Template Provided By:

Cancer Imaging Program

National Cancer Institute

Investigating Out of Specification (OOS) QC Test Results Form

(Refer to GEN-Q015)

Investigation Number: _____ Date of Occurrence: _____

Batch Number: _____ QC Test Control Number: _____

OOS Test Result: _____

Reason for the Investigation: _____

_____

Analytical/Sampling Checklist:

	Laboratory Checklist	Supervisor	Analyst
1	Data recording and transcription.		
2	Calculations, standard curves and reference values, measurements		
3	Equipment operation, calibration, maintenance and suitability checks, and operational features (e.g., settings, temperatures, cleanliness of cuvettes and detector windows).		
4	Compliance with assay or sampling procedures.		
5	Quality and expiration of reagents and other materials.		

- Is the OOS test result due to laboratory error? **Y** **N**
- If yes, then the investigation is complete. Invalidate the original test data and perform a retest. Document the information on Form MVR-001, a Manufacturing Variance Report Form. Complete the OOS **Form IOS-001**, **page 2**. If the OOS Test result is not a laboratory error, then continue the checklist below.

INCONCLUSIVE OR PROCESS CHECKLIST

- Check Trend Data for likely source of the OOS result? **Y** **N** **N/A**
- Evaluate Master Production Record and other relevant documentation for identifying whether a production or other process error occurred? **Y** **N** **N/A**

Summarize Manufacturing Process Sequences that may have attributed to the aberrant test result (if applicable)**:** _____

_____

_____

_____

Other Potentially Affected Batches of Product: _____

_____

Has this problem been observed previously? If yes, explain: _____

_____

_____

_____

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RETEST

Do the results of the investigation warrant a retest of the sample? Yes ___ No ____

QC REVIEW & RELEASE/REJECT DECISION

Discussion of Investigation Results and Status of the Batch: _____

Release _____ Reject _____

Corrective Actions (if applicable)**:** _____

Date Investigation Completed: _____

(Attach all relevant data to this investigation form. Copies of the completed OOS investigation should be kept with the Final QC Test Form of the corresponding Master Batch Record. The original copy of the OOS investigation paperwork should be filed in a separate file of OOS investigations for later reference.)

Performed By: _____ **Date:** _____
Signature

QA Review: _____ **Date:** _____
Signature

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