

**Important: If reaction or injury has occurred call  
Fresenius Kabi Post-Market Quality Assurance at 1-855-354-6387**



# Agilia Infusion Set Performance Report

Was there any injury/adverse reaction? Yes  No   
 Was the infusion stopped before completion? Yes  No   
 Was the infusion successfully completed? Yes  No   
 Check box if you do **NOT** wish to receive response letters.

Incident Date: \_\_\_\_\_ Pump Serial Number: \_\_\_\_\_ Software Version: \_\_\_\_\_  
 UDI Number: \_\_\_\_\_ Reference Code: \_\_\_\_\_ Lot Number: \_\_\_\_\_

**When was the incident detected?**

Before Use    Set Up    Prime    During Procedure    After Procedure

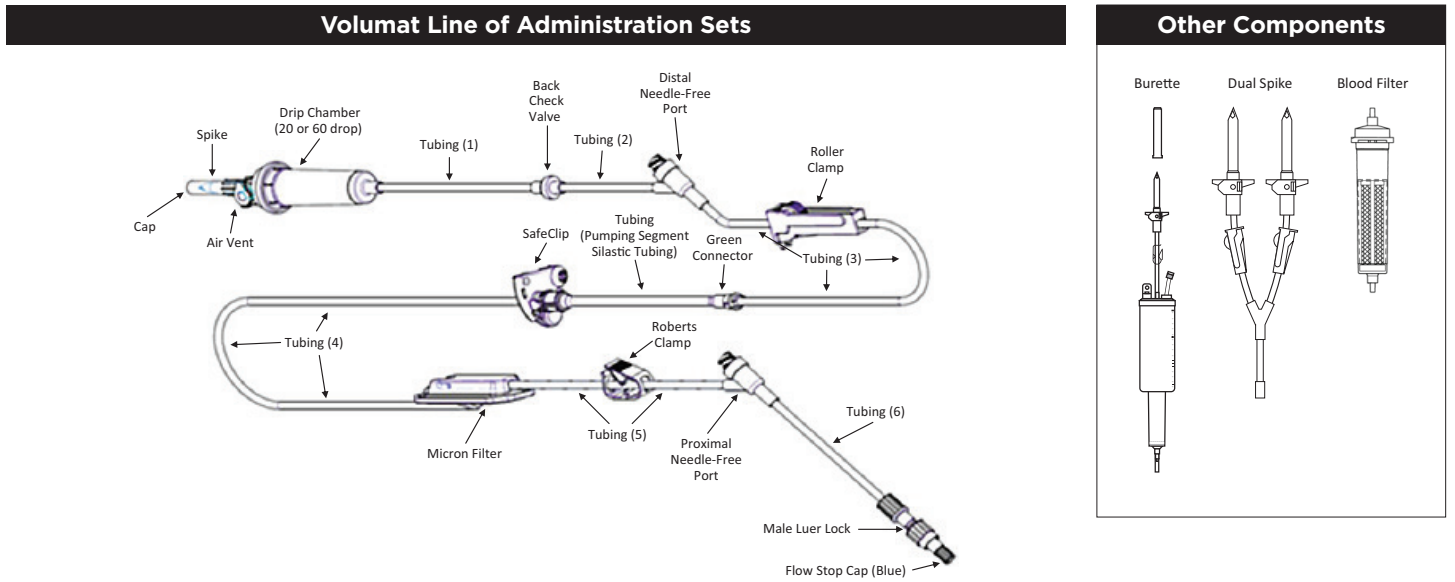
**Incident Type** (Mark all applicable)

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

**Additional Questions**

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.)? \_\_\_\_\_

**Please circle specific components on the diagram where issues occurred**



**Additional Incident Description / Explanation**

\_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

**Set Return To Fresenius Kabi**

1. Check box if sample is available for evaluation.
2. Sample return box needed? Yes  No  Return label only
3. Picture taken of defective set? Yes  No  (if yes, send picture to email below)
4. Other instructions \_\_\_\_\_

**Site Authorized Signature/Date:**

**Fresenius Kabi Reviewed By/Date:**

\_\_\_\_\_

\_\_\_\_\_

**Please Print**

Account #: \_\_\_\_\_  
 Site Name: \_\_\_\_\_  
 Contact Person: \_\_\_\_\_  
 Street Address: \_\_\_\_\_  
 City/State/Zip: \_\_\_\_\_  
 Phone Number: \_\_\_\_\_  
 E-Mail address for response letter(s): \_\_\_\_\_

**Fax this report to 1-888-858-2983 or E-mail to pmqateam@fresenius-kabi.com and include a copy of this form when returning a set.**

**47-50-08-840 REV: B**

Notification No. (Fresenius Kabi Personnel Only)