

# Cue X6R5006 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.: \_\_\_\_\_

### 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., keeper)

**Tubing:**  Flattened    Kinked    Hole    Cut/Sliced    Blocked/Occluded    Discolored    Incorrect Length  
 Separated (e.g. from Cassette)

**Female Luer:**  Cracked    Leaking    Discolored    Blocked/Occluded    Poor Fit    Disconnected

**Male Luer:**  Cracked    Leaking    Discolored    Blocked/Occluded    Poor Fit    Disconnected

**Pouch:**  Flattened    Kinked    Hole    Cut/Sliced    Blocked/Occluded    Discolored

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

Other: \_\_\_\_\_ Associated Alert Name/Code (if applicable): \_\_\_\_\_

### Additional Problem Description / Explanation

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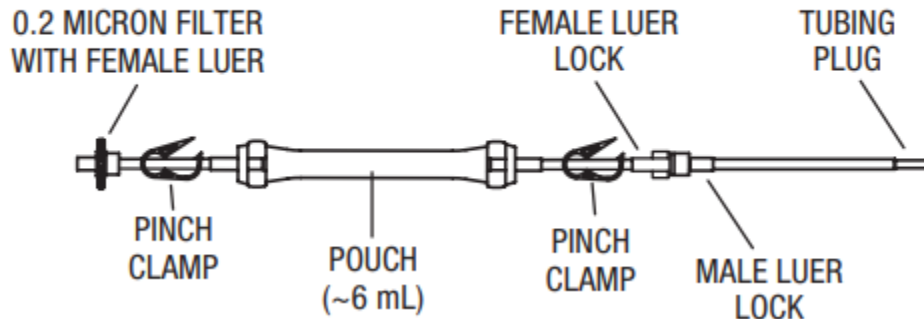
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Please circle specific components on the diagram where incident occurred.

### Cue X6R5006 Sampling Set

#### Cue Sampling Set



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)

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**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)

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**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 [mdpmpqa.usa@fresenius-kabi.com](mailto:mdpmpqa.usa@fresenius-kabi.com) and include a copy of this form when returning a kit.**

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**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: \_\_\_\_\_