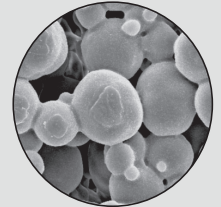
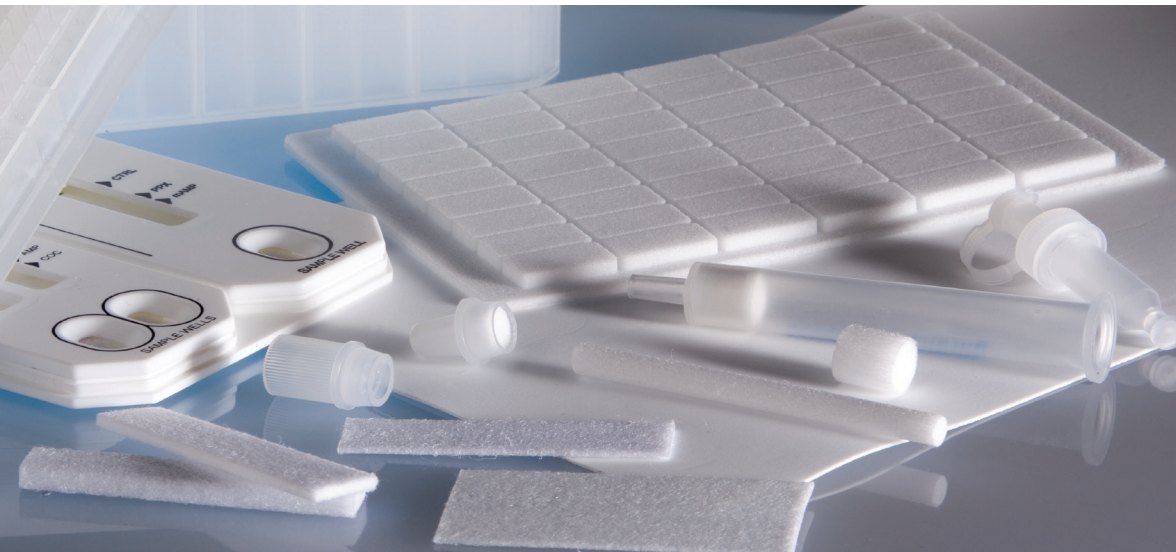
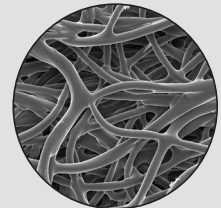


# Technical Performance and Diagnostic Media Certification Program



POREX® PE



POREX® Bonded Fiber

## Program Results:

CERTIFIED PURE POREX PLUS+ materials were found to be compatible for use with analytes ranging from albumin to uric acid. No patterns of interferences were found for up to 7 days or as noted on the accompanying chart on the following page. Based on our findings, this is the first extensive and important clinical diagnostic qualification program for porous polymeric materials that fills a critical gap in the progression of developing standardized methodologies for the analysis of materials used in laboratory and diagnostic consumables.

## Program Objective:

Independent qualification of porous polymeric materials via stringent clinical validation and compatibility testing.

## Program Design:

A broad spectrum of porous polymeric materials was tested in contact with pooled human serum and/or plasma for up to 7 days for validation and compatibility with 30 constituents. Samples were tested after: 8 hours, 24 hours, 3 days, 4 days, 5 days and 7 days of material contact.

## Clinical Instrument Platform:

Beckman Coulter AU5800

## POREX® Diagnostic Materials:

16 different POREX® diagnostic materials were tested.

## CERTIFIED PURE POREX PLUS+:

CERTIFIED PURE POREX PLUS+ is available as hydrophobic, hydrophilic, functionalized and bio-activated, and available in a wide assortment of geometries that can be engineered to meet various density, permeability and wicking performance requirements.

In addition to porous polyethylene, bi-component and non-woven fiber choices, POREX offers proprietary coatings that help minimize non-specific binding and improve clinical outcomes.

Due to the differences in applications and operating conditions, POREX recommends customers undertake their own appropriate tests to determine their performance of CERTIFIED PURE POREX+ materials and filters specific to the application and test condition.

*Data on file and available upon request.*

## Summary Result Table:

The below table showcases the summary results of the independent 7-day clinical compatability study of POREX® diagnostic materials.

|                     | POREX A | POREX B | POREX C | POREX D | POREX E | POREX F | POREX G | POREX H | POREX I | POREX J | POREX K | POREX L | POREX M | POREX N | POREX O | POREX P |
|---------------------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|---------|
| Albumin             | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       |
| Alkaline Phoshalase | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       |
| ALT                 | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓*      | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       |
| Amylase             | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       |
| AST                 | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       |
| Bilirubin (Total)*  | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       |
| BUN                 | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       |
| Calcium             | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       |
| Chlorine            | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       |
| C02                 | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓*      | ✓       | ✓       | ✓       | ✓*      | ✓       | ✓       | ✓       |
| Cholesterol         | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       |
| Creatinine          | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       |
| Creatinine Kinase   | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       |
| Cholesterol LDL     | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       |
| Glucose             | ✓       | ✓       | ✓       | ✓*      | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓*      |
| GGT                 | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       |
| HDL                 | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       |
| Iron                | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       |
| Iron - UIBC         | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       |
| LDL                 | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       |
| Lipase              | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓*      | ✓       | ✓       | ✓       |
| Magnesium           | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       |
| Phosphorous         | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       |
| Potassium           | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       |
| Sodium              | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       |
| Total Protein       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       |
| T3Up                | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       |
| T4                  | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       |
| Triglycerides       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓*      | ✓       | ✓       | ✓       |
| Uric Acid           | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       | ✓       |

- Bilirubin (Direct) compatibility was acceptable for up to (5) days with all POREX Materials.
- POREX material D tested for Glucose was beyond stability which resulted in a less reactive result.
- POREX material G tested for ALT was beyond stability which resulted in a less reactive result.
- POREX material I tested for C02 showed deterioration of 52% after 7 days of testing.
- POREX material M tested for C02, Lipase, Triglycerides was beyond stability which resulted in a less reactive.
- POREX material P tested for Glucose was beyond stability which resulted in a less reactive result.



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