Cue X6R5004 Product Performance Report

Important: If reaction or injury has occurred call Fresenius Kabi Post-Market Quality Assurance at 1-800-933-6925.

Incident Date: _____ Instrument S/N.: _____ Software Version: ____ UDI No.: _____
Lot No.: _____ Spinner Video Jet No.: _____

Problem Detected with:
☐ Primary Set ☐ Sampling Set(s)* ☐ Both

*Note: Each Primary Set includes three, individually packaged Sampling Sets. Sampling Sets are not available as a separate product code.

Primary Set *(Complete this section if problem was detected with Primary Set)*

When Was the Problem Detected?

☐ Before Use ☐ Set Installation ☐ Set Checks ☐ Set Prime ☐ During Procedure ☐ After Procedure

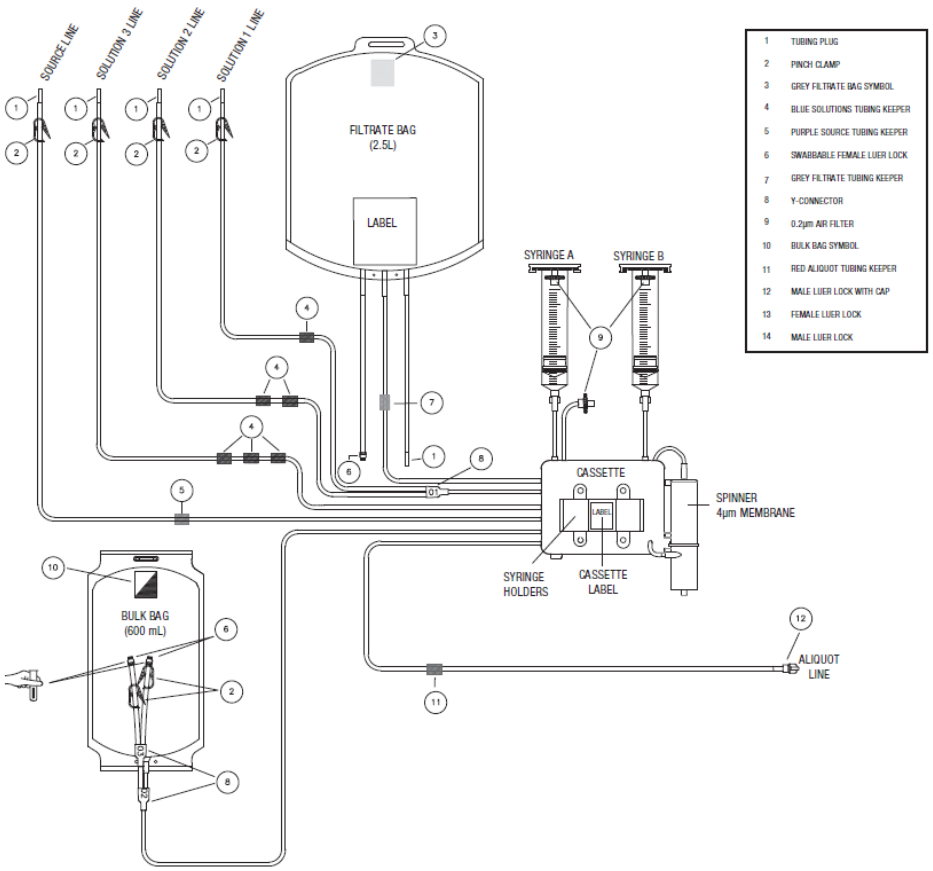
Problem Type (*Mark all applicable*)

Packaging: ☐ Packaging Open ☐ Mispacked ☐ Discolored ☐ Missing or Illegible Label ☐ Missing or Separated Component (e.g., keeper)
Tubing: ☐ Flattened ☐ Kinked ☐ Hole ☐ Cut/Sliced ☐ Blocked/Occluded ☐ Discolored ☐ Incorrect Length ☐ Separated (e.g. from Cassette)
Spinner (Separation Device): ☐ Cracked ☐ Leaking ☐ Noise
Cassette: ☐ Cracked ☐ Hole ☐ Leaking ☐ Poor Fit in Cassette Enclosure
Syringe Assemblies: ☐ Cracked ☐ Leaking ☐ Missing or Separated Component ☐ Poor Fit on Syringe Guides
Air Filter: ☐ Cracked ☐ Leaking ☐ Discolored ☐ Blocked/Occluded
Swabbable Female Luer Lock: ☐ Cracked ☐ Leaking ☐ Discolored ☐ Blocked/Occluded
Container: ☐ Hole ☐ Improper Seal around Container Port ☐ Leaking ☐ Discolored ☐ Missing Label

Other: _____ Associated Alert Name/Code (if applicable): _____

Please circle specific components on the diagram where incident occurred

Cue X6R5004 Primary Set



Sampling Set *(Complete this section if problem was detected with Sampling Set)*

When Was the Problem Detected?

☐ Before Use ☐ During Use ☐ After Use

Problem Type *(Mark all applicable)*

Packaging: ☐ Packaging Open ☐ Mispacked ☐ Discolored ☐ Missing or Illegible Label ☐ Missing or Separated Component (e.g., pinch clamp)

Tubing: ☐ Flattened ☐ Kinked ☐ Hole ☐ Cut/Sliced ☐ Blocked/Occluded ☐ Discolored ☐ Incorrect Length ☐ Separated

Pouch: ☐ Hole ☐ Cut/Sliced ☐ Leaking ☐ Discolored

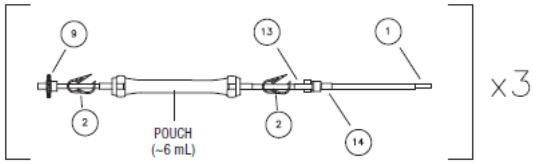
Air Filter: ☐ Cracked ☐ Leaking ☐ Discolored ☐ Blocked/Occluded

Male/Female Luer Locks: ☐ Cracked ☐ Leaking ☐ Discolored ☐ Blocked/Occluded ☐ Poor Fit

Other: _____

Please circle specific components on the diagram where incident occurred

Cue Sampling Set



Additional Problem Description / Explanation

Picture available for evaluation? Yes ☐ No ☐

If a picture is available, please e-mail a clear picture **along with this report** to **mdpmqa.usa@fresenius-kabi.com**

Please answer the following questions:

1. Was there any adverse event or injury? Yes ☐ No ☐
2. Was the procedure successfully completed? Yes ☐ No ☐ N/A ☐
3. If no, was the procedure stopped due to a soft goods incident? Yes ☐ No ☐ N/A ☐
4. Was product lost? Yes ☐ No ☐ N/A ☐
5. Did the procedure involve clinical or patient material? Yes ☐ No ☐ N/A ☐

Check box if you do **NOT** wish to receive response letters. ☐ _____

E-mail address for letter recipient (if applicable)

Kit Return to Fresenius Kabi

1. Sample available for evaluation? Yes ☐ No ☐
2. Return label needed? Yes ☐ No ☐
3. Sample return box needed? Yes ☐ No ☐

Center Authorized Signature/Date:

Fax this report to 1-888-858-2983 or E-mail this report to mdpmqa.usa@fresenius-kabi.com and include a copy of this form when returning a kit.

Customer Information (please print)

The following information is required to receive a credit

Facility Name: _____

Contact Name: _____

Account Number (if known): _____

Operator Name: _____

Street Address: _____

City/State/Zip: _____

Phone Number: _____

Contact Person's E-mail: _____