

Certificate of Analysis



PrepFiler Express™ Forensic DNA Extraction Kit

Product No. **4441352**
Lot No. **1404087**
Date of Manufacture **02Jun2014**
Expiration Date **04Jan2015**

DESCRIPTION

The PrepFiler Express™ 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)	1402050
4441394	PrepFiler™ Lysis Buffer (pouch)	1401028
4441405	BTL, PREPFILER LYSIS BUFFER 29ML	1401024
4468235	PrepFiler Express™ Plastics (box)	1401017
4443022	AutoMate Express™ Tips and Tip Holders (bag)	J1402001

KIT SPECIFICATIONS

RESULT

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.

Pass

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

No detectable human DNA contamination:

PrepFiler™ Lysis Buffer 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 Identifiler® Plus STR profiling @ 29 cycles does not detect reproducible, typeable peaks above background levels over 50 rfu within the read region for each extraction (9/9 extractions need to meet this criteria).

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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Quality Assurance
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KIT SPECIFICATIONS	RESULT
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PrepFiler Express™ Cartridge reagent test specifications:	Pass
• Lysis Buffer: pH 7.25 – 7.45 Conductivity 19.80 – 24.20 mS/cm	
• Magnetic Particles: RNase, Endonuclease, Exonuclease activity not detected	
• 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:	
• Cartridges undergo visual inspection to ensure the following:	
o No evidence of leakage or penetrating damage to foil surface	Pass
o Foil alignment and placement is checked for consistency relative to label and top well	
o Cartridge label is checked to ensure it is visually straight with consistent placement	
o 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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