

AmpFℓSTR® Identifiler® Plus PCR Amplification Kit

- Amplifies the same loci as the Identifiler® Kit with enhanced performance, data quality, and efficiency for casework samples
- Helps significantly improve performance on severely inhibited casework samples through the use of a high-performance PCR buffer system and optimized thermal cycling parameters
- Yields higher peak heights from low-level samples and minor contributors in mixtures to facilitate interpretation
- Enables additional analytical flexibility by utilizing fully validated 28- and 29-cycle protocols
- Provides streamlined workflow with reduced amplification time
- Maintains the small amplicon size range of the Identifiler® Kit (<360 bp) for recovery of information from degraded samples; works in conjunction with the MiniFiler™ Kit to help maximize recovery from heavily degraded samples
- Maintains primer sequences to enable genotype concordance with samples typed with the Identifiler®, Identifiler® Direct, Profiler Plus®, COfiler®, and SGM Plus® Kits
- Utilizes an improved primer manufacturing process that results in the reduction of artifacts



Introduction

Forensic DNA casework laboratories have always encountered a percentage of challenging samples that are difficult to analyze successfully. However, sample submissions for DNA analysis have expanded in recent years to cover a much wider range of case types, including property crimes and lesser felonies. As a result, forensic laboratories now have to process more samples that suffer from one or more of a variety of complicating factors (e.g., low-level DNA, degradation, new or unfamiliar PCR inhibitors, two or more contributors). All of these challenging conditions can impact significantly the ability of the analyst to obtain a DNA profile that can be interpreted with confidence. Many laboratories have sought to modify

their workflows in an effort to obtain better results from difficult samples. These modified approaches include dilution or filtration of samples, addition of more enzyme to the reaction, or optimization of capillary electrophoresis conditions. The advent of sophisticated magnetic particle-based extraction methods, such as the PrepFiler™ Forensic DNA Extraction Kit, have also helped to improve the quantity and quality of DNA isolated from forensic samples, thereby increasing the quality of downstream results. Significant strides have been made, but additional capabilities are clearly needed by laboratories as they accept the growing number of complex DNA casework samples being collected by law enforcement.

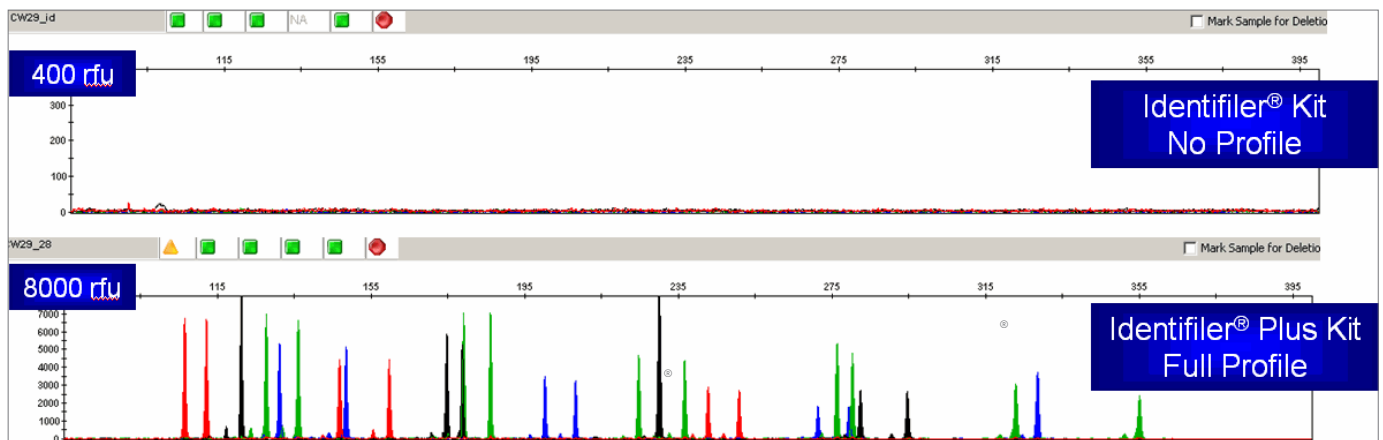


Figure 1. A comparison of the performance of the Identifiler® Plus Kit and the Identifiler® Kit on an inhibited casework sample. The Identifiler® Kit is unable to amplify a blood sample from a leather glove. The Identifiler® Plus Kit helps deliver a full profile as a result of its enhanced formulation. One nanogram of input DNA and 28 cycles of amplification were used for both kits.

