

Indiana Blood Center

Indianapolis, IN 46208



Product Quality Summary Report

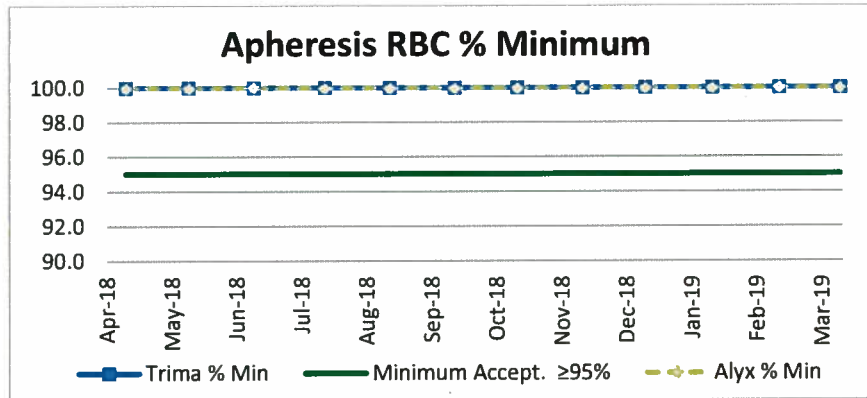
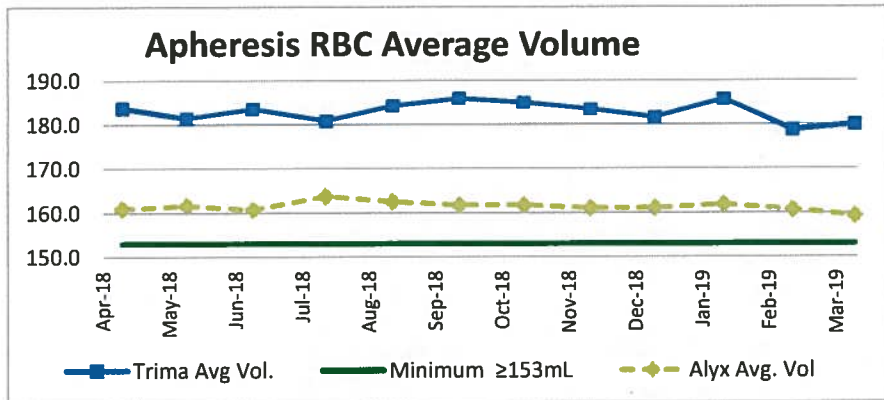
Rolling 12 Month Report

1st Quarter, 2019

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Product Quality Summary Report
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Apheresis RBC Abs. RBC Vol.

	<u>Trima</u> Avg Vol. (Accept. $\geq 153\text{mL}$)	<u>Alyx</u> Avg Vol. (Accept. $\geq 153\text{mL}$)	<u>Trima</u> % Min (153mL) (Accept. $\geq 95\%$)	<u>Trima</u> % Min (>128ml) (Accept. 100%)	<u>Alyx</u> % Min (>128ml) (Accept. 95%)
Apr-18	183.8	161.0	100.0	100.0	100.0
May-18	181.4	161.6	100.0	100.0	100.0
Jun-18	183.5	160.8	100.0	100.0	100.0
Jul-18	180.8	163.7	100.0	100.0	100.0
Aug-18	184.2	162.5	100.0	100.0	100.0
Sep-18	185.9	161.7	100.0	100.0	100.0
Oct-18	184.9	161.7	100.0	100.0	100.0
Nov-18	183.4	161.1	100.0	100.0	100.0
Dec-18	181.6	161.1	100.0	100.0	100.0
Jan-19	185.7	161.9	100.0	100.0	100.0
Feb-19	178.8	160.7	100.0	100.0	100.0
Mar-19	180.0	159.3	100.0	100.0	100.0

