DATA DIGEST

GENE-UP® & MicroTally™ Swabs: Verified Performance for EHEC Detection

An independent study was conducted by Fremonta Corporation to demonstrate the compatibility of the GENE-UP EHEC real-time PCR assay with the MicroTally Swab, a Manual Sampling Device.

FREMONTA

BACKGROUND

Increasing adoption of Manual and Continuous Sampling Devices (MSD / CSD), as N60 sampling alternatives require fit-for-purpose detection methods to ensure reliable results. FSIS guidance provides that for previously validated methods, such as GENE-UP EHEC, a matrix extension approach for verification is appropriate for laboratories analyzing the MicroTally swab. The FSIS extension protocol requires a side-by-side study with a minimum of 20 data points each at a fractional recovery (20-80%).

STUDY DESIGN SUMMARY

- N=30 MicroTally swabs were used to swab the surface of beef stew trim for 30-60 seconds and stored at 4°C overnight to cold stress naturally occurring organisms.
- Spike organism *E. coli* O26:H11 (CDC 03-3014) culture was also stored at 4°C overnight for cold stress.
- N=20 swabs were then inoculated with cold stressed *E. coli* O26:H11 at an enumerated low-inoculum level of 0.94 CFU / sample. N=5 swabs were inoculated at an enumerated high-inoculum level of 5.64 CFU / sample. Inoculated swabs were held at 4°C for an additional 2 hours.

- N=5 swabs remained un-inoculated.
- Individual samples were diluted and homogenized in 200mL of pre-warmed (42°C +/- 0.5) Buffered Peptone Water.
- The individual samples were incubated at 42°C +/- 1°C for 10 hours.

Following individual incubation, N=6 secondary samples were created by mixing equal volumes (5mL minimum) of N=4 un-inoculated samples with N=1 inoculated sample. Each individual sample and the respective secondary samples were analyzed by GENE-UP EHEC following bioMérieux specifications. All samples were confirmed by culture.

RESULT SUMMARY:

- *E. coli* O26:H11 was detected in 90% of the individual low-level inoculated samples at 10-hour incubation, meeting the fractional positive target recommended by FSIS.
- 100% detection was obtained for high-level inoculated sample.
- For the secondary samples, all results matched the individual screened results as expected.
- Culture confirmation results matched the screened result.
- 24-hour results matched the initial incubated results.

Inoculation Time	GENE-UP Positive Individual Screened Results*		GENE-UP Positive Secondary Sample Results*	GENE-UP Positive Un-inoculated Results*
	Low	High		
10 hr	18/20	5/5	6/6	0/5

*Cultural confirmation results showed 100% agreement with screened results

CONCLUSION:

The test concluded that GENE-UP EHEC can be successfully used for the detection of *E. coli* O26:H11 from MicroTally swabs at 10-hour incubation protocols.

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