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Validation of the GENE-UP® PRO™ Cannabis STEC/Salmonella Assay in Dried Cannabis Flower

Presenter: John Mills, Senior Scientific Affairs Manager, BioMerieux

Abstract: The GENE-UP® PRO™ Cannabis STEC/Salmonella is a real-time PCR assay for the simultaneous presumptive detection of pathogenic Escherichia coli carrying Shiga toxin 1 and/or 2 (stx1 and/or stx2) genes and Salmonella species. Objective: To evaluate the candidate method for one matrix, dried cannabis flower (delta 9-tetrahydrocannabinol >0.3%; 10 g and 1 g sample size), according to AOAC Appendix J and SMPR 2020.002 and 2020.012 validation requirements. Methods: Dried cannabis flower was evaluated at three contamination levels: 20 replicates at a low-level of ~2.0 CFU/test portion, five replicates at a high-level of ~20 CFU/test portion, and five replicates at an un-inoculated control level of 0 CFU/test portion. Results were confirmed according to procedures outlined in the SMPRs. Inclusivity and exclusivity were also evaluated.

Results: Data analysis indicated no statistically significant difference between presumptive and confirmed results for the GENE-UP method for these analytes. Inclusivity and exclusivity testing indicated the method was highly selective for the target analytes.

Conclusion: The GENE-UP PRO Cannabis STEC/Salmonella assay provides the cannabis industry a rapid method for the simultaneous detection of STEC and Salmonella in dried cannabis flower.

Highlights: The GENE-UP PRO Cannabis STEC/Salmonella assay becomes the first AOAC Performance Tested MethodSM validated multiplex assay for the simultaneous detection of Salmonella and STEC in dried cannabis flower.