# 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: ____
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

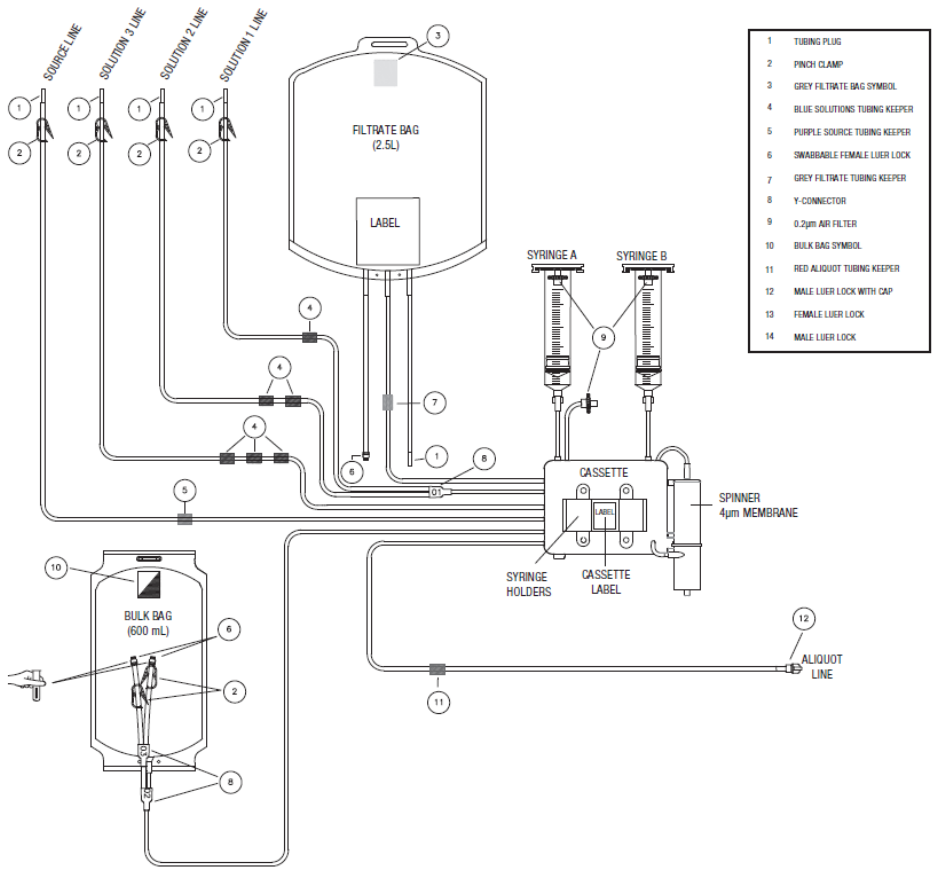
**Problem Type** (*Mark all applicable*)

*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**



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FRESENIUS KABI

**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

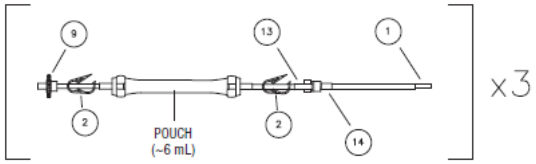
*Air Filter:* ☐ Cracked ☐ Leaking ☐ Discolored ☐ Blocked/Occluded

*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 MDComplaintSupport@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 MDComplaintSupport@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: _____