

Versiti Indiana

Indianapolis, IN 46208



Product Quality Summary Report

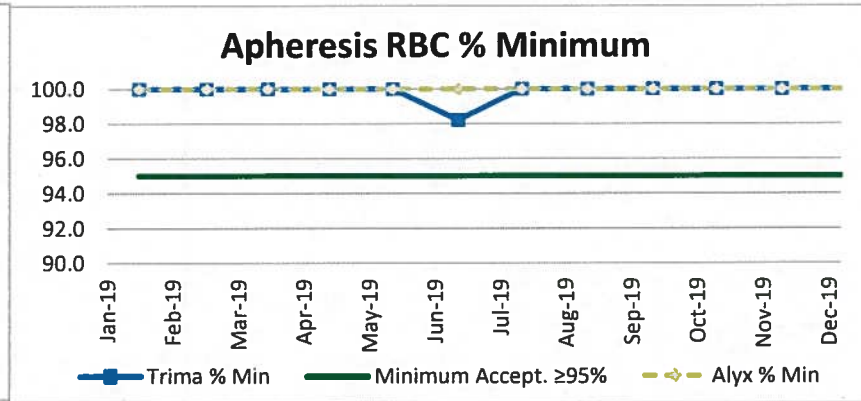
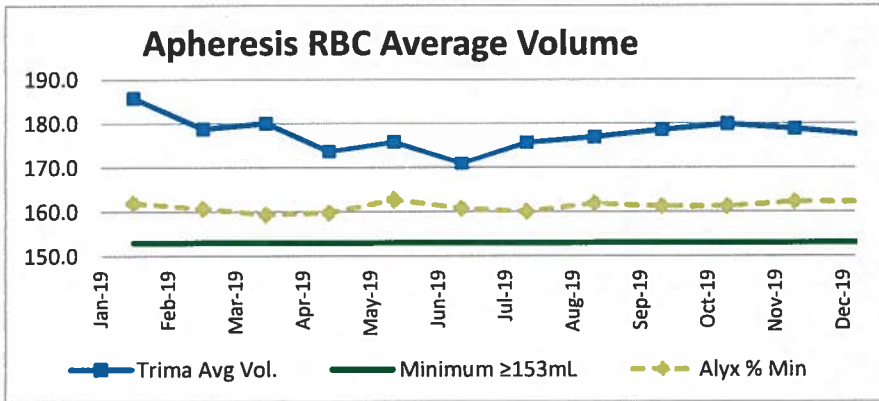
Rolling 12 Month Report

4th Quarter, 2019

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Apheresis RBC Abs. RBC Vol.

	<u>Trima</u>	<u>Alyx</u>	<u>Trima</u>	<u>Trima</u>	<u>Alyx</u>
	Avg Vol.	Avg Vol.	% Min (153mL)	% Min (>128ml)	% Min (>128ml)
	(Accept. ≥ 153mL)	(Accept. ≥ 153mL)	(Accept. ≥95%)	(Accept. 100%)	(Accept. 95%)
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
Oct-19	179.8	161.2	100.0	100.0	100.0
Nov-19	178.7	162.2	100.0	100.0	100.0
Dec-19	177.4	162.1	100.0	100.0	100.0