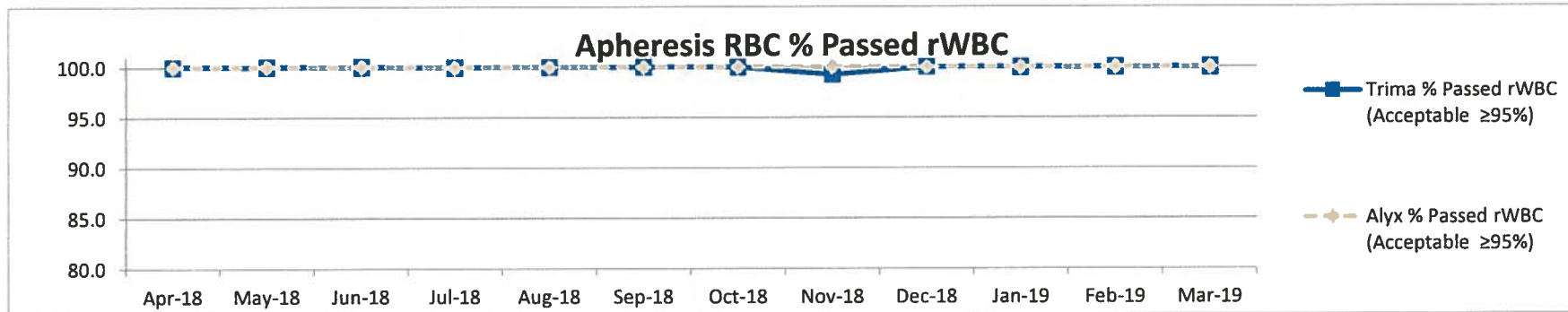


Per manufacturer's specifications and AABB standards, Apheresis Red Blood Cells Leukocytes Reduced shall be prepared by a method known to ensure final components contain a mean red cell volume of 153 mL. All products ≤ 128 mL are discarded.

**Product Quality Summary Report
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Apheresis RBC Leukoreduction

	<u>Trima</u>	<u>Alyx</u>	<u>Alyx</u>	
	% Passed rWBC (Acceptable ≥ 95%)	% Passed rWBC (Acceptable ≥ 95%)	# Units with < 85% Recovery	
Apr-18	100.0	100.0	4	See Deviations DEV-18-00759, -00862, -00908, & -00968
May-18	100.0	100.0	0	
Jun-18	100.0	100.0	1	See Deviation DEV-18-01630
Jul-18	100.0	100.0	2	See Deviations DEV-18-01742, -01961
Aug-18	100.0	100.0	5	See Deviations DEV-18-01997, -01998, -01999, -02069, -02070
Sep-18	100.0	100.0	2	See Deviations DEV-18-02189 and DEV-18-02196
Oct-18	100.0	100.0	1	See Deviation DEV-18-02672
Nov-18	99.2	100.0	4	See QCF-0008 and DEV-18-02778, -02779, -02780, -02944
Dec-18	100.0	100.0	0	
Jan-19	100.0	100.0	0	
Feb-19	100.0	100.0	0	
Mar-19	100.0	100.0	0	

