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:

Table 1: Processing Analyst, Reading Analysts and Sample Morphology Description

Processing Analyst	Reading Analyst	Sample ID	Events	Confirmed Microbial Events	Morphology Description
Guanchen Li	Gerald Anyangwe	ETX-251113-0167	245	23	***Oval**-Shaped Morphology*

Table 2: Environmental Monitoring from Testing Performed on 15Nov2025

Environmental Monitoring (EM) Sampling Site	Frequency	Date	Analyst	Day /Week(s)	Observation	EM Plate ETX Number	Microbial ID	Notes
Personnel EM for 15Nov2025								
Personal (Left Touch and Right Touch)	Daily	15Nov2025	GL	Date of Testing	No Growth	Not Applicable	Not Applicable	None
Biological Safety Cabinet E001311 and E001312 for 15Nov2025								
Surface Sampling of ISO 5 BSC E001311 (4 Locations)	Daily	15Nov2025	GL	Date of Testing	No Growth	Not Applicable	Not Applicable	None
Surface Sampling of ISO 5 BSC E001312 (4 Locations)	Daily	15Nov2025	GL	Date of Testing	No Growth	Not Applicable	Not Applicable	None
Settling Sampling of ISO 5 BSC E001311	Daily	15Nov2025	GL	Date of Testing	No Growth	Not Applicable	Not Applicable	None
Settling Sampling of ISO 5 BSC E001312	Daily	15Nov2025	GL	Date of Testing	No Growth	Not Applicable	Not Applicable	None
Environmental Monitoring (EM) Sampling Site	**Frequency**	**Date**	**Analyst**	**Observation**	**EM Plate ETX Number**	**Microbial ID**	**Notes**	
Weekly Active Air and Surface Sampling of Cleanroom Suite 116 with Processing BSC For 15Nov2025								
Active Air Sampling of Cleanrooms	Weekly	21Nov2025	DS	No growth	Not Applicable	Not Applicable	None	
Surface Sampling of Cleanrooms	Weekly	21Nov2025	DS	1 CFU (Table 116) 1 CFU (Celsis Table in 116) 3 CFU (Floor in 116A) 1 CFU (Floor in 116B)	ETX-251201-0554 ETX-251201-0558 ETX-251201-0562 ETX-251201-0567	Gram (+) cocci Gram (+) cocci *Bacillus clausii* (Gram (+) rods) *Bacillus pumilus* (Gram (+) rods) *Bacillus kochii* Gram (+) rods	None	

Table 3: Trend of Past OOS Results

OOS#	Analyst	ETX-Submissions	Sample Name	Morphology Description
252228	Guanchen Li	ETX-251014-0124	Tirzepatide/Levocarnitine Injection	***Rod**-Shaped Morphology*