Agilia Infusion Set Performance Report

FRESENIUS KABI

Important: If reaction or injury has occurred call Fresenius Kabi Product Complaint and Support at 1-800-933-6925.

Incident Date: _____ Pump S/N: _____ Software Version: _____

UDI No.: _____ Reference Code: _____ Lot No.: _____

When was the incident detected?

☐ Before Use ☐ Set Up ☐ Prime ☐ During Procedure ☐ After Procedure

Incident Type (*Mark all applicable*)

☐ Discolored ☐ Illegible ☐ Deformed/Damaged ☐ Incorrect Labeling ☐ Foreign Matter ☐ Connection Problems
☐ Kinked ☐ Missing ☐ Misassembly ☐ Leak ☐ Blocked/Restricted ☐ Separated ☐ Alarm _____

Please answer the following questions:

1. Was there any adverse event or injury? Yes ☐ No ☐
2. Was the infusion stopped before completion? Yes ☐ No ☐ N/A ☐
3. Was the infusion successfully completed? Yes ☐ No ☐ N/A ☐
4. What drug was used for the infusion? _____ Cytotoxic? Yes ☐ No ☐

What company manufactured the container that was spiked? _____

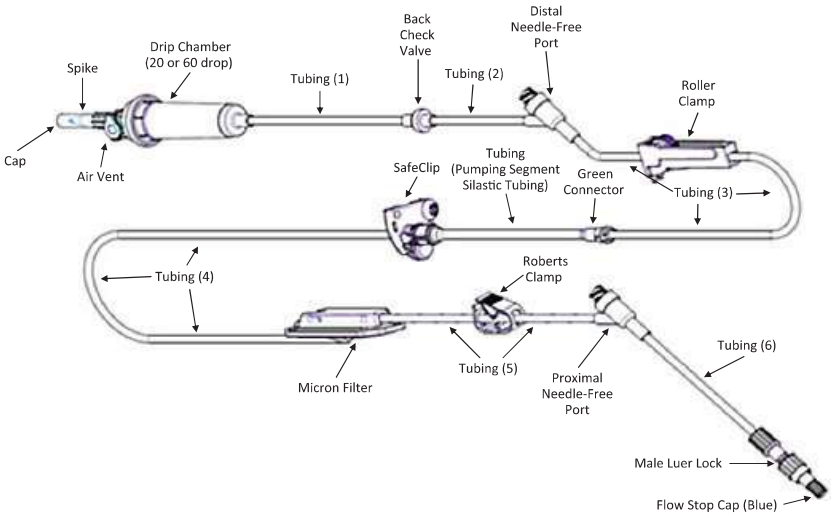
What type of container was spiked (glass bottle, plastic bag, etc.)? _____

Check box if you do **NOT** wish to receive response letters. ☐ _____

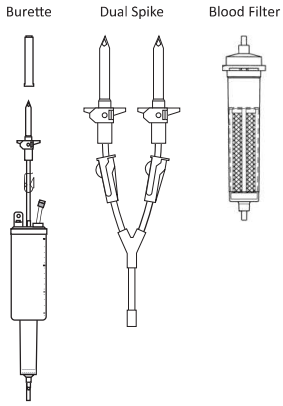
E-mail address for letter recipient (if applicable)

Please circle specific components on the diagram where issues occurred

Volumat Line of Administration Sets



Other Components



Additional Incident Description / Explanation

Kit Return To Fresenius Kabi

1. Sample available for evaluation? Yes ☐ No ☐
2. Sample return box needed? Yes ☐ No ☐ Return label only ☐
3. Picture available for evaluation? Yes ☐ No ☐
   Please e-mail a clear picture **along with this report** to **MDComplaintSupport@Fresenius-kabi.com**

Center Authorized Signature/Date:

Fax this report to 1-888-858-2983 or E-mail 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 Person: _____
Account Number (if known): _____
Operator Name: _____
Street Address: _____
City/State/Zip: _____
Phone Number: _____
Contact Person's E-mail: _____