

Certificate of Analysis

PrepFiler Express BTA™ Forensic DNA Extraction Kit

Product No. **4441351**
Lot No. **1709162**
Date of Manufacture **19SEP2017**
Expiration Date **18JAN2019**

DESCRIPTION

The PrepFiler Express BTA™ Forensic DNA Extraction Kit contains reagents and plastics for use in lysis of cells, removal of PCR inhibitors and elution of bound DNA.

KIT CONFIGURATION

Part No.	Component Description	Lot No.
4441349	PrepFiler Express™ Cartridges (box)	1709127
4441396	PrepFiler BTA™ Lysis Buffer (pouch)	1708090
	4441404 BTL, PrepFiler BTA Lysis Buffer 14mL	1706037
4441401	Proteinase K (pouch)	1708092
	4441400 Tube Proteinase K	1707084
4468236	PrepFiler Express BTA™ Plastics (box)	1707018
4443022	AutoMate Express™ Tips and Tip Holders (bag)	J61611004

KIT SPECIFICATIONS

Positive sample extraction test:

Diluted human DNA (corresponding to 100ng DNA per sample) is processed using the AutoMate Express™ automated extraction system and the recovered DNA quantified by RT-PCR.

RESULT

PASS

*A passing result is achieved based on a detectable quantity of DNA as determined by RT-PCR.

No detectable human DNA contamination:

PrepFiler BTA™ Lysis Buffer and Proteinase K without the addition of any sample or sample DNA is processed using the AutoMate Express™ automated extraction system and the recovered material is tested for the presence of human DNA contamination using a sensitive STR profiling assay.

PASS

*A passing result is achieved if Globalfiler® STR profiling @ 31 cycles meets the specifications as detailed in ISO18385 Section A.4.3 using an instrument-specific analytical threshold of 1 x LOQ (mean signal + 10SD) within the read region.

For Research, Forensic or Paternity Use Only. Not for use in diagnostic procedures.

Manufactured in compliance with our ISO 9001 and ISO 13485 certified quality management system. Site: Warrington, UK

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KIT SPECIFICATIONS

RESULT

PrepFiler Express™ Cartridge Analytical specifications:

PASS

- Lysis Buffer: pH 7.25 – 7.45 Conductivity 19.80 – 24.20 mS/cm
- Wash Buffer A: Density 0.85 – 0.87 g/mL
- Wash Buffer B: Density 0.89 – 0.91 g/mL
- Elution Buffer: pH 7.96 – 8.04, Conductivity 400.0 – 650.0 mS/cm, DNase/RNase free

Additional checks:

PASS

- Cartridges undergo visual inspection to ensure the following:
 - No evidence of leakage or penetrating damage to foil surface
 - Foil alignment and placement is checked for consistency relative to label and top well
 - Cartridge label is checked to ensure it is visually straight with consistent placement
 - Sampling of cartridges is subjected to fill volume and vacuum leak testing checks during manufacture
- Kit and kit components undergo further visual inspection at both intermediate and final stages of kit manufacture

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