The AmpF ℓ STR® Identifiler® Plus PCR Amplification Kit has been developed specifically to address the needs of forensic casework laboratories. The Identifiler® Plus Kit utilizes the same primers as the widely used Identifiler® Kit and harnesses next-generation PCR amplification technology to enable a new level of performance, data quality, and efficiency. This helps forensic analysts recover more interpretable results from challenging casework samples with increased confidence.

Improved Performance on Inhibited Samples

Improving upon innovations in buffer formulation made during the development of earlier AmpF ℓ STR® Kits such as the MiniFiler™ Kit, the Identifiler® Plus Kit has been designed to overcome high levels of PCR inhibition and promote more robust and efficient amplification. The new formulation delivers results from samples which could not be analyzed using the current Identifiler® Kit (Figure 1).

Greater Sensitivity

The buffer and master mix enhancements in the Identifiler® Plus Kit promote more robust amplification— even in samples that do not contain PCR inhibitors. Purified samples amplified with the Identifiler® Plus Kit yield peak heights 40–100% higher than the current Identifiler® Kit, without any increase in the number of

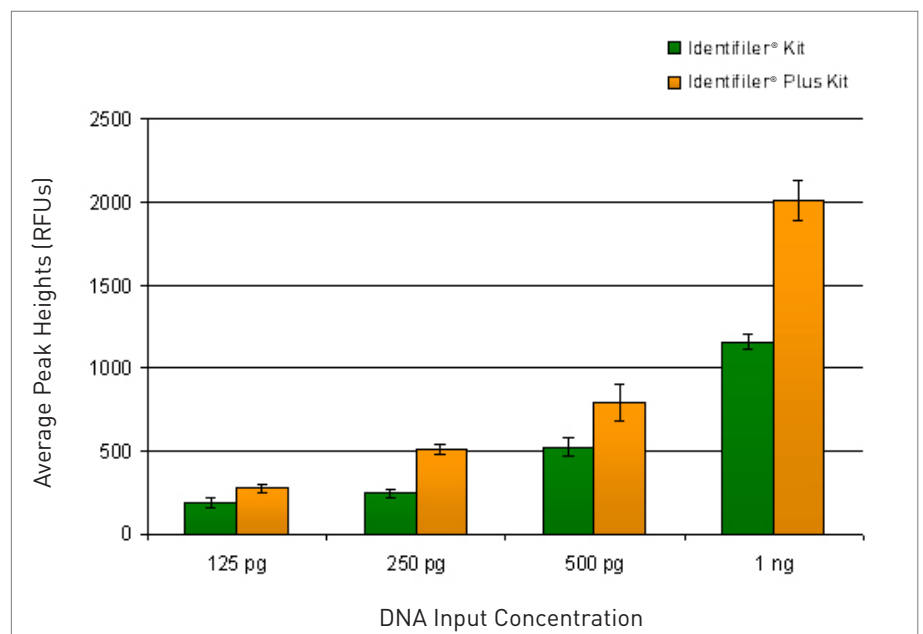


Figure 2. Illustration of the improved sensitivity of the Identifiler® Plus Kit. This figure shows the average peak heights obtained for 4 different dilutions of a control DNA sample amplified for 28 cycles using the Identifiler® Kit (green bars) and Identifiler® Plus Kit (orange bars). On average, the Identifiler® Plus Kit peak heights were approximately 1.7 times higher than Identifiler® Kit peak heights.

