U.S. Pharmacopeial Convention

Enverify™ Viable Surface Sampling Performance Report

Sampling Date: Report Reference:

Participant:

Table 1. Sampling Information

Sampling Device	Manufacturer	Cat#	Lot#	Expiration Date

Enverify™ Test Surface	Lot#	Average CFU/Live Sample

Results:

Table 2. Live Sample Results.

Sample Description	CFU/Sample	% Recovery
Live Sample 1		
Live Sample 2		
Live Sample 3		
Mean		
Standard Deviation		N/A

Table 3. Blank Sample Results.

Sample Description	CFU/Sample
Blank Sample 1	
Blank Sample 2	

Table 4. Summary of Results.

Test	Result	Specification	PASS/FAIL
Live Sample % Recovery (Mean)	%	≥ 20.0%	
Blank (Mean)	CFU	0 CFU	

Table 5. Method Suitability Criteria

Criteria	Description
A) Consistent Colony Morphology	All colonies were consistent with the morphology of *E. coli.*
B) CFU/Plate	CFU/plate was within the countable range of CFU that can be reliably quantified on a 55-65mm contact plate, < 150 CFU/contact plate.

The criteria described above are necessary conditions which must be met in order to determine operators' performance. Failure to meet criteria may indicate inadequate operator performance or may be attributable to other test factors; test marked "INVALID".

Table 6. Percent Recovery Range Interpretation

Recovery Range	Suggested Interpretation	Implications
<20%	Inadequate	Indicates the analyst or method is not adequately recovering viable microorganisms. Additional training or method qualification is required.
20-60%	Meets Expectations	Performance is within the typical range of recovery achieved by most Enverify™ participants[1] but may benefit from additional training or support. Sites may define their own threshold for trending and parameters for qualifying EM analysts.
>60%	Exceeds Expectations	Performance exceeds the typical range of recovery achieved by most Enverify™ participants.[1] Indicates strong performance and reliable surface recovery. Method and analyst are capable of detecting low-level microbial contamination.

1) Based on greater than 1000 sampling events from Enverify™ participants. The majority of participants in the Enverify™ program come from the compound pharmacy industry in North America. Average performance of Enverify™ participants may not be representative of other sectors, pharmaceutical industry or other geographic regions.

Factors Influencing Performance
Several elements throughout a sampling event could impact surface recovery performance:

- **Media Type and Vendor:** Growth medium composition, formulation, and fill into the molded dish all have the potential to affect quality and therefore, organism recovery.
- **Media Quality:** Expiry, storage, and handling conditions may influence performance.
- **Analyst Experience:** Familiarity with recovery methods correlates with better consistency and technique adherence.
- **Sampling Method:** Pressure, contact time, and surface characteristics can vary and should be standardized.
- **Analyst Technique:** Aseptic handling, plate placement/removal, and glove control have the potential to directly impact recovery rates.