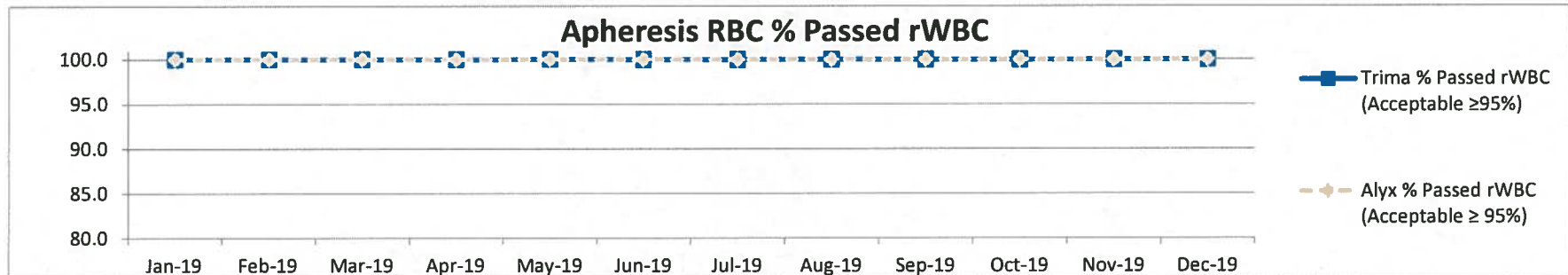


Per manufacturer's specifications and AABB standards, Apheresis Red Blood Cells Leukocytes Reduced shall be prepared by a method known to ensure final components contain a mean red cell volume of 153 mL. All products ≤128 mL are discarded.

**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	
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
Oct-19	100.0	100.0	0	
Nov-19	100.0	100.0	0	
Dec-19	100.0	100.0	4	See DEV-20-00082

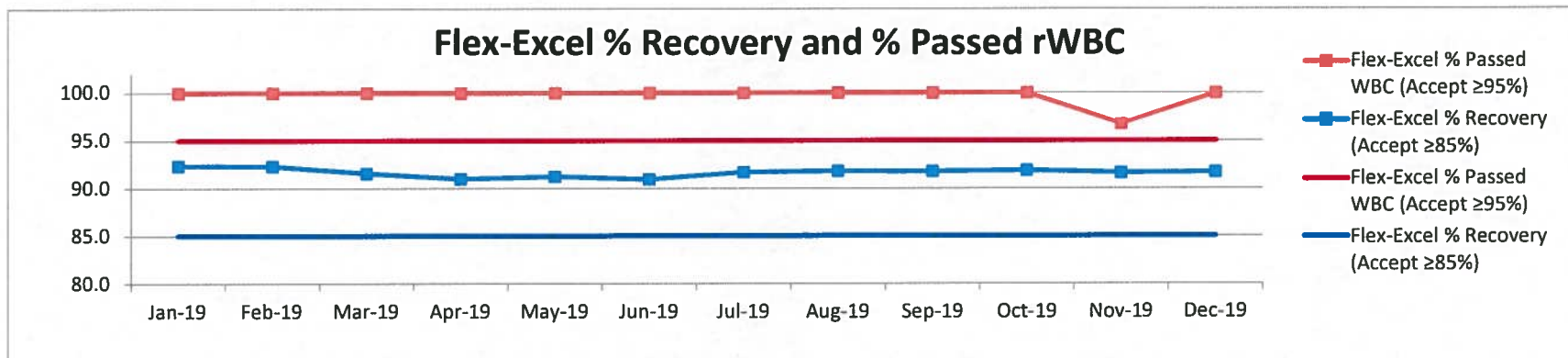


Per FDA guidelines and AABB standards, 95% of units sampled shall contain 5×10^6 residual white cells. All products containing $\geq 5 \times 10^6$ residual white cells are discarded. Percent recovery cannot be calculated for Trima collected apheresis RBCs but can be manually calculated for MCS+ QC units 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%)
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
Oct-19	91.9	100.0
Nov-19	91.6	96.8
Dec-19	91.7	100.0

