

Certificate of Analysis

ThermoFisher
SCIENTIFIC

PrepFiler™ BTA Forensic DNA Extraction Kit

Product No. **4463352**
Lot No. **2205078**
Date of Manufacture **20MAY2022**
Expiration Date **01SEP2023**

DESCRIPTION:

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

KIT CONFIGURATION:

<u>Part No.</u>	<u>Component Description</u>	<u>Lot No.</u>
4463357	PrepFiler™ Lysis Buffer	2205066
4463559	PrepFiler™ BTA Lysis Buffer	2205062
4464236	PrepFiler™ Magnetic Particles & Proteinase K	2205071
	4463556 Tube, Proteinase K 0.9 mL	2204059
	4463553 Tube, PrepFiler™ Magnetic Particles	2109093
4463598	PrepFiler™ Wash Buffer A Concentrate	2205100
4463548	PrepFiler™ Wash Buffer B Concentrate	2205106
4392349	PrepFiler™ Elution Buffer	2205107

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

Manufactured in compliance with our ISO 18385 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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(A) No detectable human DNA contamination:

Four reaction samples of PrepFiler™ Lysis Buffer, PrepFiler™ BTA Lysis Buffer, and Proteinase K from the kit under test without the addition of any sample DNA are processed using the AutoMate Express™ DNA extraction system using the extraction kit under test and the standard PrepFiler™ Express BTA instrument protocol. The recovered material is tested for the presence of human DNA by quantifying six replicates of each sample using the Quantifiler™ Trio DNA Quantification kit small autosomal, large autosomal, and male targets to the method described in the Quantifiler™ Trio User Guide.

PASS

The kit under test is deemed free from human DNA contamination if greater than or equal to 22 of the 24 replicates produce an 'Undetermined' result. In addition, no more than one replicate per sample can have a Ct value other than 'Undetermined'.

(B) Positive Sample Extraction Efficiency:

Six samples of diluted human genomic DNA (corresponding to 5ng DNA per sample) are processed using the kit under test with the AutoMate Express™ DNA extraction system using the standard PrepFiler™ Express BTA instrument protocol. Six replicates of the recovered DNA and a sample of the same diluted DNA that has not been through the extraction workflow are quantified by RT-PCR using the Quantifiler™ Trio DNA Quantification kit using the method described in the User Guide.

PASS

Extraction Efficiency is calculated by comparing the average quantification results from the pre- and post- extracted material and expressing this as a percentage.

Extraction Efficiency Specification Limits: 44-100% (inclusive)

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