

Versiti Indiana

Indianapolis, IN 46208



Product Quality Summary Report

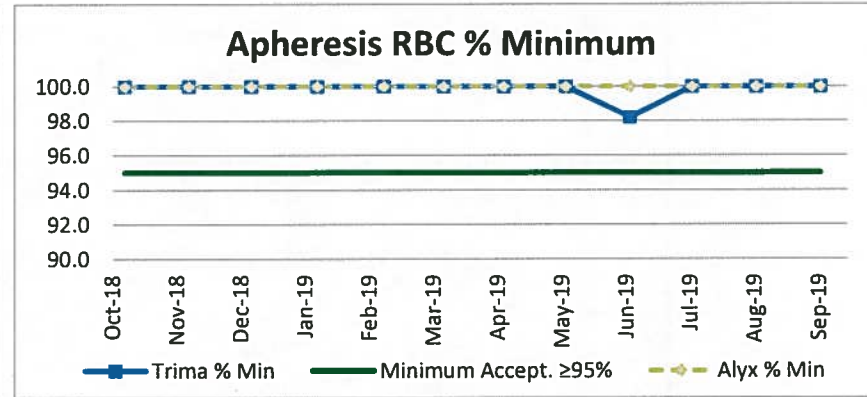
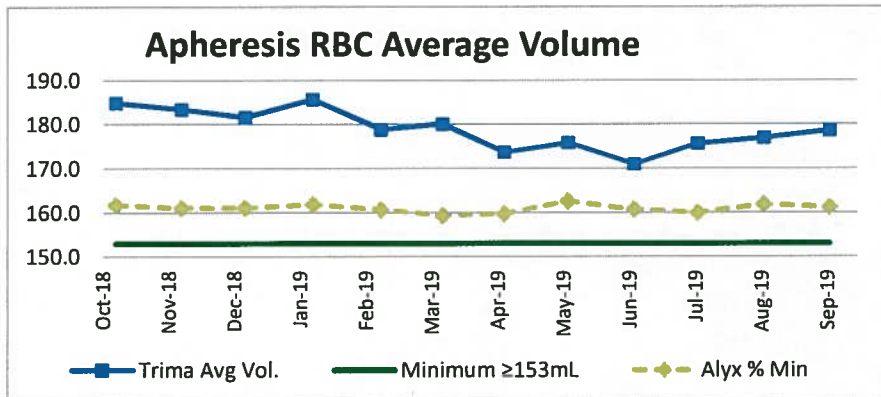
Rolling 12 Month Report

3rd Quarter, 2019

Versiti Indiana  
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**Product Quality Summary Report**  
**Rolling 12 Month Report**

**Apheresis RBC Abs. RBC Vol.**

	<b>Trima</b> Avg Vol. (Accept. ≥ 153mL)	<b>Alyx</b> Avg Vol. (Accept. ≥ 153mL)	<b>Trima</b> % Min (153mL) (Accept. ≥95%)	<b>Trima</b> % Min (>128ml) (Accept. 100%)	<b>Alyx</b> % Min (>128ml) (Accept. 95%)
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
Apr-19	173.7	159.7	100.0	100.0	100.0
May-19	175.8	162.7	100.0	100.0	100.0
Jun-19	171.0	160.7	98.2	98.2	100.0
Jul-19	175.7	160.0	100.0	100.0	100.0
Aug-19	176.9	161.9	100.0	100.0	100.0
Sep-19	178.6	161.2	100.0	100.0	100.0

