Sample Submission Instructions

Purpose

To provide instructions for submission of samples by Users of the OICR Genomics platform.

Scope

OICR Genomics receives fresh frozen (FF) tissue, formalin-fixed paraffin embedded (FFPE) tissue, whole blood, blood components, cells collected using laser-capture microdissection (LCM), and nucleic acids (DNA, RNA) for use in downstream molecular assays. This Standard Operating Procedure (SOP) provides instructions for Users to guide their submission of samples to OICR, ensuring that all materials are appropriate for testing. The SOP applies to all staff who receive samples, and all Users who ship samples. This SOP does not apply to the transfer of pre-prepared libraries.

Responsibilities

Management:
Define acceptable sample submission criteria
Review criteria at least annually to ensure that they are appropriate

Laboratory Staff:
Inspect samples, submission forms and other required documents to ensure criteria are met

User:
Review and follow Sample Submission Instructions

Sample Submission Procedure

Project details are determined and documented by the Production Manager, Genomics Program Manager and the User as per QM-023 Project Life Cycle Procedure.

Once the project has been approved and the OICR Project Code has been supplied by the Genomics Production Manager, users will be referred to TP for sample submission.

a. For RUO projects, users will complete the TW. OICR Genomics Sample Submission Form and email it to tissue.portal@oicr.on.ca at time of sample submission.
b. For clinically reported assays, they will submit a single requisition per patient through the OICR Genomics Requisition System, as described in QM. Requisition and Reporting System.
c. If human derived samples or animal samples are being submitted, the User must forward their REB approval letter for verification before samples will be accepted. This is not required for commercially-available cell lines.

2. Samples will be received by Tissue Portal in accordance with TM. Genomics Sample Receipt.

Sample Submission Requirements

Drop off and shipment conditions are detailed in OICR Tissue Portal's General Shipping Guidelines and Sample Drop-off Instructions (located on the TP Sharepoint) and these will be provided to Users at time of sample submission coordination.

All samples must follow the following labeling requirements:

a. The User must de-identify samples prior to submission and ensure that **no PHI** is sent to OICR.
b. All samples must be clearly labeled with sample IDs matching those listed on the Sample Submission Form or Requisition Form.
c. Sample IDs must be unique within the batch submitted and for validated clinical assays, two identifiers must be used.

Nucleic Acids

1. Sample Volume
   a. DNA should be suspended in 1X TE buffer to a total volume of at least 12ul.
   b. RNA should be suspended in RNAse-free water to a total volume of at least 12ul.
2. Containers
   a. Low-bind (low-retention) plastic tubes or plates should be used to contain the samples.
   b. Containers must not be leaking or broken in any way.

FFPE Tissue

1. Amount of Tissue
   a. 10x 10um sections cut within one month of submission, mounted on slides are recommended for biopsy or small tissues
   b. 5x 10um sections cut within one month of submission, recommended for larger tissues

    c. Tissue block
2. Tumour Content
    a. For validated clinical assays, a tumour content ≥30% is required within marked regions of interest with ≥40% recommended.
3. Corresponding H&E
    a. If macrodissection is needed, a corresponding H&E section reviewed and marked by a pathologist must be submitted with the tissue, unless prior agreement has been made for an H&E to be cut at Tissue Portal (RUO) and reviewed by a pathologist.
    b. The following information (when applicable) should be listed for all validated assays:
        - % Necrosis of the tumor area.
        - % Tumor cellularity of the tumor area

Fresh Frozen Tissue

1. Amount of Tissue
    a. Tissue pieces >5mm^3 are recommended to be mounted in OCT and reviewed by a pathologist ahead of transfer.
        i. For validated clinical assays, a fresh frozen tissue block must be submitted.
    b. If LCM tissue is being accepted, a pilot project must be completed to determine the amount of material that is required to be submitted, as this is highly variable across tissue types and regions of interest.
2. Tumour Content
    a. For validated clinical assays, a tumour content ≥30% is required within marked regions of interest with ≥40% recommended.
3. Corresponding H&E
    a. The following information (when applicable) should be listed for all validated assays:
        - % Necrosis of the tumor area.
        - % Tumor cellularity of the tumor area
4. Containers
    a. Tubes should be used to contain the samples if not embedded. If embedded, a mold wrapped with aluminum foil is acceptable.
    b. Containers must not be leaking or broken in any way.

Blood for Reference DNA

1. Sample Volume
    a. A minimum of 200uL of buffy coat or whole blood is recommended.
2. Containers
    a. Well-sealed cryovials or microcentrifuge tubes of any volume may be submitted.

b. Containers must not be leaking or broken in any way.

Blood Plasma for cfDNA Extraction

1. Sample Volume
    a. 4mL of plasma is recommended.
2. Containers
    a. Well-sealed cryovials, conicals or microcentrifuge tubes should be submitted.
    b. Containers must not be leaking or broken in any way.

Rejected Samples

1. If samples do not meet the requirements upon receipt, the following procedure should be followed:
    a. A note of the issue will be made in TW. Genomics Q-Notes Log.
    b. The User will be notified that their samples do not meet minimum requirements for testing.
    c. The User will authorize sample return/destruction sample re-submission or one of the options in the table below depending on failed criteria.

Criteria Not Met	Action (other than sample return or destruction)
Volume	DNA and RNA ▪ User to be notified and additional material to be requested if sample does not meet yield requirements.
Containers: Tubes or plates leaking or broken	▪ Sample destruction and request for re-submission.
Labeling: Sample labels not clear or unique	▪ Tissue Portal to relabel samples following clarification from User.
Shipping: Frozen samples arrive thawed	▪ User to authorize sample to proceed for DNA only. Accredited assay may not proceed. ▪ User to provide additional sample to be processed.
Amount of tissue: Insufficient sample volume, material or number of sections	▪ User to provide additional material or authorize sample to proceed.

2. If a sample intended for clinical assay cannot be tested, this will be noted on the VACA Rejected Samples Log.

3. If the sample is considered sub-optimal, but has been authorized for testing in a Research Use Only (RUO) capacity, communication of this authorization and the action to be taken will be documented via email and noted in MISO by changing the QC status to: “OKd by User”.
4. Clients or sites that frequently submit samples improperly will be contacted by the Production Manager or Genomics Program Manager to correct the situation.
    a. A non-conformance will be filed, and corrective actions may result, depending on the nature of the non-conformance.