Development and Validation of the VetMAX™-Gold MAP Detection Kit

Angela Burrell, Ivan Leyva-Baca, Rohan Shah and Daniel Kephart, Thermo Fisher Scientific, 2130 Woodward Street, Austin, Texas, 78744

ABSTRACT

Mycobacterium avium subsp. paratuberculosis (MAP) is the causative agent for Johne’s disease in cattle and causes severe economic losses in the cattle industry due to reduced productivity, reproductive losses, and the eventual death or culling of the infected animal. The VetMAX™ Gold MAP Detection Kit is a real-time qPCR assay for the rapid in vitro detection of MAP DNA from fecal samples using a unique sequence element in the MAP genome to provide highly sensitive and specific results.

The validation of the assay was performed at the Wisconsin Veterinary Diagnostic Laboratory, University of Wisconsin Veterinary Diagnostic Laboratory, and the University of Wisconsin Veterinary Diagnostic Laboratory. The assay demonstrated a 96.2% predictive value of a positive test and 96.4% predictive value of a negative test for individual bovine fecal samples. Samples that were confirmed correct (testing of individual samples) produced a 100% concordance of diagnostic results. The assay also demonstrated a 96.2% predictive value of a positive test and 96.4% predictive value of a negative test for individual bovine fecal samples. Samples that were confirmed correct (testing of individual samples) produced a 100% concordance of diagnostic results.

RESULTS

Table 1. Individual Sample S&S Results

Table 2. Pooled Sample Culture Characterization

Table 3. Individual Sample S&S Results

Table 4. Pooled Sample S&S Results

Table 5. Final S&S Results

CONCLUSIONS

We would like to thank the following laboratories for participating in the USDA field study for the VetMAX™-Gold MAP Detection Kit: Cornell University Animal Health Diagnostic Laboratory, University of Minnesota Veterinary Diagnostic Laboratory, and the University of Wisconsin Veterinary Diagnostic Laboratory.

ACKNOWLEDGEMENTS

The results of this study were under review by MYHSF Center for Veterinary Biologics in support of a Biological Product License application.

Thermo Fisher Scientific • 5781 Van Allen Way • Carlsbad, CA 92008 • thermofisher.com

Thermo Fisher Scientific • 5781 Van Allen Way • Carlsbad, CA 92008 • thermofisher.com