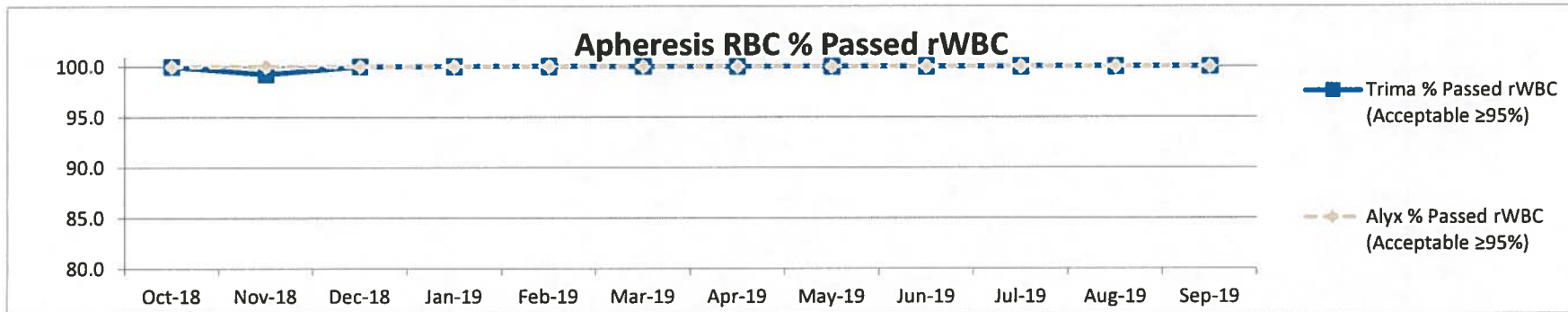


Per manufacturer's specifications and AABB standards, Apheresis Red Blood Cells Leukocytes Reduced shall be prepared by a method known to ensure final components contain a mean red cell volume of 153 mL. All products ≤128 mL are discarded.

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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	
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	
Apr-19	100.0	100.0	0	
May-19	100.0	100.0	0	
Jun-19	100.0	100.0	4	See DEV-19-01130, -01131, -01249, -01250
Jul-19	100.0	100.0	0	See DEV-19-01614
Aug-19	100.0	100.0	0	
Sep-19	100.0	100.0	1	See DEV-19-02252, 01961

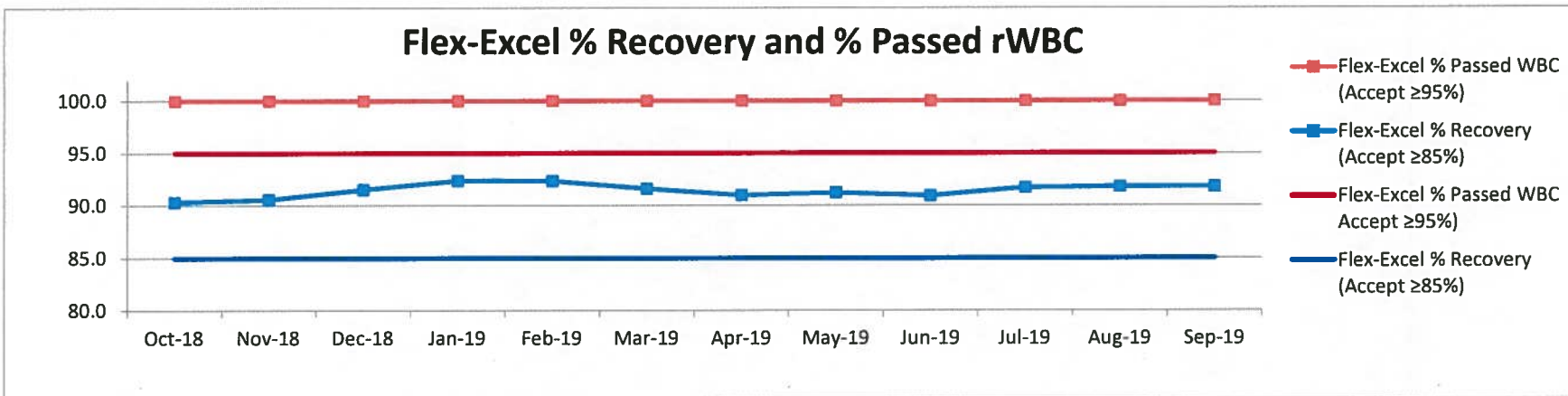


Per FDA guidelines and AABB standards, 95% of units sampled shall contain <math>5 \times 10^6</math> residual white cells. All products containing  $\geq 5 \times 10^6$  residual white cells are discarded. Percent recovery cannot be calculated for Trima collected apheresis RBCs but can be manually calculated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

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**WB Leukoreduction**

	<b>Flex-Excel</b> % Recovery (Acceptable ≥85%)	<b>Flex-Excel</b> % Passed rWBC (Acceptable ≥ 95%)
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
Apr-19	91.0	100.0
May-19	91.2	100.0
Jun-19	90.9	100.0
Jul-19	91.7	100.0
Aug-19	91.8	100.0
Sep-19	91.8	100.0