PCR cycles or injection times (Figure 2). In addition, the validation of two different cycle number protocols (28 and 29) enables the laboratory to adapt the amplification to standard input samples and those containing low levels of DNA.

Improved Performance on Mixtures

The performance enhancements made to the Identifiler® Plus Kit greatly facilitate the analysis of casework mixtures, which often contain PCR inhibitors, and where the minor component may be present at

a very low level. The enhanced sensitivity, greater capability to overcome inhibition, and improved heterozygote and intracolor balance afforded by the Identifiler® Plus Kit allow the analyst to analyze and interpret mixtures more easily and reliably than was previously possible (Figure 3).

Cleaner Baseline

Applied Biosystems has implemented significant improvements to its primer manufacturing process, and has incorporated these improvements into

the Identifiler® Plus Kit. These improvements yield purer primers that generate fewer dye artifacts and thus help deliver cleaner baselines. This feature enables the analyst to interpret results, including results obtained from difficult mixtures, with maximum confidence and efficiency.

Other Improvements and Benefits

The improvements in the kit formulation also allow for more rapid amplification—eliminating approximately one hour from the amplification step, when compared to the current Identifiler® Kit. In addition, the Identifiler® Plus Master Mix includes the AmpliTaq Gold® DNA Polymerase, which eliminates 2 tubes and an extra box from the kit packaging, and enables streamlined reaction setup.

None of the formulation enhancements included in the Identifiler® Plus Kit have required modifications to the Identifiler® Kit's allelic ladder or 5-dye configuration. This configuration allows for optimal locus spacing and amplicon size ranges no greater than 360 bp, enabling better data recovery from degraded samples as compared to other multiplex systems with significantly larger amplicon size ranges. For heavily degraded samples, the MiniFiler™ Kit has been designed to work in conjunction with the Identifiler® Plus Kit, utilizing miniSTR technology to help maximize recovery of information.

In addition, the Identifiler® Plus Kit maintains primer sequences to help ensure genotyping concordance for samples previously typed using the Identifiler®, Identifiler® Direct, Profiler Plus®, COfiler®, or SGM Plus® Kits, and facilitate comparison with existing DNA databases.

The Confidence to Do More

The Identifiler® Plus Kit is part of a new generation of AmpFℓSTR® Kits from Applied Biosystems that harnesses significant advances in PCR amplification technology to enable recovery of more results from more samples with increased confidence. Ultimately, laboratories using the

