Milli-Q®
Lab Water Solutions

Data Sheet

BioPak® C

Clinical ultrafiltration cartridge for improved assay reliability

A final, in-line purification step for immunoassay and clinical chemistry analyzers that efficiently removes bacterial by-products such as alkaline phosphatase (ALP).

Key Features & Benefits

- **Produces ALP-free water (< 1 µUnits/µL) with bacteria levels below 10 cfu/mL (typically < 1 cfu/mL)**
- **Creates stable assay baselines, resulting in better assay reliability**
- **Reduces the need for frequent analyzer calibration**
- **Eliminates the need for frequent analyzer decontamination that results in costly downtime**

The BioPak® C unit is a disposable ultrafiltration cartridge that provides a final, in-line purification step for immunoassay and clinical chemistry analyzers. The cartridge is designed to remove alkaline phosphatase (ALP) released by bacteria that may be present in analyzer feed water used to dilute reagents, make blanks, and rinse tubing and probes. The BioPak® C cartridge can be installed easily on most immunoassay and clinical chemistry analyzers on the market today, providing improved laboratory efficiency and performance with lower overall running costs.

The BioPak® C ultrafiltration cartridge is composed of polysulfone hollow fibers. This membrane optimizes the rejection of bacterial ALP and bacteria while maintaining a high flow rate.

MilliporeSigma

The importance of water in clinical chemistry

In the clinical laboratory, water is a key factor. Its role as a major reagent in all clinical chemistry and immunoassay testing means that water-related analytical factors need to be monitored in order to optimize analyzer performance and provide the best test results. Unstable calibrations, high absorbance of blanks, reference drifts, and errors on mean patient values can stem from poor water quality, which then contributes to erroneous test results.

The Clinical Laboratory Standards Institute® (CLSI®) recognizes the importance of water quality and the impact it has on patient results. Its guideline exists to ensure the use of a minimum standard of water purity so that clinical chemistry assays can be run safely.*

*CLSI. *Preparation and Testing of Reagent Water in the Clinical Laboratory; Approved Guideline-Fourth Edition*. CLSI document GP40-A4-AMD. Wayne, PA: Clinical Laboratory Standards Institute; 2012.

ALP-free water increases assay reliability

ALP is commonly used as a detection enzyme in numerous biomedical methods, including enzyme immunoassays and ALP-labeled nucleic acid probes, where calf intestine phosphatase (CIP) is frequently employed.

Most clinical analyzer water systems include a 0.22 µm filter as part of the final filtration process before water enters the analyzer. This filter removes bacteria and particles that exceed 0.22 µm. However, dying and decaying bacteria upstream from the filter release bacterial ALP, which is then washed downstream. This bacterial ALP can interfere with the CIP often used in enzyme immunoassays.

Medical technologists, clinical analyzer manufacturers and diagnostic manufacturers are all concerned with their water quality and the effect of contaminated water on their sensitive assays. We therefore investigated if ALP might be the cause of some of their assay issues, such as high blanks and drifting calibrations.

Ultrafiltration with BioPak® C cartridge removes bacterial by-products, such as ALP, to provide optimum-quality water.

Ultrafiltration is recognized as an efficient method for removing bacterial by-products, such as bacterial ALP and endotoxins, from pure water. The BioPak® C ultrafiltration cartridge was specifically developed as a final, in-line purification step for the clinical market. Experiments by our R&D department compared the effectiveness of the BioPak® C ultrafiltration cartridge and a 0.22 µm filter and showed that ultrafiltration results in "ALP-free" water (**Figure 1**).[1] When fed with high-quality pure water from a Milli-Q® CLX 7000 or AFS® water purification system, the BioPak® C cartridge efficiently removes ALP to provide optimum-quality water for use in ALP-sensitive assays in order to provide more reliable assay results.

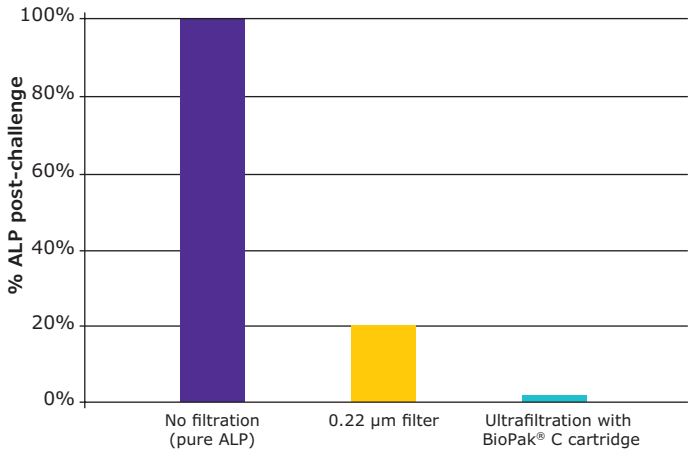

Figure 1. Comparison of ALP removal via ultrafiltration or a 0.22 µm filter.

Pure water was challenged with ALP, then filtered on an ultrafiltration unit or a 0.22 µm syringe filter. ALP concentration was measured at the outlet of each.

BioPak® C ultrafiltration cartridge delivers ALP- and bacteria-free water

Experiments performed in our R&D laboratories have demonstrated that, when fed with CLSI® Clinical Laboratory Reagent Water† (resistivity > 10 MΩ.cm @ 25°C; TOC level < 500 ppb) and after a 5L rinsing step, the BioPak® C ultrafiltration cartridge delivers ALP-free water (< 1 µUnits/µL) with a bacteria count of less than 10 cfu/mL (typically < 1 cfu/mL). Low bacteria count reduces the need for frequent analyzer calibration and decontamination. BioPak® C cartridge performance is maintained for 120 continuous days when used according to instructions, with the filter outlet located in a clean environment.