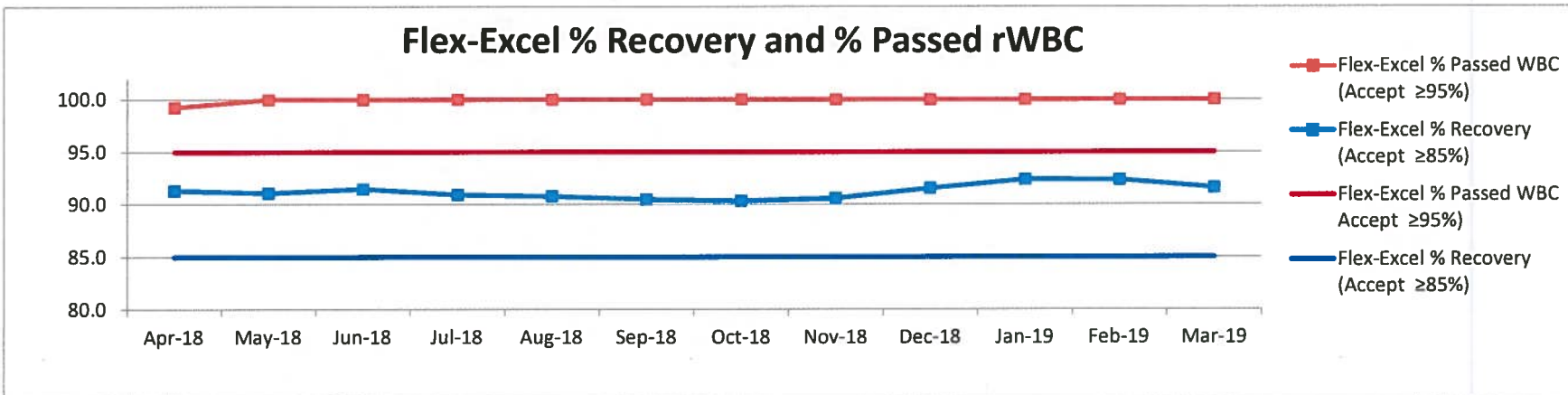


Per FDA guidelines and AABB standards, 95% of units sampled shall contain 5×10^6 residual white cells. All products containing $\geq 5 \times 10^6$ residual white cells are discarded. Percent recovery cannot be calculated for Trima collected apheresis RBCs but can be manually calculated for MCS+ QC units and 100% of Alyx collected apheresis RBCs are calculated by the machine.

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WB Leukoreduction

	<u>Flex-Excel</u> % Recovery (Acceptable ≥85%)	<u>Flex-Excel</u> % Passed rWBC (Acceptable ≥ 95%)	
Apr-18	91.3	99.2	See DEV-18-00773
May-18	91.1	100.0	
Jun-18	91.5	100.0	
Jul-18	90.9	100.0	See DEV-18-01826
Aug-18	90.8	100.0	
Sep-18	90.5	100.0	
Oct-18	90.3	100.0	
Nov-18	90.6	100.0	
Dec-18	91.5	100.0	
Jan-19	92.4	100.0	
Feb-19	92.3	100.0	
Mar-19	91.6	100.0	

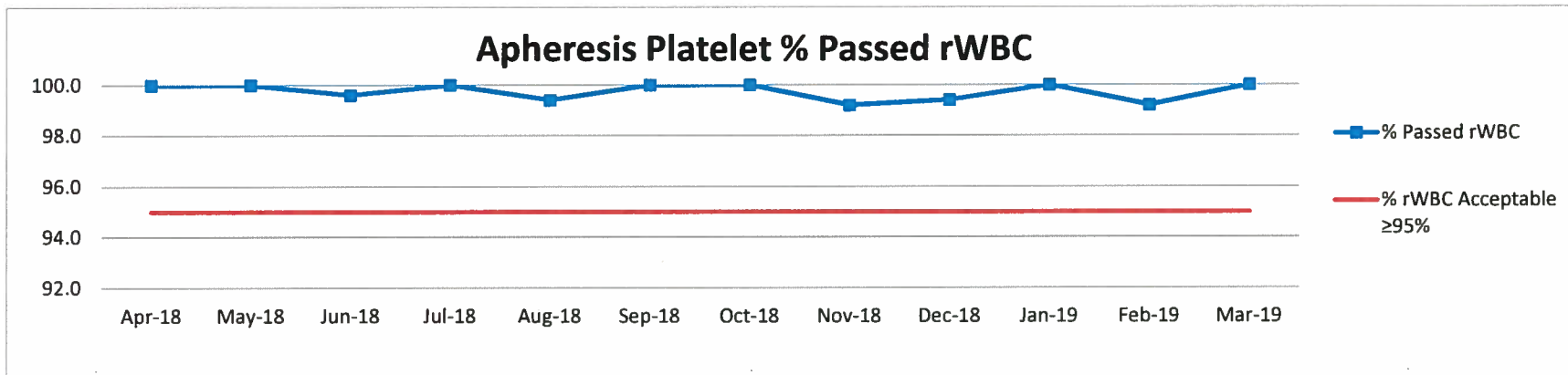


Per FDA guidelines and AABB standards, 95% of units sampled shall contain $<5 \times 10^6$ residual white cells. All products containing $\geq 5 \times 10^6$ residual white cells are discarded. Per AABB standards, the leukocyte reduction process must result in recovery of $\geq 85\%$ of the residual red cell volume. Any product with $< 85\%$ RBC recovery is discarded.

