SOP Title: **Sample Accessioning and Trafficking**
SOP Number: **22907**
Revision: **06**

TABLE OF CONTENTS

1. PURPOSE

This procedure describes the method for trafficking of samples through the Process Analytics/Quality Control (PA/QC) Laboratory and receiving/ distributing samples for PA/QC Testing and Inventory by the PA/QC Accessioning Office [redacted].

2. SCOPE

This procedure applies to PA/QC personnel who implement the methods for sample trafficking through the PA/QC Laboratories and personnel who receive or distribute QC samples for testing and/or retention.

3. RESPONSIBILITIES

3.1 Director PA/QC

- Defines the procedure.

3.2 Supervisor PA/QC

- Provides training.
- Provides additional check of MS, Release Letter, and SOP before submitting Release Letter to Purchasing.
- Submits input form.

3.3 PA/QC personnel

- Receives Sample Input form (**22907-01**).
- Enters sample information in FreezerWorks database.
- Submits release letter for external testing to Purchasing.

3.4 Purchasing

- Assigns P.O. to Release Letter request.

4. ACCESSIONING OF STABILITY AND REFERENCE MATERIALS

4.1 The requestor submits a Sample Input, **Form 22907-01**, with Lot number, Storage Temperature, Sample Description, Date, and Quantity entered. The form is to be used to document the submission of reference materials, standards, or other non-clinical lots to PA/QC Accessioning for long-term storage and retention for use as controls.

4.2 Accessioning personnel assign a Freezer/Refrigerator Number [redacted] (MEF number for the appropriate temperature) Rack, Box, Location within Box, and enters the information in the Stability FreezerWorks database.

4.3 Accessioning personnel signs Sample Input, **Form 22907-01** on the line "Stored By/Date."

4.4 The requestor signs Sample Input, **Form 22907-01** on line "Reviewed By/Date." This is acknowledging Lot number, Storage Temperature, Sample Description, Date, and Quantity entered are correct.

4.5 Materials that require storage under liquid nitrogen conditions may be stored in MMIC dewars or at the FNLCR Repository under a BDP PA/QC account.

5. SAMPLING HANDLING FOR OFF-SITE VENDOR TEST SUBMISSIONS

5.1 If an outside vendor is needed for testing, Accessioning personnel must complete the following:

5.1.1 A letter requesting the test ("Release Letter") to the vendor along with the Test Request Form of the vendor, if applicable. The release letter must include PA/QC's Request number, sample(s) and test(s) identity, and BDP's project number for cost center charging. Release letter/Distribution numbers are assigned via the BDP QC Shipment Log [redacted] spreadsheet.

5.1.2 Distribution Record (see **SOP 22953 Distribution of Process Analytic Samples, Form 22953-01**).

5.1.3 The Release Letter and Distribution Record undergo an additional check before samples are sent to contract labs. A second person (supervisor / PA/QC) verifies all testing matches current MS, as well as vendor SOP information before submitting (Release Letter) to purchasing.

5.1.4 An online submission request through the https://ncifrederick.cancer.gov/Cad/ShippingWizard/Dashboard/Default.aspx and print a copy of the final shipping form.

5.2 Place samples in proper storage until they are shipped (Documents must be signed by the Director of PA/QC, or designee, before distribution).

5.3 Place samples on dry ice/wet ice or room temperature, as appropriate, for pickup by Safety/ Transportation [redacted] loading dock and subsequent shipment to the Contract Lab for testing.

5.4 Test results from the Contract Labs are sent to the Director of PA/QC, designee, or QC Accessioning personnel via email or hard-copy, and data is matched with the QC request for PA/QC and BQA review.

5.5 PA/QC Accessioning personnel complete the QC Test Request form with the vendor test information.

5.5.1 PA/QC completes **Form 22002-01** with the results of test, name of the vendor, and the date the vendor completed their report.

