

# Cue X6R5003 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

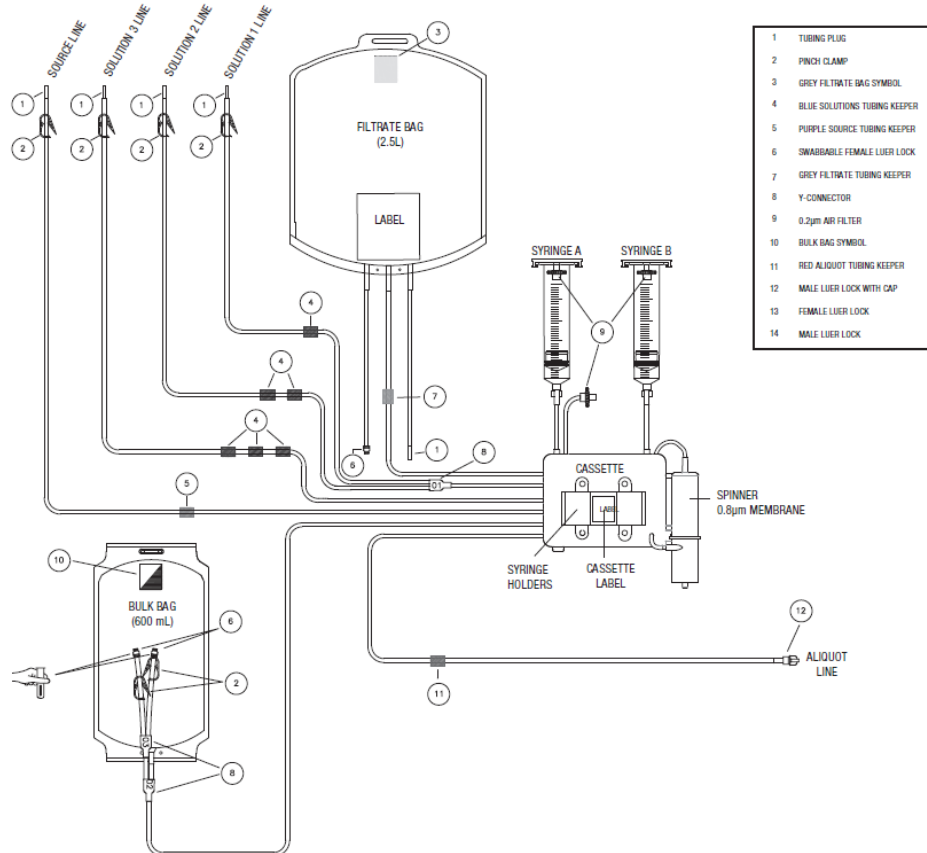
**Swabbable Female Luer Lock:**  Cracked    Leaking    Discolored    Blocked/Occluded

**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 X6R5003 Primary Set**



**Continued on Next Page**

**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)

**Tube:**  Flattened    Kinked    Hole    Cut/Sliced    Blocked/Occluded    Discolored    Incorrect Length  
 Separated

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

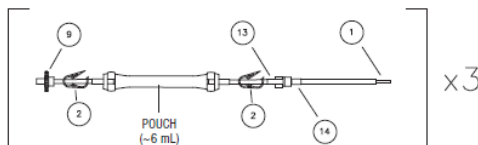
**Air Filter:**  Cracked    Leaking    Discolored    Blocked/Occluded

**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](mailto: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><b>Kit Return to Fresenius Kabi</b></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><b>Customer Information (please print)</b></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>
<p><b>Center Authorized Signature/Date:</b></p> <p>_____</p>	
<p>Fax this report to 1-888-858-2983 or E-mail this report to <a href="mailto:mdpmqa.usa@fresenius-kabi.com">mdpmqa.usa@fresenius-kabi.com</a> and include a copy of this form when returning a kit.</p>	