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Apheresis Platelet Leukoreduction

	<u>% Passed rWBC</u> (Acceptable ≥95%)	<u>No. Failed</u>	
Apr-18	100.0	0	
May-18	100.0	0	
Jun-18	99.6	1	See DEV-18-01424
Jul-18	100.0	0	
Aug-18	99.4	1	See QCF-18-0005
Sep-18	100.0	0	
Oct-18	100.0	0	
Nov-18	99.2	2	See QCF-18-0009, -0010
Dec-18	99.4	1	See QCF-18-0011
Jan-19	100.0	0	
Feb-19	99.2	2	See QCF-19-0001, -0002
Mar-19	100.0	0	

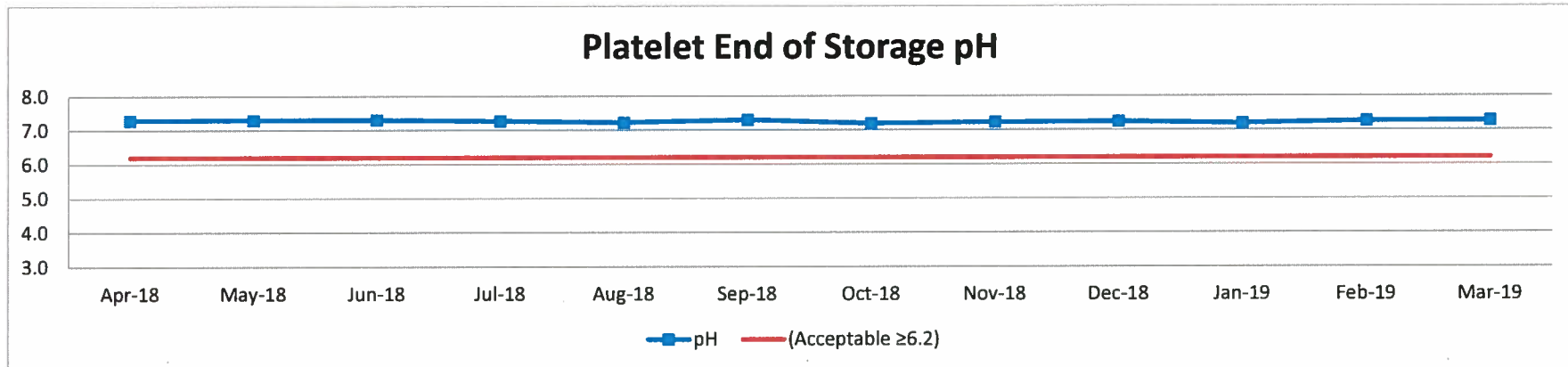


These products are initially leukocyte reduced during the collection process. Per FDA guidelines and AABB standards, 95% of units sampled shall contain $<5 \times 10^6$ residual white cells. All products containing $\geq 5 \times 10^6$ residual white cells are filtered and retested. Platelet % recovery is not calculated.

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Plateletpheresis End-Of-Storage (MD157-02.1)

	<u>pH</u>
	(Acceptable ≥ 6.2)
Apr-18	7.3
May-18	7.3
Jun-18	7.3
Jul-18	7.3
Aug-18	7.2
Sep-18	7.3
Oct-18	7.2
Nov-18	7.2
Dec-18	7.2
Jan-19	7.2
Feb-19	7.3
Mar-19	7.3

