

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

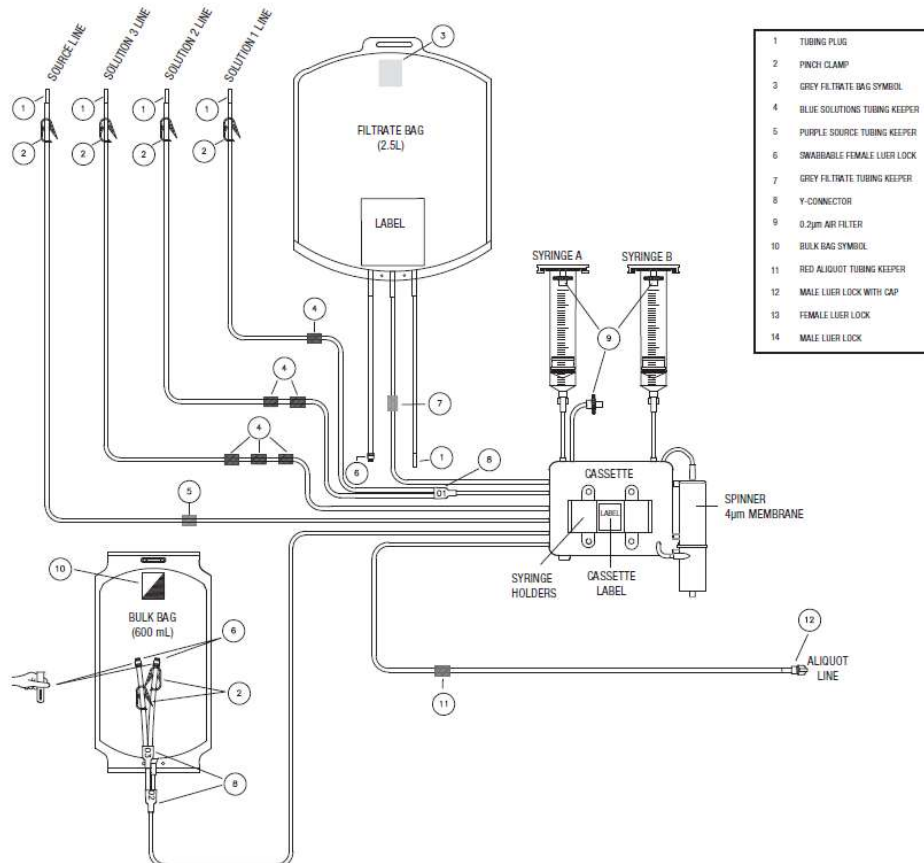
Problem Type (Mark all applicable)

- 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?

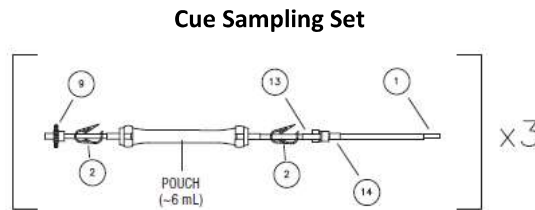
- Before Use During Use After Use

Problem Type (Mark all applicable)

- Packaging:** Packaging Open Mispicked 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



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)

<p>Kit Return to Fresenius Kabi</p> <p>1. Sample available for evaluation? Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>2. Return label needed? Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>3. Sample return box needed? Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Center Authorized Signature/Date:</p> <p>_____</p> <p>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.</p>	<p>Customer Information (please print)</p> <p>The following information is required to receive a credit</p> <p>Facility Name: _____</p> <p>Contact Name: _____</p> <p>Account Number (if known): _____</p> <p>Operator Name: _____</p> <p>Street Address: _____</p> <p>City/State/Zip: _____</p> <p>Phone Number: _____</p> <p>Contact Person's E-mail: _____</p>
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