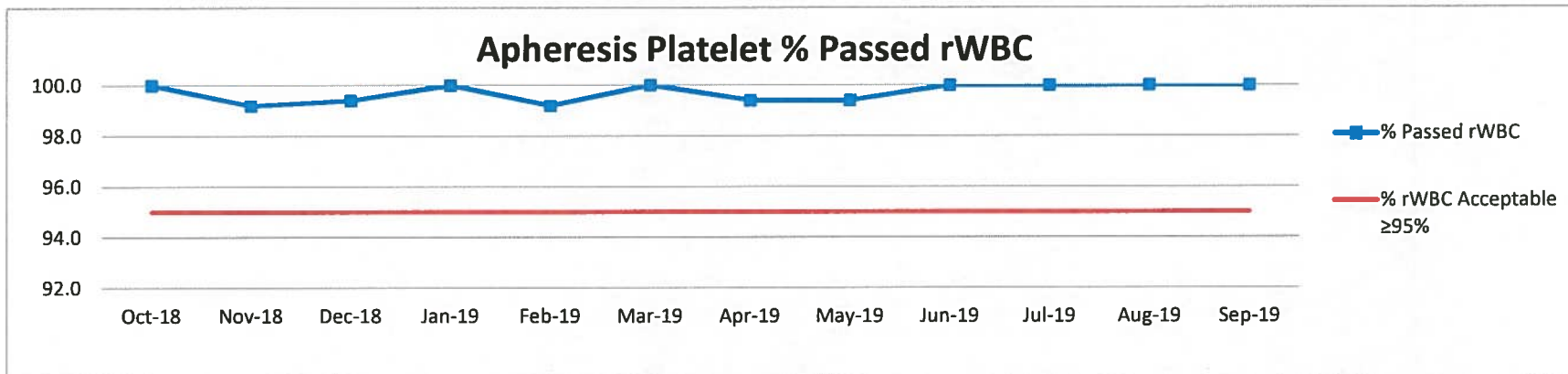


Per FDA guidelines and AABB standards, 95% of units sampled shall contain  $<5 \times 10^6$  residual white cells. All products containing  $\geq 5 \times 10^6$  residual white cells are discarded. Per AABB standards, the leukocyte reduction process must result in recovery of  $\geq 85\%$  of the residual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

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**Apheresis Platelet Leukoreduction**

	<u>% Passed rWBC</u> (Acceptable $\geq 95\%$ )	<u>No. Failed</u>	
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	
Apr-19	99.4	1	See QCF-19-0003
May-19	99.4	1	See QCF-19-0004
Jun-19	100.0	0	
Jul-19	100.0	0	See DEV-19-01617
Aug-19	100.0	0	
Sep-19	100.0	0	

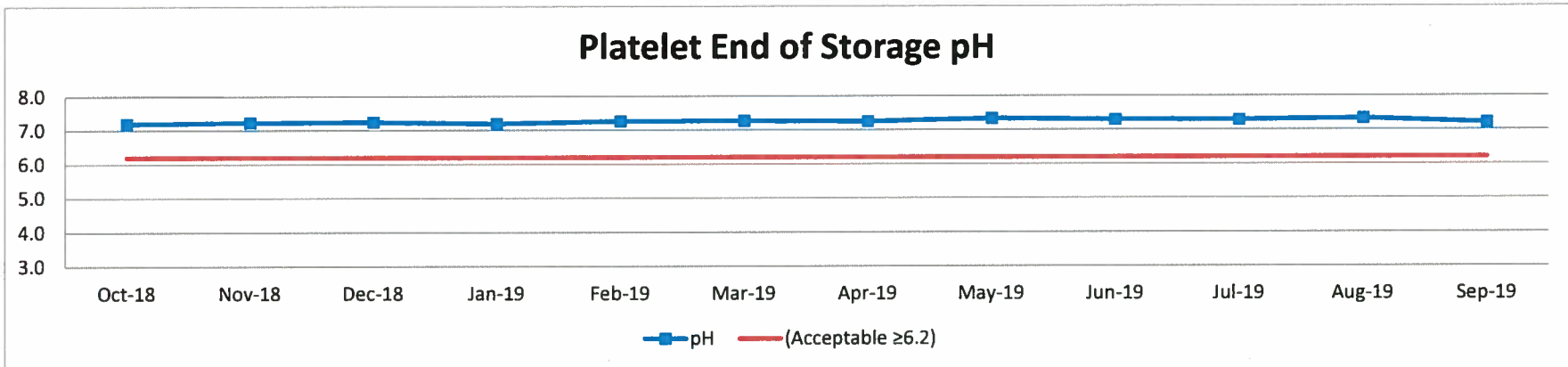


These products are initially leukocyte reduced during the collection process. Per FDA guidelines and AABB standards, 95% of units sampled shall contain  $< 5 \times 10^6$  residual white cells. All products containing  $\geq 5 \times 10^6$  residual white cells are filtered and retested. Platelet % recovery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

