Aurora Xi 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.: | |
|--|---|--|
| Product Code: | Lot No.: | UDI No.: |
| Batch Tag Time: : | : Line No.: | Separator No.: |
| Donor Bleed No.: | Volume | e of Plasma Collected:mL |
| When Was the Proble | em Detected? Incoming Ins | |
| | | ns Prime Blood Prime Collection (specify cycle) |
| | | |
| | re □ Reinfusion (specify cycle) | |
| ☐ Kinked ☐ Blood/P | | Flow □ Cut/Slice □ Red Plasma (Visual) □ Illegible Label |
| ☐ Dented ☐ Installation | | ☐ HB Detect ☐ Missing (not in box) ☐ Other (specify Belo |
| 2. Was the procedure3. If no, was the proced4. Was product lost? | rse event or injury? Yes □ No □ successfully completed? Yes □ dure stopped due to a soft good | s incident? Yes □ No □ N/A □ |
| | | |
| | components on the diagram wl | |
| Solutio | n Container | Plasmacell Xi Disposable Set |
| Top Seal — | Hanger Holder | \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ |
| Side Seal — | (Hole/Slit) Side Seal | Saline Line Separator |
| Injection Site —— | Bottom Seal Closure Site | P1 Line Tubing Keepers (purple) |
| Plasma Tra | insfer Pack Unit | Saline Spike/Luer Reservoir Vent |
| Interlink Y | Plasma Tubing | Saline Cap |
| Luer Connector | Top Seal | Tuhing Keepers (inside reservoir) |
| Luer Cap Hange | | (red) Reinfusion Line |
| Holes Side Seal | Label Side Seal | Blood Line Y3 Connector Y2 Connector |
| | Bottom Seal | AC Line |
| Plasma F | Pooling Bottle | Tubing Keeper Plasma Line Luer (gray) |
| | — Cap | Luer Connector Cap |
| Port Connector — | Vent Tubing | AC Spike/Luer Donor Line |
| Plasma Tubing Connector Port | Connector Port Cap Door Hinge | AC Cap Y1 — Donor Short Line |
| Cap Door Snaps | Cap Door | Male Luer Cap — Luer Connector, Male |
| // | Vent Line Tubing | Apheresis Needle |
| Plasma Tubing | Bottle O Air Vent (Filter) | N |
| Plasifia fubling | Bottom Seal | Needle Cover Wing MasterGuard Needle Luer |
| Luer C | Interlink Y onnector | |
| | | Needle Tubing Luer Cap |
| | | |
| Additional Problem De | escription / Explanation | |
| Kit Return To Freseni | us Kabi | Customer Information (please print) |
| 1. Sample available for | or evaluation? Yes 🗆 No 🗆 | The following information is required to receive a credi |
| 2. Sample return box | needed? Yes \square No \square Return | label only Facility Name: |
| | or evaluation? Yes 🗆 No 🗆 | Contact Person: |
| Please e-mail a clea | r picture along with this report | Account Number (if known): |
| mdpmqa.usa@frese | enius-kabi.com | Operator Name: |
| Center Authorized Sign | ature/Date: | Street Address: |
| | , | City/State/Zip: |
| | | Phone Number: |
| Fax this report to 1-888-85 | 8-2983 or E-mail to mdpmga.usa@fre | |
| | | |

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