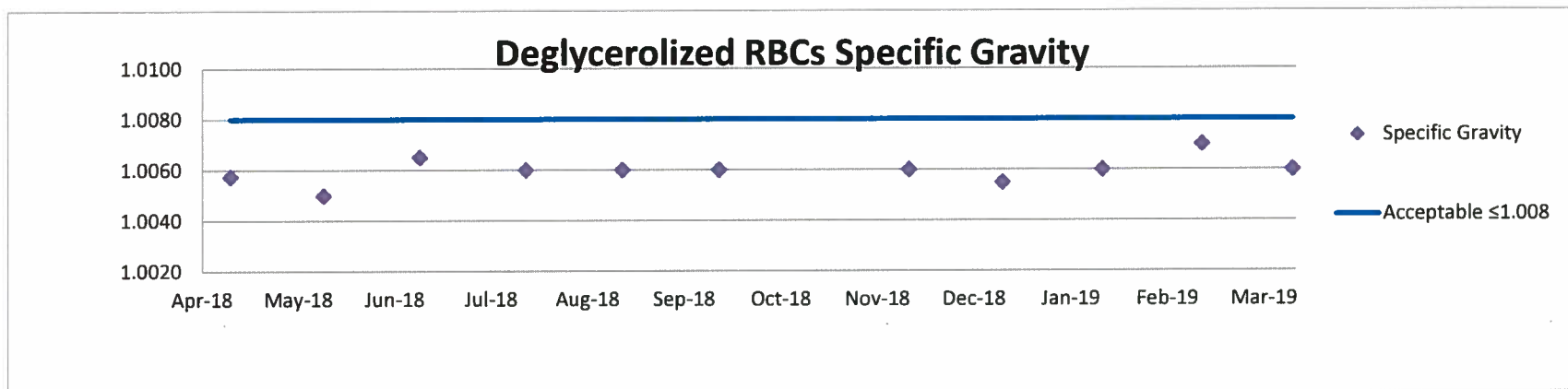


Per AABB standards and FDA guidelines, at least 90% of platelets tested shall have a pH of ≥ 6.2 . Any product with a pH of < 6.2 is discarded.

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Deglycerolized RBCs

	<u>Specific Gravity (CP301-05.1)</u> (Accept. ≤ 1.0080)	<u>Hemolysis Check (CP301-05.1)</u> Target = No Hemolysis (Hemolysis ≤ 4)	<u>% Recovery (CP803-01.1)</u> Accept. $\geq 80\%$ (Performed Quarterly)
Apr-18	1.0058	None	
May-18	1.0050	None	
Jun-18	1.0065	None	90.8%
Jul-18	1.0060	None	
Aug-18	1.0060	None	
Sep-18	1.0060	4	93.4%
Oct-18	None Tested	None	
Nov-18	1.0060	2	
Dec-18	1.0055	3	94.1%
Jan-19	1.0060	4	
Feb-19	1.0070	2	
Mar-19	1.0060	2	96.0%



Per AABB standards, deglycerolized red blood cells shall be prepared by a method known to ensure adequate removal of cryoprotective agents. The supernatant from each unit is tested for spec. gravity. Products with a S.G. ≤ 1.008 are determined to have achieved adequate removal. Additionally there must be recovery of 80% of the original red blood cells. This is tested quarterly.

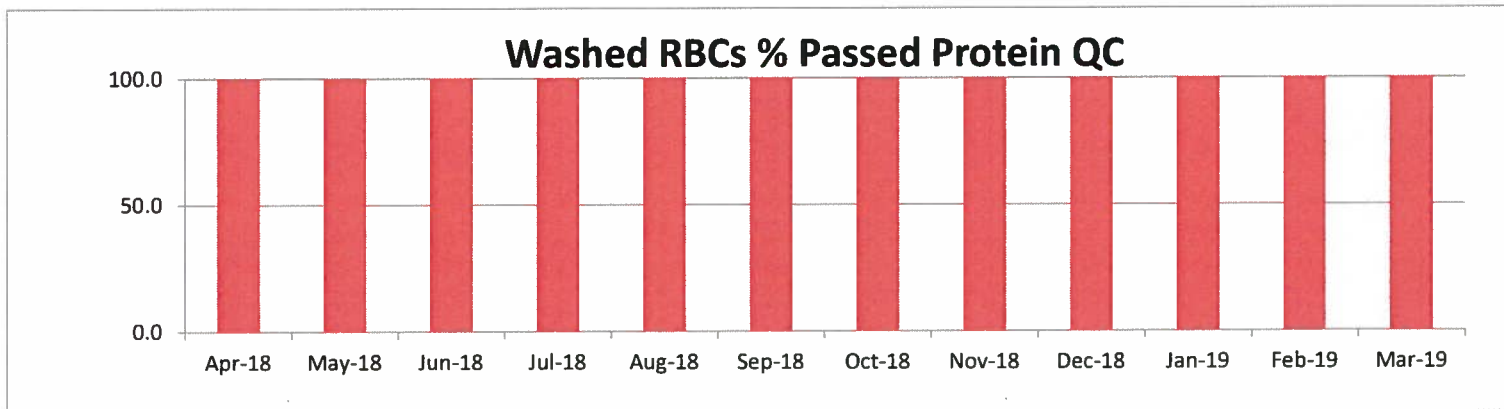
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Washed RBCs (CP310-05.1)

