



## IMPORTANT PRODUCT CHANGE NOTIFICATION

**Notification Date:** June 21, 2018

**Reference Notification Number:** 41-5107-CN

**Topic 1:** Change in preservative for Sample Diluent and Kinetics Buffer 10X

**Products affected:**

Part Number	Product Description	Includes	New Part Number
18-1048	Reagent / Sample Diluent	Preservative changed to Kathon	18-1104
18-1092	Reagent / Kinetics Buffer 10X		18-1105
18-1031	Reagent / IgG Calibrators Extended Range		
18-5081, 18-5123	Assay Kit / Host Cell Protein (HCP)	Sample Diluent	No change in Part Number
18-5095	Reagent / Amine Coupling Second Generation Reagent Kit	Kinetics Buffer 10X	
18-5128	Ready BLI Detection Kit – Residual Protein A	Sample Diluent and Detection Diluent	
45-5003	BLItz™ Starter Kit	Sample Diluent	

### Overview:

Pall ForteBio will be switching to Kathon as the preservative in Sample Diluent, Kinetics Buffer 10X and IgG Calibrators. As stated in the above table – HCP assay kits, Amine Coupling reagent kit, Residual Protein A kit and BLItz™ Starter Kit all include either Sample Diluent or Kinetics Buffer 10X.

### Timeline for Changes:

**Kits:** The change will be gradually implemented over the period of Q3 (July-September) 2018. Please continue using the same part numbers.

**Sample Diluent and Kinetics Buffer 10X:** New part numbers will be available starting July 15, 2018. All product shipped starting August 1, 2018 will contain Kathon. Old part numbers will no longer be available to purchase starting August 1, 2018. Please plan your transition accordingly.

### Rationale for Change:

Due to restrictions placed by the Environmental Protection Agency (EPA) on our vendors, we are no longer able to procure the current preservatives. This change is part of our continued efforts to comply with government environmental regulations and to ensure continuous supply of raw materials used in our products.

### Impact on Customer Operations:

Extensive performance qualification, testing and validation have been performed to confirm intended use of the above products manufactured with Kathon. Data from our internal testing indicate little to no impact on product quality or performance using our model binding systems. These products still meet all current ForteBio specifications and acceptance criteria.

### Additional Information:

Please contact Pall ForteBio Technical Support with any questions or concerns about this change. Our technical support scientists can be reached at <https://www.fortebio.com/support>.



## IMPORTANT PRODUCT CHANGE NOTIFICATION

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**Topic 2:** Change in antibody used for Residual Protein A kit (18-5128)

**Products affected:**

Part Number	Product Description	Change
18-5128	Ready BLI Detection Kit – Residual Protein A	Antibody procured from new vendor

### Overview:

Pall Fortebio will be switching our vendor for the antibody used in Ready BLI Detection Kit – Residual Protein A (Part number 18-5128).

### Timeline for Changes:

The effective date of this change will be August 1, 2018. There will be no change in part number so please continue using 18-5128.

### Rationale for Change:

The current antibody used in Ready BLI Detection Kit – Residual Protein A was unable to meet the 0.1 ng/mL specification at the low end of the dynamic range. To provide customers with a robust kit, we have optimized the kit with a different antibody source that is sensitive at the low end and provides better binding separation.

### Impact on Customer Operations:

Extensive performance qualification, testing and validation have been performed to confirm intended use of the kit. Data from our internal testing indicate little to no impact on product quality or performance using our model binding systems. The kit still meets all current ForteBio specifications and acceptance criteria.

### Additional Information:

Please contact Pall ForteBio Technical Support with any questions or concerns about this change. Our technical support scientists can be reached at <https://www.fortebio.com/support>.

We value your business and appreciate your continued use of Pall ForteBio products.

Sincerely,  
Viraj Palkhiwala  
Product Manager, Consumables