OOS Number: OOS-

Phase II

Section A – Sample Detail					
Sample Name:		**Re-Test Date:**		**Original Result:**	
Name of Analyst who Performed Re-Test:		**Sample ID:**		**Re-Test Result:**	

Section B – Investigation and Root Cause				
Investigation	Is the test conducted in accordance with the same method /process?	☑ Yes ☐ No	SOP#: 2.600.023	If the answer is NO to any of the investigation item(s), mark the item(s) with sequential number starting with one (1) and comment here: N/A QYC
	Is reagents (reference standards, solvent, etc.) stored in proper condition and not expired?	☑ Yes ☐ No	Lot #: Scan Consumables: See the attached data packet Environmental Plates: TSA and Surface Plate: see attached environmental logs Monthly Cleaning: H2O2 strips and IPA: See attached monthly cleaning logs	
			Exp. Date: Scan Consumables: See attached data packet Environmental Plates: TSA and Surface Plate: see attached environmental logs Monthly Cleaning: H2O2 strips and IPA: See attached monthly cleaning logs	
	Equipment/Instruments Used:	Are they functional and calibrated/PM?	Calibration / PM due date	
		☑ Yes ☐ No	Dec26	
		☑ Yes ☐ No	Dec26 Dec26	
		☑ Yes ☐ No	Jun26	
	E001034, E001031 (EM Plate)	☑ Yes ☐ No	Aug26 Aug26	
	E001501, E001505 (Incubator Sensors)	☑ Yes ☐ No	Feb26 Feb26	
	Is the clean room facility certified?	☑ Yes ☐ No ☐ N/A	Certified due date: 30-Jun-2026	
	Do the controls (i.e. positive, negative, C3, etc.,) conform to the required standards?	☑ Yes ☐ No ☐ N/A	See Phase II Summary	
	Do the environmental monitoring results conform to required standards?	☑ Yes ☐ No ☐ N/A	SOP#: See Phase II Summary	
	System Performance Check (if applicable)	☑ Yes ☐ No ☐ N/A		
	System Suitability RSD < 2% (PDA)	☐ Yes ☐ No ☑ N/A		
	System Suitability RSD <10 % (QDA,CAD)	☐ Yes ☐ No ☑ N/A		

	Is the analyst trained to perform the test?	☑ Yes ☐ No	
	Are the Test Result Records Attached & Calculations Verified and Correct?	☑ Yes ☐ No	
	Does the processing method/ method set conform to the required specification?	☑ Yes ☐ No	
	Re-Testing from the same vial?	☐ Yes ☑ No ☐ N/A	
	Is formula worksheet provided and verified?	☐ Yes ☑ No	

Section C – Evaluation of Laboratory Testing/Hypothesis Testing (if applicable)

- ☐ N/A
- ☐ Re-injection of sample vial
- ☐ Re-injection of original standard vial
- ☐ Re-vialing of original working standard solution
- ☐ Re-vialing of original working sample solution
- ☐ Re-dilution of a working sample solution from the original stock
- ☐ Re-dilution of a working standard solution from the original stock standard
- ☑ Other: Retest of same lot from different vials

Section D – Phase II Summary

OOS Number: OOS-

Phase II Summary (continued):

Phase II Summary (continued):

N/A QYC

OOS Number: OOS-

Has root cause been identified? ☑ Yes ☐ No	The most probable cause is: the non-uniform distribution of microorganisms, which can result in two valid but differing results. Client Care notified: Yes☑ No☐

Section E – Corrective and Preventive Action

Corrective Action(s): N/A QYC	**OOS cause (select all)** ☐ Equipment Error ☐ Procedure ☐ Analyst ☐ Training ☐ System ☑ External Phenomena ☐ Other: N/A QYC
Preventive Action(s) N/A QYC	CAPA required: ☐ Yes, CAPA # N/A QYC ☑ No
FOLLOW-UP REQUIRED: ☐ Yes ☑ No	FOLLLOW-UP DATE:

Section F – Acknowledgement and Closure

Prepared by:	Print Name:	Date:
Reviewed by:	Print Name:	Date:
Approved by (QA):	Print Name:	Date: