

# ChromaSorb™ Process Development Kit

Catalogue Number: CHRFA1PD09  
Lot Number: C9JN20983  
Membrane Lot No. 040909

## Nominal Membrane Volume = 0.079mL

### Good Manufacturing Practices

This product was manufactured in a Millipore facility which adheres to Good Manufacturing Practices.

### ISO 9001 Quality Standard

This product was manufactured in a Millipore facility whose Quality Management System is approved by an accredited registering body to the appropriate ISO 9001 Quality Systems Standard

### Component Materials Toxicity

Component materials were tested and meet the Criteria for the USP Class VI Biological Tests for Plastics.

### Animal Origin Statement

The materials used to manufacture this product are not of animal origin.

### European Pressure Equipment Directive

Millipore Corporation certifies that this product complies with the European Pressure Equipment Directive, 97/23/EC of 29 May 1997. This product has been classified under Article 3 § 3 of the Pressure Vessel Directive. It has been designed and manufactured in accordance with sound engineering practice to ensure safe use. In compliance with Article 3 § 3 of this Pressure Equipment Directive, this product does not bear the CE mark.

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## Quality Assurance Lot Release Criteria

This manufacturing lot was sampled, tested and released by Quality Assurance to the following specifications:

### Membrane BSA Capacity

Samples of the ChromaSorb membrane exhibited an average 50 mg/ml or greater BSA binding capacity at 0.9M NaCl concentration

### Membrane Extractable (TOC)

Samples of the ChromaSorb membrane demonstrate  $\leq 10 \mu\text{g C} / \text{cm}^2$ .

### Device Permeability

This product was tested for permeability and demonstrated a flow rate equal to or greater than 90 LMH/psid

### Device 100% Aerosol Integrity Test

Each ChromaSorb small scale 0.08 mL device has been aerosol tested and shown to be integral.

### Device Diffusion Test

This product was tested for integrity and shown by air water diffusion to have at flow less than or equal to 1.00 cc/min at 10 psid

## Quality Performance Criteria

This product was designed and manufactured to meet the following specifications.

### Device Extractable TOC

This product was tested for TOC extractable and exhibited 0.5 ppm or less of TOC after flush (post sanitization in Milli-Q® water flush at 1ml/min for 9 min)

### Hydraulic Stress

This product was tested for hydraulic stress and exhibited integrity after pressurizing to 30 psid forward at 4-30° C and 5 psid reverse at 4-30° C.



Peter Eicheit  
Quality Manager

