# 75205 Performance

**(a)**

The dialyzer shall be subjected to in-vitro functional tests after the cleaning procedure has been completed. Such test shall include: (1) Clearance test using the test solutes, i.e.: urea, creatinine, insulin, vitamin B12, or other solutions formulated to allow assessment of low and middle molecule weight molecular clearances. Dialyzers with a reduction in the clearance of urea or creatinine greater than 10 percent or of insulin or vitamin B12 greater than 20 percent of that specified by the manufacturer for new dialyzers of the same model shall not be reused. (2) Ultrafiltration test over the range of transmembrane pressures spanning those encountered clinically, but never at pressures exceeding the maximum specified by the manufacturer. Dialyzers with a reduction in the ultrafiltration rate greater than 10 percent of that specified by the manufacturer for new dialyzers of the same model shall not be reused. (3) Membrane Integrity test shall be performed on the reprocessed dialyzer if the leak rate observed clinically for reprocessed dialyzers exceeds that for new dialyzers of the same type and model.

**(1)**

Clearance test using the test solutes, i.e.: urea, creatinine, insulin, vitamin B12, or other solutions formulated to allow assessment of low and middle molecule weight molecular clearances. Dialyzers with a reduction in the clearance of urea or creatinine

greater than 10 percent or of insulin or vitamin B12 greater than 20 percent of that specified by the manufacturer for new dialyzers of the same model shall not be reused.

**(2)**

Ultrafiltration test over the range of transmembrane pressures spanning those encountered clinically, but never at pressures exceeding the maximum specified by the manufacturer. Dialyzers with a reduction in the ultrafiltration rate greater than 10 percent of that specified by the manufacturer for new dialyzers of the same model shall not be reused.

**(3)**

Membrane Integrity test shall be performed on the reprocessed dialyzer if the leak rate observed clinically for reprocessed dialyzers exceeds that for new dialyzers of the same type and model.

**(b)**

Indirect test methods for the assessment of dialyzer functionality may be employed in place of the tests specified in subsection (a) of this section provided that such test methods are suitably validated to demonstrate that they can be reliably used to verify compliance with the limits established in part (a) of this section. For hollow fiber dialyzers, the measurement of residual fiber bundle volume (FBV) is an acceptable indirect test method. Reprocessed hollow fiber dialyzers with a reduction in the FBV greater than 20 percent of the volume specified by the manufacturer for new dialyzers of the same model shall not be reused. If FBV is determined by the facility it shall be determined for every individual new dialyzer prior to its use.

**(c)**

The results of the functional requirement tests shall be included in the Device History Record.