% Passed Protein QC

(Target = 100%)

Apr-18	100.0
May-18	100.0
Jun-18	100.0
Jul-18	100.0
Aug-18	100.0
Sep-18	100.0
Oct-18	100.0
Nov-18	100.0
Dec-18	100.0
Jan-19	100.0
Feb-19	100.0
Mar-19	100.0

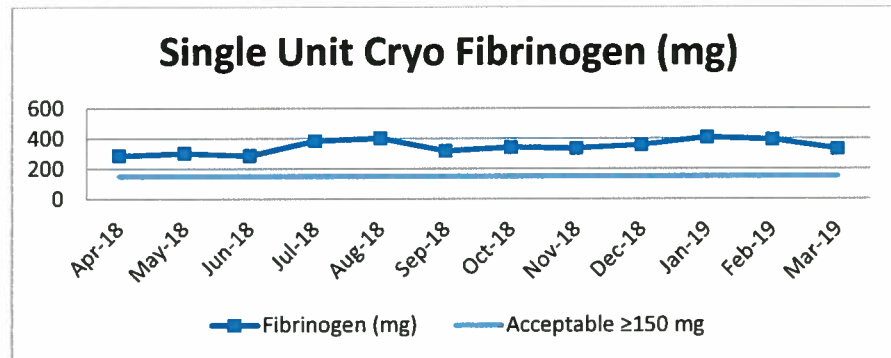
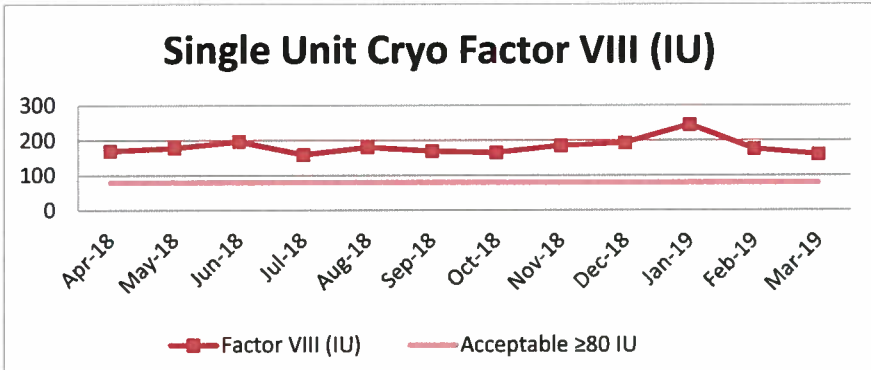


Per AABB standards, washed red blood cells shall be prepared by a method known to ensure that the red cells are washed with a volume of compatible solution that will remove almost all of the plasma. This is determined by testing each product for residual supernatant protein.

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Cryoprecipitate Single Unit (CP806-01.1)

	<u>Factor VIII</u> (Acceptable ≥ 80 IU)	<u>Fibrinogen</u> (Acceptable ≥ 150 mg)
Apr-18	170	286
May-18	179	302
Jun-18	197	286
Jul-18	159	384
Aug-18	180	402
Sep-18	169	317
Oct-18	166	342
Nov-18	185	335
Dec-18	193	358
Jan-19	245	408
Feb-19	176	393
Mar-19	160	330



Per AABB standards, cryoprecipitated AHF shall be prepared by a method known to result in a minimum of 150 mg of fibrinogen and a minimum of 80 IU of coagulation factor VIII.

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Granulocyte QC (MD164-01.1)

Granulocyte Yield

(Accept. $\geq 1.0 \times 10^{10}$)

Apr-18	None tested
May-18	None tested
Jun-18	None tested
Jul-18	None tested
Aug-18	None tested
Sep-18	None tested
Oct-18	None tested
Nov-18	None tested
Dec-18	None tested
Jan-19	None tested
Feb-19	2.0
Mar-19	None tested

Passing Rate (for 12 months)

(Accept. > 75% Passing)

100

