

BioPak[®] C

Clinical Ultrafiltration Cartridge



Final in-line purification step for immunoassay and clinical chemistry analyzers efficiently removes bacterial Alkaline Phosphatase (ALP)

Key Benefits

- Produces ALP-free water with bacteria levels lower than 10 cfu/ml (typically < 1 cfu/ml)
- Creates stable assay baselines, resulting in better reliability
- Reduces the need for frequent analyzer calibration
- Eliminates the need for frequent decontamination and resulting costly downtime
- Results warranted within specifications for 120 days of use water for LC-MS
- Maintenance-free

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 minimize 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 cartridge is composed of polysulfone hollow fibers in a white ABS housing. The BioPak[®] C ultrafiltration membrane optimizes the rejection of bacterial alkaline phosphatase (ALP) and bacteria while maintaining a high flow rate and minimizing the release of ionic and organic materials.

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. Drifting calibrations, high blanks and patient values trending toward the high/low end of the assay 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 basic level of water purity so that clinical chemistry assays can be run safely.*

* "Preparation and Testing of Reagent Water in the Clinical Laboratory; Approved Guideline--Fourth Edition" (C3-A4 Vol 26 No. 22), July 2006.

ALP and its removal using ultrafiltration

The use of ALP as a detection enzyme is common in numerous biomedical methods, including enzyme immunoassays and ALPlabeled nucleic probes, where calf intestine ALP (CIP) is frequently used. Following investigations with medical technologists, clinical analyzer manufacturers and diagnostic manufacturers concerning the importance of water quality and the effect of contaminated water on sensitive assays, Merck Millipore developed research based on the assumption that ALP might be the cause of some of the problems.

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, but dying and decaying bacteria upstream from the filter release bacterial ALP, which is then washed downstream. This bacterial ALP can then create interferences with the CIP often used in enzyme immunoassays.

Ultrafiltration methods are recognized as an efficient way to remove bacteria by-products such as bacterial ALP and endotoxins from pure water. Experiments by Merck Millipore's R&D department comparing the effectiveness of an ultrafiltration device and a 0.22 µm filter showed that ultrafiltration does result in "ALP-free" water.¹

The BioPaK® C is an ultrafiltration device that has been developed by Merck Millipore as a final in-line purification step for the clinical market.

When fed with high quality pure water from a Merck Millipore Elix® Clinical or AFS® system, the BioPak® C cartridge provides optimum quality water for use in ALP-sensitive assays.

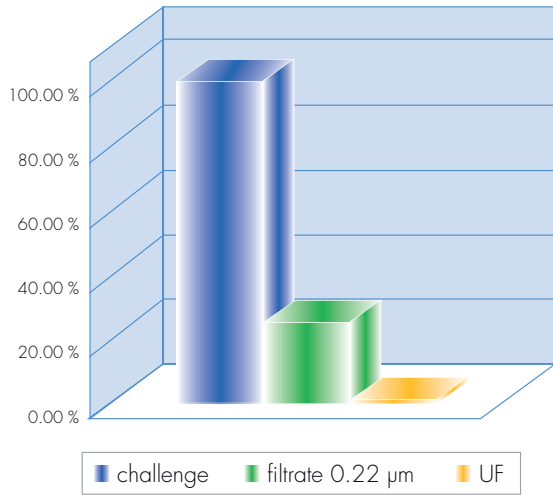


Figure 1: Challenge with pure ALP

Bacteria-free water production

Experiments performed in Merck Millipore's R&D laboratories have demonstrated that when fed with CLSI Clinical Laboratory Reagent Water** (resistivity > 10 MΩ.cm @ 25 °C; TOC level < 500 ppb), the BioPak® C ultrafiltration cartridge will deliver ALP-free water with a bacteria count of less than 10 cfu/ml (typically < 1 cfu/ml) after a 5 l rinsing. BioPak® C cartridge performance will be maintained for 120 continuous days when used according to instructions with the filter outlet located in a clean environment.

**CLRW type

High 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, as shown by the graph below.

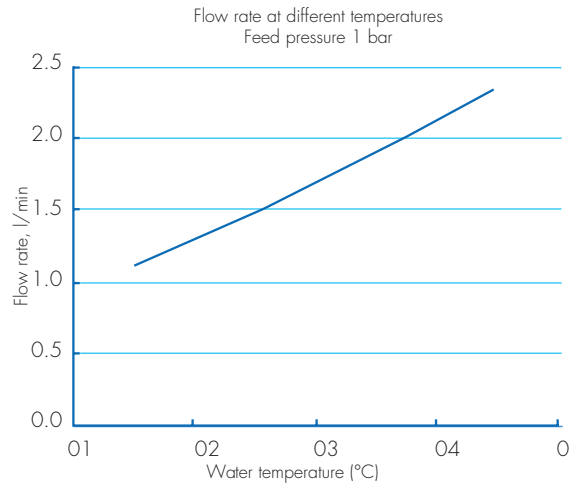


Figure 2: BioPak® C ultrafiltration cartridge flow rate at different temperatures

Certificate of Quality

Each BioPak® C unit has been individually tested for efficiency and flow rate and is delivered with a Certificate of Quality.

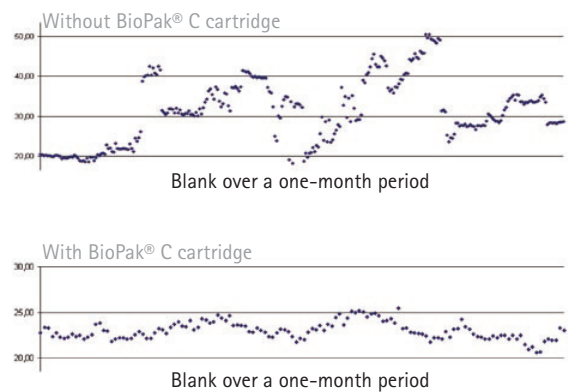


Figure 3: Typical impact on a blank

Ordering information

Description	Comments
BioPak® C Ultrafiltration Cartridge (1/pk) delivered with a self-adhesive label (with space to note installation and replacement dates), Certificate of Quality	CDUFBC001
BioPak® C Mounting Kit including: <ul style="list-style-type: none">• 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

Merck Millipore delivers a broad and innovative range of systems for clinical and immunochemistry instruments that improve laboratory productivity and ensure accurate daily results. Its clinical products benefit users in hospitals, physicians' offices, reference and forensic labs, as well as diagnostic manufacturers.

Merck Millipore's Lab water 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. Merck Millipore improves their laboratory productivity and efficiency through optimized workflows.

References

1. J. Bôle and S. Mabic, «Bacterial Alkaline Phosphatase: Relevance, Origin and Removal», *Application Note*, Merck Millipore Corporation, 2006.
2. J. Bôle and S. Mabic, «Utilizing ultrafiltration to remove Alkaline Phosphatase from clinical analyzer water», *Clin. Chem. Med.*, 2006.