5.5.2 The vendor report and any associated data are printed and attached **Form 22002-01**.

5.5.3 The completed QC Test Request report is then submitted for PA/QC review followed by BQA review, per **SOP 22002 Request for Quality Control Testing.**

5.5.4 Upon QA review and approval, the report is scanned to the [redacted] drive, and the original form and data are returned to BQA for archiving per **SOP 22009 Quality Control Test Request Scanning, Verification, and Adobe File Archiving**.

6. SAMPLING TRAFFICKING THROUGH THE PA/QC LABORATORY

6.1 The sample is brought to the PA/QC lab by the requestor; the PA/QC Test Request (**Form 22002-01**) must be completed electronically completely and accurately – NO HANDWRITTEN FORMS WILL BE ACCEPTED. Only one analysis is to be requested per form, though multiple samples (for the same, single assay for the same project) are permitted. QC Accessioning or QC personnel review the samples submitted, checks the form for inaccuracies and omissions, signs and dates (with time of receipt) and indicates the location of the samples.

6.2 Samples are labeled with the QC test request number (where feasible), placed in a plastic bag or container labeled with the QC number, and stored at the appropriate temperature until analysis. QC test request forms are placed in analyst folders in the Accessioning office [redacted] for pick-up and subsequent PA/QC analysis.

6.3 When necessary, QC samples can be aliquoted or shared by BDP personnel for each test requested.

6.4 QC test request (QCTR) forms are completed by BDP personnel for all QC test requests. For off-site testing, PA/QC Accessioning personnel assigns a sequential release letter number using the release letter log and generate a vendor Release Letter to the on-post (i.e. non-BDP labs at FNLCR) or contract/outside lab requesting the test. Refer to Section 5 for details.

6.5 Following sample shipment, PA/QC Test Request Forms are placed in the Accessioning QCTR file along with the associated vendor forms (protocols, etc.) and FNLCR shipping documentation until the test report is received.

6.5.1 When the Release Letter has been signed by the Director, PA/QC, or designee, samples are delivered by FNLCR Transportation to either on-post (i.e. non-BDP FNLCR) labs or outside vendors via courier or FedEx.

6.5.2 A note is made in the PA/QC Release Letter log indicating when the samples were sent.

6.5.3 Receiving labs or vendors should sign and date the PA/QC Sample Distribution, **Form 22953-01**, sent with each shipment, indicating their receipt of the sample and provide the original (or a copy) to PA/QC. Some vendors will provide their own sample receipt documentation in lieu of completing **Form 22953-01**.

6.6 Test results and reports are returned from vendor as hard-copies or via email to the QC Director or Accessioning personnel. Following receipt of all vendor documentation the reports are handled per Section 5.4.

6.7 If the vendor's results are not within assigned specifications, then an Out-of-Specification (OOS) (**SOP 22004 Investigating Out-of-Specification Test Results or Unexplained Discrepancies**) investigation is initiated by PA/QC (see **Attachment 1**). In conjunction with the BDP OOS investigation, the off-site vendor must also be contacted to have them initiate a procedural review and OOS investigation at BDP request.

7. DOCUMENTATION AND RECORDS

7.1 One of the following documents needs to be submitted to QC Accessioning with the sample(s):

- Samples for analytical analysis by QC personnel or off-site vendors require the use of PA/QC Test Request, **Form 22002-01**. Refer **SOP 22002 Request for Quality Control Testing** for details on this submission process.

- Stability samples, Reference Standards, QC retains, or other control materials provided to QC for long-term inventory storage and periodic use will require completing Sample Input, **Form 22907-01**.

7.2 Products and Samples submitted to PA/QC Inventory for long-term storage. Each entry on **Form 22907-01** is logged with the following information:

- Lot Number
- Storage Temperature
- Sample Description
- Date Received
- Quantity
- Freezer Number
- Rack
- Location in Box(es)

7.3 **Form 22907-01** is stored electronically on the QC shared limited drive.

8. REFERENCES AND RELATED DOCUMENTS

Document Number	Title
22002	Request for Quality Control Testing
22002-01	QC Test Request
22004	Managing Out-of-Specification Test Results or Unexplained Discrepancies
22907-01	Sample Input Form
22953	Distribution of QC Samples
22953-01	Distribution of QC Samples