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**Plateletpheresis End-Of-Storage (MD157-02.1)**

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

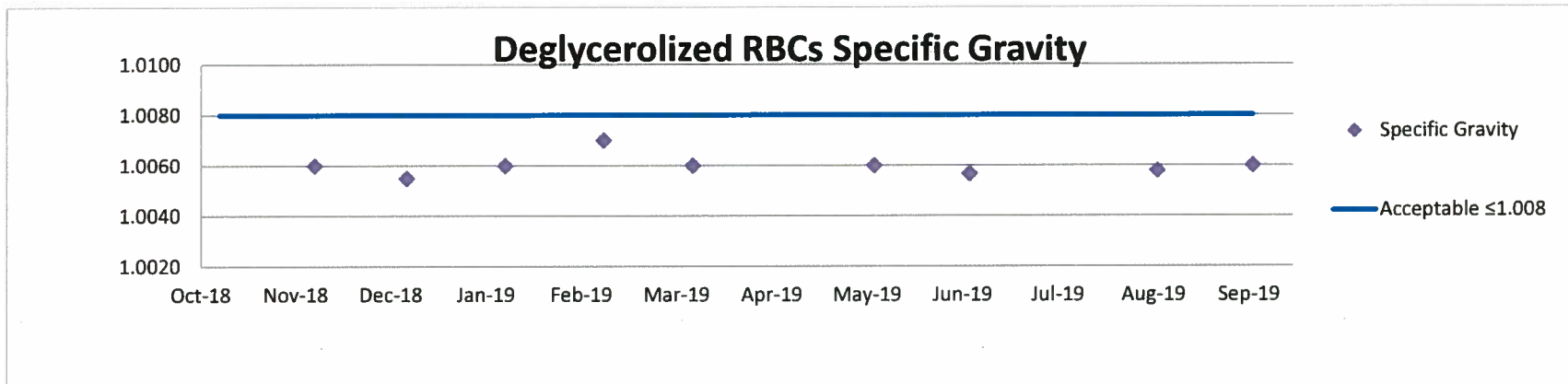


Per AABB standards and FDA guidelines, at least 90% of platelets tested shall have a pH of  $\geq 6.2$ . Any product with a pH of  $< 6.2$  is discarded.

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**Deglycerolized RBCs**

	<b><u>Specific Gravity (CP301-05.1)</u></b> (Accept. $\leq 1.0080$ )	<b><u>Hemolysis Check (CP301-05.1)</u></b> Target = No Hemolysis (Hemolysis $\leq 4$ )	<b><u>% Recovery (CP803-01.1)</u></b> Accept. $\geq 80\%$ (Performed Quarterly)
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%
Apr-19	None Tested	None	
May-19	1.0060	4	
Jun-19	1.0057	3	93.0%
Jul-19	None Tested	None	
Aug-19	1.0058	4	88.0%
Sep-19	1.0060	3	87.0%



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.  $\leq 1.008$  are determined to have achieved adequate removal. Additionally there must be recovery of 80% of the original red blood cells. This is tested quarterly.

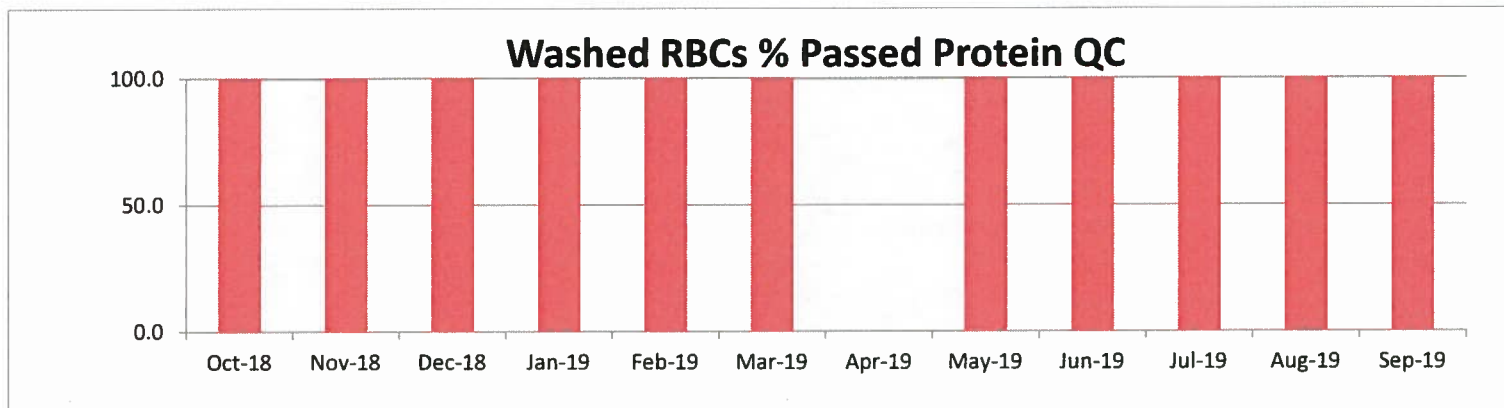
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**Washed RBCs (CP310-05.1)**