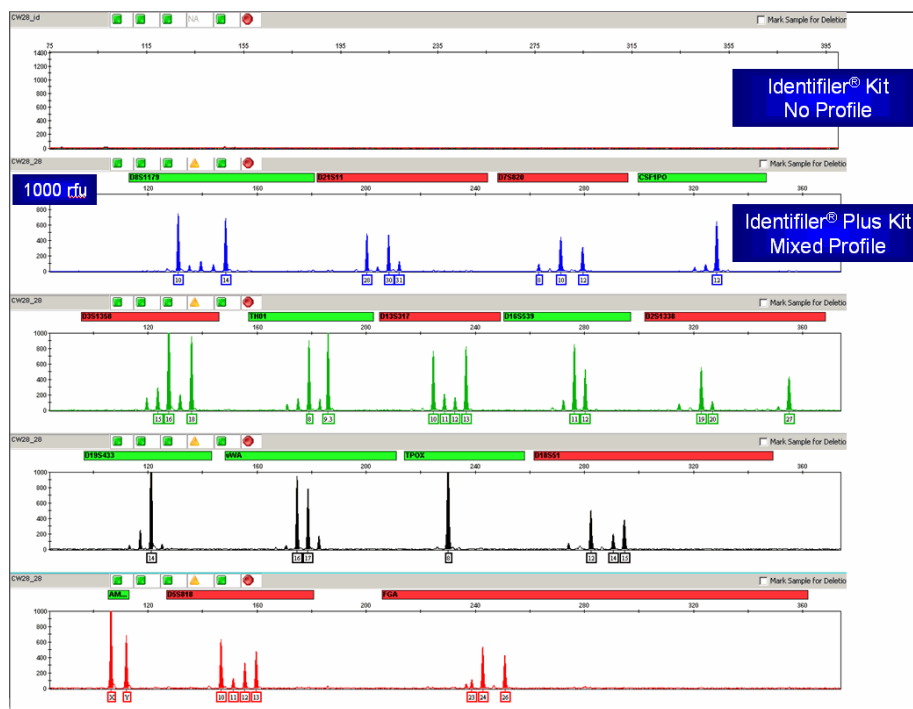


Figure 3. An example of a casework sample that yielded no profile when analyzed with the Identifiler® Kit but yielded a high-quality, interpretable mixture profile with the Identifiler® Plus Kit. One nanogram of input DNA and 28 cycles of amplification were used for both kits.

Identifiler® Plus Kit could significantly increase their ability to process difficult and challenging casework samples, and expand the types of cases from which probative results can be generated.

Complete Validated Solution

Applied Biosystems offers a complete solution to meet the needs of the human identification community. Our system includes DNA extraction and quantification kits, a range of AmpFℓSTR® STR Kits, instrumentation, software, and consumables.

The Identifiler® Plus Kit is part of the most comprehensively validated systems for STR-based human identification. The PCR reaction components, primer sequences, and amplification protocols have been developed, optimized, and validated together with Applied Biosystems instrumentation and software to provide specific, robust amplification. Validation experiments for the Identifiler® Plus Kit were performed by Applied Biosystems scientists according to the DNA Advisory

Board and the Scientific Working Group on DNA Analysis Methods (SWGDM) Revised Validation Guidelines for use in human identification testing. However, each laboratory using the Identifiler® Plus Kit should perform its own internal validation studies to ensure that the products and services it obtains from Applied Biosystems satisfy or will satisfy the applicable guidelines used by the forensic community and are fit for the laboratory's human identification applications.

The Identifiler® Plus Kit is subjected to rigorous quality control testing to help ensure consistent performance. Applied Biosystems develops and manufactures its products in accordance with ISO 9001 quality system requirements. Additionally, a Certificate of Analysis is available upon request that confirms that the specific combination of components within each lot meets quality assurance testing specifications.

Experience Matters™

Applied Biosystems is the only company in the world that designs and validates its reagents, instruments, and data analysis software together as an integrated system for DNA testing. Technical Service Scientists and Field Application

Specialists are available to answer your technical questions, review data, and make recommendations on how to perform assays and troubleshoot results. Our team of forensic experts is also available to provide in-depth training and can support the planning and efficient execution of

internal validation projects in your laboratory. All of these resources help streamline implementation and help ensure success when using Applied Biosystems human identification solutions in your laboratory.

MATERIALS PROVIDED WITH THE AmpFℓSTR® IDENTIFILER® PLUS PCR AMPLIFICATION KIT

AmpFℓSTR® Identifiler® Plus Master Mix (contains enzyme)
AmpFℓSTR® Identifiler® Plus Primer Set
AmpFℓSTR® Identifiler® Plus Control DNA 9947A (0.1 ng/μL) of a known genotype
AmpFℓSTR® Identifiler® Plus Allelic Ladder

ORDERING INFORMATION

Description	Quantity	P/N
AmpFℓSTR® Identifiler® Plus PCR Amplification Kit	200 tests, 25 μL/test	4427368
AmpFℓSTR® Identifiler® Plus PCR Amplification Kit User Guide	1 manual	4440211
GeneScan™ 500 LIZ® Size Standard	800 reactions	4322682
Matrix Standard Set DS-33 (6-FAM™, VIC®, NED™, PET®, LIZ® dyes) for use with 3100, 3100-Avant, 3130, and 3130xl systems	1 tube with 5 dyes	4345833
Validation Support and Training for AmpFℓSTR® Kit Implementation	Contact Sales Representative	

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