

Certificate of Analysis



GlobalFiler™ PCR Amplification Kit (1000 Reactions)

Product No. **4482815**
Lot No. **2205060**
Date of Manufacture **27MAY2022**
Expiration Date **27NOV2023**

KIT CONFIGURATION

PART NO.	COMPONENT DESCRIPTION	LOT NO.	EXPIRATION DATE
4482814	GlobalFiler™ PCR Reagents (Box)	2205059	27NOV2023
4482873	GlobalFiler™ Master Mix (Bottle)	2112039	N/A
4482874	GlobalFiler™ Primer Set (Bottle)	2205041	N/A
4487873	Control DNA 007 (0.1ng/μL) (Tube)	2204036	N/A
4482813	GlobalFiler™ Allelic Ladder (Box)	2108028	05MAY2025
4482813	GlobalFiler™ Allelic Ladder (Tube)	2108028	N/A

Functional QC

QC Method: Samples are amplified using a kit 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™ Kit User's Guide.


TEST	SPECIFICATION	RESULT
Human DNA Contamination	10/12 non-template controls (NTC) amplified for 31 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	One nanogram of Control DNA 007 amplified for 29 cycles 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.

Life Technologies
5781 Van Allen Way
Carlsbad, CA, USA 92008
www.thermofisher.com
For enquiries, contact us at
cofarequests@thermofisher.com


Quality Assurance
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