†CLRW type.

BioPak® C ultrafiltration cartridge increases the stability of blanks to improve assay reliability

Ultrafiltration with the BioPak® C cartridge removes bacterial by-products from purified water used in blanks and for sample dilution. This results in a more stable baseline **(Figure 2)** and better assay reliability.

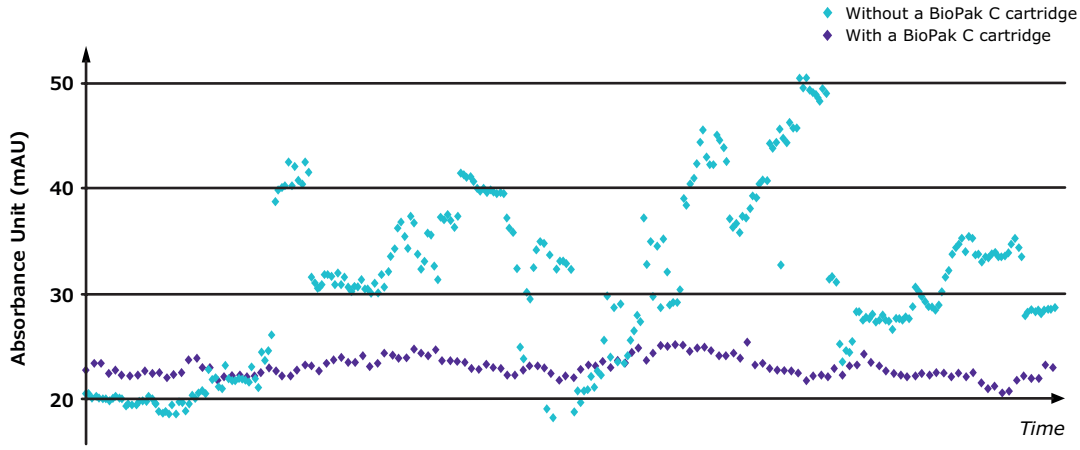

Figure 2. Typical impact of BioPak® C ultrafiltration cartridge on blank values over a 30-day period.

BioPak® C ultrafiltration cartridge does not compromise flow rate

The large ultrafiltration membrane surface of the BioPak® C cartridge makes it possible to produce ALP-free ultrapure water without compromising the flow rate **(Figure 3)**.

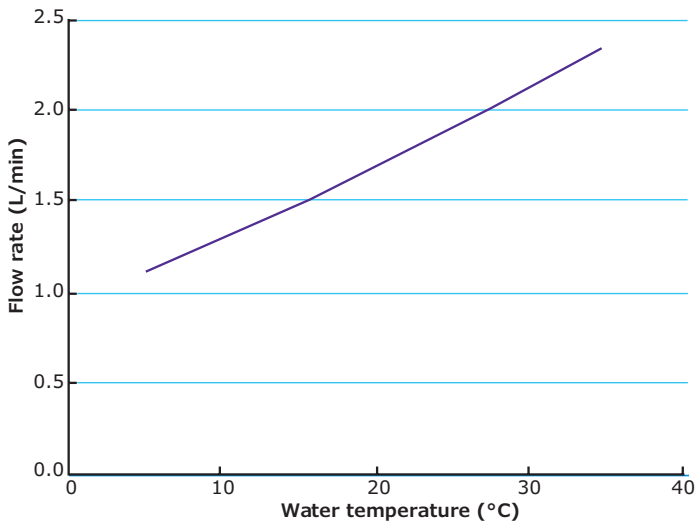

Figure 3. BioPak® C ultrafiltration cartridge flow rate at different temperatures (Feed pressure: 1 Bar).

We offer a broad and innovative range of water purification systems for use with clinical and immunochemistry instruments that improve laboratory productivity and ensure accurate daily results. Our clinical water purification systems benefit users in hospitals, physicians' offices, reference and forensic labs, as well as diagnostic manufacturers.

MilliporeSigma provides innovative tools, services and biological reagents that drive advancements in biomedical and academic research, as well as support the discovery and development of new pharmaceuticals. Our customers work in leading research laboratories across a variety of industries throughout the world. MilliporeSigma improves their laboratory productivity and efficiency through optimized workflows.

References

1. Bôle J, Mabic S. Bacterial Alkaline Phosphatase: Relevance, Origin and Removal. *Application Note*, MilliporeSigma, 2012.
2. Bôle J, Mabic S. Utilizing ultrafiltration to remove alkaline phosphatase from clinical analyzer water. *Clin Chem Med* 2006;44(5):603-8.

Ordering information

Description	Cat. No.
BioPak® C Ultrafiltration Cartridge (1/pk) delivered with a self-adhesive label (with space to note installation and replacement dates) and a Certificate of Quality; Material: Polysulfone hollow fibers in ABS housing; Results warranted within specifications for 120 days of use	**CDUFBC001**
BioPak® C Mounting Kit includes: • Metal bracket with adhesive strips • ¼ in. GazF – 8 mm stem connector • 8 mm – 6 mm T reducer • 8 mm – 6 mm elbow (Qty.: 2) • Installation instruction insert	**MBPKMNKIT**

To place an order or receive technical assistance

In the U.S. and Canada, call toll-free 1-800-645-5476

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