

NxStage Pureflow SL Culture and LAL Collection Using the NxStage Sample Bag

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Background

- The NxStage Pureflow SL
 - Fully integrated system incorporating the water treatment and dialysate mixing into one small, package
 - Works seamlessly to produce sterile dialysate for use within 72 hours of mixing
- In August 2007, CMS mandated the system be sampled at least monthly (at the end of SAK life) for culture and LAL of the dialysate to ensure patient safety
 - CMS guidelines were developed after consulting with CDC and FDA

The Recommended Sample Process

- The system was not designed to be broken for sampling
 - A safe process had to be developed to meet the sampling requirements mandated by CMS as well as state regulators
- The original process was a modification of the industry standard
 - Traditional dialysis equipment culture procedure using 15 ml Corning tubes

The Recommended Sample Process cont'd.

- The original process was effective, but labor intensive
 - Required a coordination of patient and healthcare provider time schedules
- Additionally, the remaining batch had to be drained due to the possibility of contamination

Objective

- This study was done to validate the accuracy of a simpler, more cost effective method that would allow the use of the remaining batch.

Pilot Study Methods

- In February 2008, DaVita at Home™ initiated a collaborative pilot study
 - Collect 60 samples in both the NxStage Sample bag and the 15 ml Corning tube
- Cultures and endotoxins were each performed on 30 samples using both containers

Sampling

- Samples received in the...
 - NxStage Sample bags were aliquoted into 15 ml Corning tubes using a sterile syringe, and then processed according to the same laboratory guidelines
 - 15 ml Corning tubes were accessioned and processed according to the laboratory guidelines

Testing

- Endotoxin testing was performed using
 - Kinetic turbidimetric testing methodology
 - Automated pipettor
- Water cultures were prepared using a 100ul pipette, sterile spreader, and BD TSA media.
 - Cultures were incubated 48 hours
 - Read for colony count

Results

- The 60 samples showed there was not variability between the 15 ml Corning tube and the NxStage Sample bag.
- The results validated the accuracy of the new NxStage Sample Bag.

Conclusion

- The new process...
 - Less labor intensive
 - Reliable
 - Could be completed by the patients because there was less risk of contamination
 - Allowed for use of the remaining batch

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