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TSE/BSE Statement for TaqPath™ 1-Step Multiplex Master Mix Cat. No. A28525 / A28526 / A28527

The catalog numbers referred above are dual sourced from both Frederick, MD, USA and Vilnius, Lithuania. These two sites refer to CPMP/CVMP Guideline EMA/410/01, 'Note for Guidance on Minimizing the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products' for minimizing risk of animal material contamination.

- The raw bovine material is sourced from healthy animals and from TSE/BSE risk negligible countries. Suppliers provide certificates of suitability (CEP) as applicable.
- The product also contains other bovine material that comes from TSE/BSE risk negligible countries.
- Environmental controls, cleaning, and monitoring procedures for equipment and facilities are in place to mitigate cross contamination risk.

Jurgita Žilinskienė Manager of Quality Control Group Thermo Fisher Scientific

29 January 2024