisition

A study specific SH requisitions which is created by the RSO and outlines the requirements for collection, processing and shipping for a particular visit.

Properly Completed Requisition

A study test requisition which has been filled out completely so as to indicate that an appropriate specimen has been collected to correspond to the orders on the requisition

Internal Referral Laboratory

SH reference laboratories: Westman Laboratory, Health Sciences Centre and St Boniface General Hospital

External Referral Laboratory

Non-SH laboratories to which diagnostic testing is referred (i.e. Mayo Clinic, Hospitals-in-Common, etc).

Biological Materials

Human tissue (including normal and abnormal organ materials), hair, blood serum or plasma, body fluids, DNA, etc.

Designated Pathologist

The pathologist who has been contacted by the principal investigator, has agreed to be the main pathology contact person in partnership with the Principal Investigator, and will be responsible for the selection of tissue (blocks/slides) to be released.

Reporting Pathologist

The pathologist that is responsible only for the diagnosis of the biological material and is the reporting pathologist for legal purposes. A reporting pathologist may also serve as a Designated Pathologist through a consensual agreement between the Reporting Pathologist and the Principal Investigator.

Essential Tissue Blocks

Any paraffin blocks containing patient tissue deemed to be of diagnostic importance for the staging of disease.

Non-Essential Tissue Blocks

Paraffin blocks containing patient tissue deemed not to be of diagnostic importance for the staging of disease.

SH Committee for Impact Resource Assessment (CIRA)

The committee established by SH to oversee use laboratory staff and services including the requirements for tissue release.

Principal Investigator

A clinician or basic scientist with proven qualifications.

The person who is designated as being responsible for the intellectual direction of a particular clinical trial or other research project.

U of M Research Ethics Board

The University of Manitoba Biomedical Research Ethics Board (BREB) and the Health Research Ethics Board (HREB)

Laboratory Services

Clinical trial/research study setup/admin fees

Protocol review & summary, laboratory impact assessment, management review & sign off, communications, estimate/quote preparation, requisition preparation, computer system setup (delphic), laboratory setup, staff in-services, document management and billing

Local Testing Only

Central Laboratory Study

Pathology Only

Complex Study

Alternate/additional site setup/admin fee

Cost of admin/set up to provide service at alternate/additional site(s) – per site Example: additional hospital or laboratory site

Protocol change fee

Subsequent protocol review due to change and/or amendment that requires additional/modified requisitions, updated cost estimate, etc.

Miscellaneous admin work / meetings

Attending study meetings, attending courses, pulling reports, compiling results, etc.

Venipuncture / Specimen Collection

Per patient / per collection

Identification, laboratory or unit collection, labeling and transportation of specimens

Specimen Accessioning

Verification, computer registry and sample labeling

In-House Processing / Instrument Load Fee

Centrifugation and individual instrument load and analysis, completion and filing of paperwork

Central Laboratory Processing

All Central Laboratory Processing is per patient / per collection and includes specimen/aliquot labeling, completion and filing of paperwork as well as one of the criteria below

Basic Processing

- One centrifugation at required temperature and speed for samples
- Up to 5 aliquots or preparation of differential slides

Intermediate Processing

- Up to 2 different centrifugation cycles at required temperature and speed for samples
- Up to 10 aliquots or preparation of differential slides

Complex Processing

- More than 2 different centrifugation cycles at required temperature and speed for samples
- Up to 20 aliquots or preparation of differential slides
- Specialty separation

Advanced Processing

- More than 2 different centrifugation cycles at required temperature and speed for samples
- Greater than 20 aliquots or preparation of differential slides
- Specialty separation

Aliquot/Slide Preparation Only

- Up to 5 aliquots or preparation of differential slides

Shipping / Handling Charge

All shipping / handling charges are per shipment and include coordination of sending out samples including retrieving packing materials/containers, completion of shipment paperwork, proper packaging of specimens, labeling containers and ensuring transport to courier pick up

Ambient or Refrigerated, Same Day

No additional / unique criteria

Frozen, Same Day

Ensuring sample(s) are frozen prior to shipping, dry ice sufficient for transportation

Ambient or Refrigerated, Batch Shipment

Retrieving samples, coordinating sending out multiple samples, short-term storage of samples according to specifications

Frozen, Batch Shipment

Retrieving samples, coordinating sending out multiple samples, short-term storage of samples according to specifications, dry ice sufficient for transportation

Long-Term Sample Storage

Per patient / per visit Storage greater than 6 months

Notes:

- Batch shipment charges are applied after shipment has been sent. Information will be recorded at time of shipment including # of samples / aliquots sent, quantity of dry ice, etc.
- Shipping supplies must be supplied by the clinical trial or research study.
- Clinical trial or research study must supply preprinted waybills and customs declarations (if applicable) and are responsible for all charges
- Cancelled clinical trials/research studies will be charged setup/admin fee as appropriate
- Shipping cost of tests being conducted at MAYO / HICL not included