

Rev.1 April 2022



**Biotage**

[www.biotage.com](http://www.biotage.com)

Uppsala April 26, 2022

**Transmissible Spongiform Encephalopathy (TSE), Bovine Spongiform Encephalopathy (BSE)**

The Biotage® PhyPrep kit<sup>1</sup> contains articles as listed below. The buffers and column resin are made from inorganic salts and chemically synthesized materials. There are no animal or animal-derived products used in the production. Materials in plastic bottles, column and tubes are either free of animal products or are treated through an approved process<sup>2</sup> to assure that the final material is BSE/TSE free.

RNase is made from bovine pancreas which is a tissue with lower infectivity risk<sup>2</sup>.

- Växel Column
- Resuspension Buffer
- Lysis Buffer
- Precipitation Buffer
- Wash Buffer
- Elution Buffer
- Endotoxin Removal Buffer
- Equilibration Buffer
- Sample Filter Reservoir
- RNase A Tube
- PhyPrep Tube
- 20 mL Transfer Tip

Based on traceability of raw materials and supplier certifications, Biotage can confirm that, to the best of our knowledge, the PhyPrep kit components (except for RNase) do not contain materials of animal or biological origin. We therefore have every reason to expect that the kit components do not contain Transmissible Spongiform Encephalopathy (TSE) and Bovine Spongiform Encephalopathy (BSE), however, this has not been confirmed by analysis or testing.

Sincerely yours,

A handwritten signature in blue ink, appearing to read "Lisa Egelrud", is written over a white background.

**Lisa Egelrud**  
EVP Quality Assurance and Regulatory Affairs

1. DPM-16-05-72-KIT Biotage Plasmid MaxiPrep kit Endotoxin Free, DPM-16-10-72-KIT Biotage Plasmid MegaPrep kit Endotoxin Free, DPM-08-20-72-KIT Biotage Plasmid GigaPrep kit Endotoxin Free)  
2. Note for guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products (EMA/410/01 rev.3)