**% Passed Protein QC**

(Target = 100%)

Oct-18	100.0
Nov-18	100.0
Dec-18	100.0
Jan-19	100.0
Feb-19	100.0
Mar-19	100.0
Apr-19	None Tested
May-19	100.0
Jun-19	100.0
Jul-19	100.0
Aug-19	100.0
Sep-19	100.0



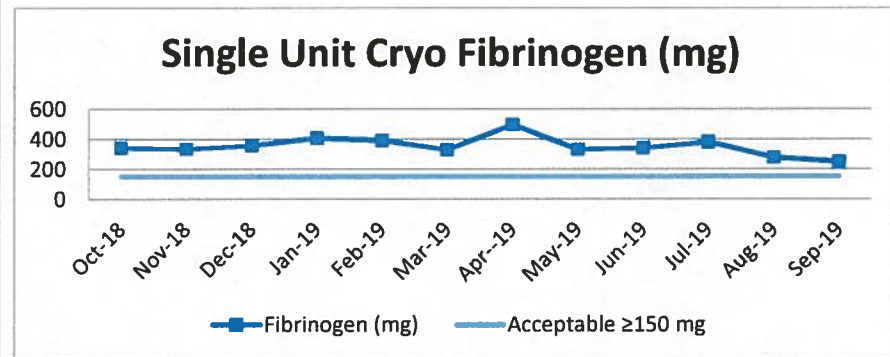
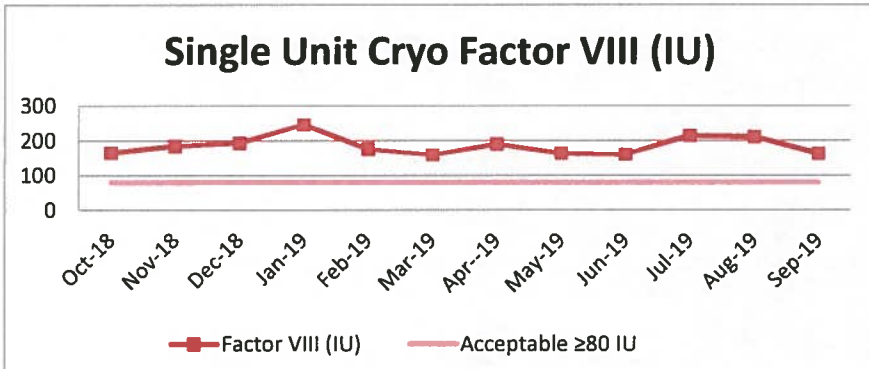
Per AABB standards, washed red blood cells shall be prepared by a method known to ensure that the red cells are washed with a volume of compatible solution that will remove almost all of the plasma. This is determined by testing each product for residual supernatant protein.



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**Cryoprecipitate Single Unit (CP806-01.1)**

	<b>Factor VIII</b> (Acceptable $\geq 80$ IU)	<b>Fibrinogen</b> (Acceptable $\geq 150$ mg)
Oct-18	166	342
Nov-18	185	335
Dec-18	193	358
Jan-19	245	408
Feb-19	176	393
Mar-19	160	330
Apr--19	190	494
May-19	164	332
Jun-19	162	343
Jul-19	214	381
Aug-19	211	277
Sep-19	163	248



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

Oct-18	None tested
Nov-18	None tested
Dec-18	None tested
Jan-19	None tested
Feb-19	2.0
Mar-19	None tested
Apr-19	None tested
May-19	None tested
Jun-19	None tested
Jul-19	None tested
Aug-19	2.0
Sep-19	3.5

**Passing Rate (for 12 months)**

(Accept. > 75% Passing)

100
100
100

