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: ____
Lot No.: _____

When Was the Problem Detected?
☐ Before Use ☐ During Use ☐ After Use

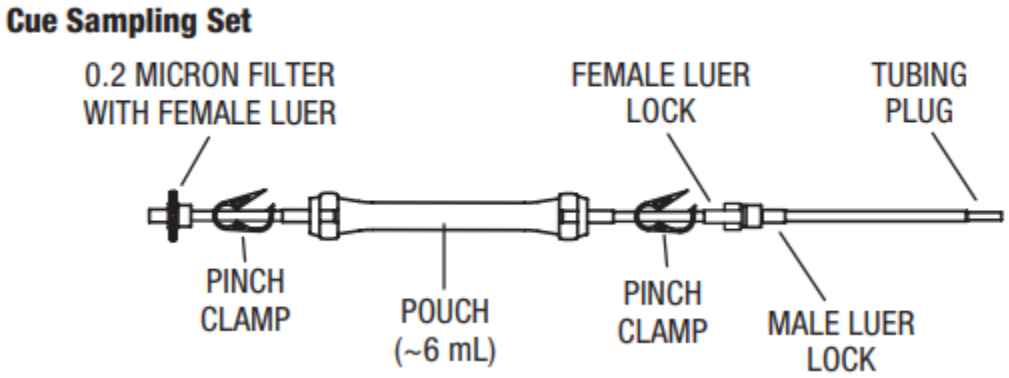
Problem Type (*Mark all applicable*)
Packaging: ☐ Packaging Open ☐ Mispacked ☐ Discolored ☐ Missing or Illegible Label
☐ Missing or Separated Component (e.g., keeper)
Tubing: ☐ Flattened ☐ Kinked ☐ Hole ☐ Cut/Sliced ☐ Blocked/Occluded ☐ Discolored ☐ Incorrect Length
☐ Separated (e.g. from Cassette)
Female 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

Please circle specific components on the diagram where incident occurred.

Cue X6R5006 Sampling Set



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

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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)

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: _____