

Manufacturing Changes to the PowerPlex® 16 System: Frequently Asked Questions

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INTRODUCTION

The Promega Genetic Identity Team is committed to continuously improving the quality of our products. To this end, we are pleased to announce that we have implemented changes to the manufacturing process for the PowerPlex® 16^(a,b,c,d), Y^(a,b) and ES^(a,b,e) Systems. These changes offer you these benefits: Improved spectral calibration performance, improved consistency from lot to lot and enhanced compatibility with future software and instrumentation changes.

Previously, the fluorescent molecules used to synthesize the dye-labeled primers for these PowerPlex® Systems were a mixture of isomers. We modified our primer synthesis protocols to use a single dye isomer for each dye label (Table 1). This process change resulted in greater control over the final isomer ratio of the dye-labeled primers and improved lot-to-lot spectral consistency.

We also instituted a process improvement for the JOE-labeled primers in the PowerPlex® 16 System to use the same linker as that used in the PowerPlex® Y and ES Systems. This change reduces the number of matrix standards required to use the PowerPlex® Systems and increases convenience for the end user.

Note: No changes were made to the primer sequences.

Table 1. Improved Dye Isomer and Linker Configurations.

System	Fluorescein (FL)	6-Carboxy-4',5'-dichloro-2',7'-dimethoxy-fluorescein (JOE)	Carboxy-tetramethylrhodamine (TMR)
PowerPlex® 16 System			
Old formulation	Mixed dye isomers	B linker	Mixed dye isomers
New formulation	Pure dye isomer	A linker	Pure dye isomer
PowerPlex® Y System			
Old formulation	Mixed dye isomers	A linker	Mixed dye isomers
New formulation	Pure dye isomer	A linker	Pure dye isomer
PowerPlex® ES System			
Old formulation	Mixed dye isomers	A linker	Mixed dye isomers
New formulation	Pure dye isomer	A linker	Pure dye isomer

When will the new kits be available?

The improved PowerPlex® 16 System was available on August 4, 2006. A notification letter, accompanied by an Application Notes (Part# AN126) with internal validation data, was mailed to laboratories that have previously ordered the PowerPlex® 16 System.

The new PowerPlex® Y and ES Systems will be available in late 2006.

How will I know if I have a new PowerPlex® 16 System?

Kits with the newly formulated components have an “Improved Product” sticker on the packaging, and a note is included in the kit box. There is also a note on the cover of the Technical Manual shipped with the new system.

PowerPlex® 16 Systems that include the new formulation of PowerPlex® 16 10X Primer Pair Mix and PowerPlex® 16 Allelic Ladder Mix are designated by system lot numbers ending with the letter “N”. Also, the cap colors for the PowerPlex® 16 10X Primer Pair and PowerPlex® 16 Allelic Ladder Mix are different in kits with the new formulation than those with the old formulation (Table 2).

Will I be able to use my current spectral calibration or matrix file with the new formulation?

No, a new spectral calibration or matrix file is required. New matrix standards are available for use with the new PowerPlex® 16 Systems; we will send them to you free of charge. If you are not prompted by the Customer Service Representative when placing your next order for the PowerPlex® Systems, be sure to request the new matrix standards.

The PowerPlex® Matrix Standards, 3100/3130 (Cat.# DG4650), should be used for the ABI PRISM® 3100 and 3100-Avant Genetic Analyzers and Applied Biosystems 3130 and 3130xl Genetic Analyzers. The PowerPlex® Matrix Standards, 310 (Cat.# DG4640), should be used for the ABI PRISM® 310 Genetic Analyzer and ABI PRISM® 377 DNA Sequencer.

Will I be able to use the new spectral calibration or matrix file with the old PowerPlex® 16 System?

No, the spectral calibration and matrix files are not interchangeable.

Do I need to install a new PowerTyper™ Macro or new GeneMapper® ID panel and bins sets?

No. The current versions of the PowerTyper™ Macro and GeneMapper® ID panel and bins sets can be used to analyze data generated using the new kit.

Table 2. Cap Colors of the Affected Components in the New and Old Formulations of the PowerPlex® Systems.

System	10X Primer Pair Mix	Allelic Ladder Mix
PowerPlex® 16 System		
Old formulation	Dark blue	Dark blue
New formulation	Light yellow	Dark yellow
PowerPlex® Y System		
Old formulation	Dark green	Dark yellow
New formulation	Light orange	Dark orange
PowerPlex® ES System		
Old formulation	Dark green	Dark yellow
New formulation	Light green	Dark green

Can components of the old and new kits be used interchangeably?

No. Using the PowerPlex® 16 Allelic Ladder Mix from one kit to analyze amplification products generated with the PowerPlex® 16 10X Primer Mix from the other kit will result in "off-ladder" calls for some alleles. This is due to slight changes in allele migration resulting from the linker and isomer modification.

Has the Technical Manual for the PowerPlex® Systems changed?

The instructions for amplification setup and thermal cycling have not changed. The format of the Technical Manual has been updated, and instructions for use with the ABI PRISM® 3100-Avant Genetic Analyzer and Applied Biosystems 3130 and 3130xl Genetic Analyzers, as well as GeneMapper® ID software, have been added.

What experiments have been performed at Promega to show that the old and new systems are comparable?

Promega has done extensive work to demonstrate the consistency and efficacy of the old and new PowerPlex® Systems. The Application Notes *PowerPlex® 16 System Validation* (Part# AN126) summarizes the results of validation experiments performed to evaluate genotyping accuracy, precision, reproducibility and stability.

Has the new PowerPlex® 16 System been reviewed by National DNA Index System in the U.S.?

Yes. Internal validation data and external validation data were sent to the National DNA Index System (NDIS) custodian for evaluation. The new formulation has been approved for NDIS use.