Mononuclear Cell (MNC) Collection



AMICUS Separator Kit 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.: _ Product Code: _____ Lot No.: ____ WB Processed: _____ mL When Was the Problem Detected? ☐ Set Up ☐ Collection □ Plasma Transfer ☐ Prime Step No. ☐ Reinfusion ☐ After Procedure/QC **Problem Type** (*Mark all applicable*) ☐ Cut/Slice □ Kink ☐ Restriction/No Flow ☐ Particulate Matter ☐ Alarms (Specify) □ Leak ☐ Separated ☐ Blood Leak ☐ Excess Air ☐ Missing □ Cracked ☐ RBC Contamination ☐ Other (Specify Below) Please answer the following questions: 1. Was there any adverse event or injury? Yes \square No \square 2. If applicable, list name of any drug administered: _ 3. Was the procedure successfully completed? Yes □ No □ N/A □ 4. If no, was the procedure stopped due to a soft goods incident? Yes \square No \square N/A \square 5. Was product lost? Yes □ No □ N/A □ 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 incident occurred Note: This Diagram is a graphic representation — Collection Bag / Final Storage Bag of an AMICUS Kit. It is not intended to accurately depict a specific code Roller Clamp PC Sample Pack Right Cassette Drip Chamber ACD Line 11> Separation Chambe Cassette Plasma Bag Umbilicus Anti-microbial Bearing Upper RBC Bag Tape Sample Centrifuge Pack Waste Bag Tubina ACD Coil→ Clear Spike Needle Wings Inlet Coil→ Balance Chambe Clamp Saline Line Return Line Roller Clamp Anti-microbial Filter Return Line Filter Drip Chamber Centrifuge Pack Left Cassette 1-6. Cassette Pump Tubing Additional Problem Description / Explanation Kit Return To Fresenius Kabi **Customer Information (please print)** The following information is required to receive a credit 1. Sample available for evaluation? Yes □ No □ Not Required □ Facility Name: 2. Sample return box needed? Yes □ No □ Return label only □ **3.** Picture available for evaluation? Yes \square No \square Contact Person: ___ Please e-mail a clear picture along with this report to Account Number (if known): mdpmqa.usa@fresenius-kabi.com Operator Name: Street Address: ___ Center Authorized Signature/Date: City/State/Zip: Phone Number: Contact Person's E-mail:

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.