

Certificate of Analysis

GlobalFiler™ Express PCR Amplification Kit (200 Reactions)

Product No. **4476609**
Lot No. **2411108**
Date of Manufacture **22NOV2024**
Expiration Date **18MAY2026**

KIT CONFIGURATION

PART NO.	COMPONENT DESCRIPTION	LOT NO.	EXPIRATION DATE
4474566	GlobalFiler™ Express PCR Reagents (Box)	2411101	18MAY2026
4474661	GlobalFiler™ Express Master Mix (Tube)	2410057	N/A
4474662	GlobalFiler™ Express Primer Set (Tube)	2407056	N/A
4478871	Control DNA 007 (2ng/μL) (Tube)	2404049	N/A
4486637	Master Mix additive (Tube)	2410030	N/A
4476139	GlobalFiler™ Express Allelic Ladder (Box)	2409042	05NOV2027
4476139	GlobalFiler™ Express Allelic Ladder (Tube)	2409042	N/A

TEST	SPECIFICATION	RESULT
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Functional QC


QC Method: Samples are amplified using two kits from the current lot manufactured. Results from the current lot are compared to previously approved lots. All analyses are performed using standard operating conditions according to the recommendations in the GlobalFiler™ Express Kit User's Guide.

Human DNA Contamination	8/10 non-template controls (NTC) amplified for 30 cycles produce no typeable peak between 60-460 bp above an instrument-specific analytical threshold of 1 x LOQ (mean signal + 10 SD).	PASS
Genotype	Four nanograms of Control DNA 007 produces the correct genotype for all 24 loci, including 21 autosomal STR markers, DYS391, Y-indel and the Amelogenin gender marker.	PASS

For Forensic or Paternity Use Only.

All components listed above are manufactured in compliance with ISO 18385 and ISO 13485 certified quality management system, excluding ISO 18385 for the Allelic Ladder (Site: Warrington, UK). The Allelic Ladder contains common alleles observed in the population, therefore this product is not amenable to ISO 18385 (minimizing the risk of human DNA contamination) testing. Product quality is not impacted.

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Quality Assurance
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