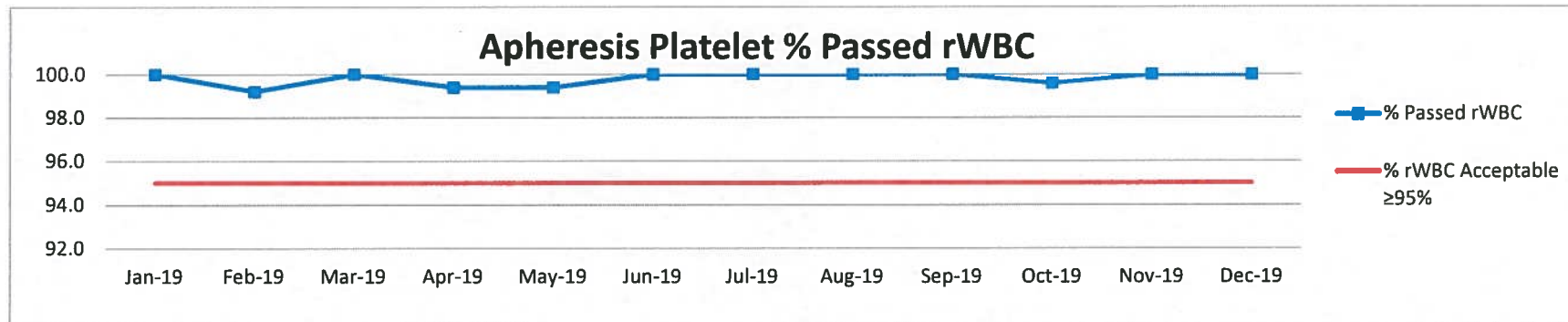


Per FDA guidelines and AABB standards, 95% of units sampled shall contain $<5 \times 10^6$ residual white cells. All products containing $\geq 5 \times 10^6$ residual white cells are discarded. Per AABB standards, the leukocyte reduction process must result in recovery of $\geq 85\%$ of the residual 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>	
Jan-19	100.0	0	
Feb-19	99.2	2	See QCF-19-0001, -0002
Mar-19	100.0	0	DEV-19-00658
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	
Oct-19	99.6	1	See QCF-19-0007
Nov-19	100.0	0	
Dec-19	100.0	0	

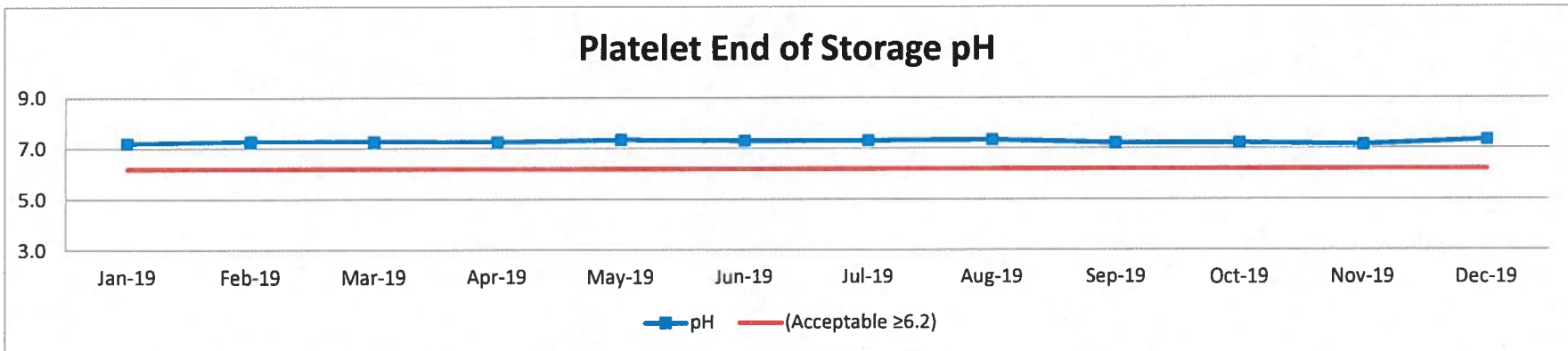


These products are initially leukocyte reduced during the collection process. Per FDA guidelines and AABB standards, 95% of units sampled shall contain $< 5 \times 10^6$ residual white cells. All products containing $\geq 5 \times 10^6$ residual white cells are filtered and retested. Platelet % recovery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

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Plateletpheresis End-Of-Storage (MD157-02.1)

	<u>pH</u>
	(Acceptable ≥ 6.2)
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
Oct-19	7.2
Nov-19	7.1
Dec-19	7.3

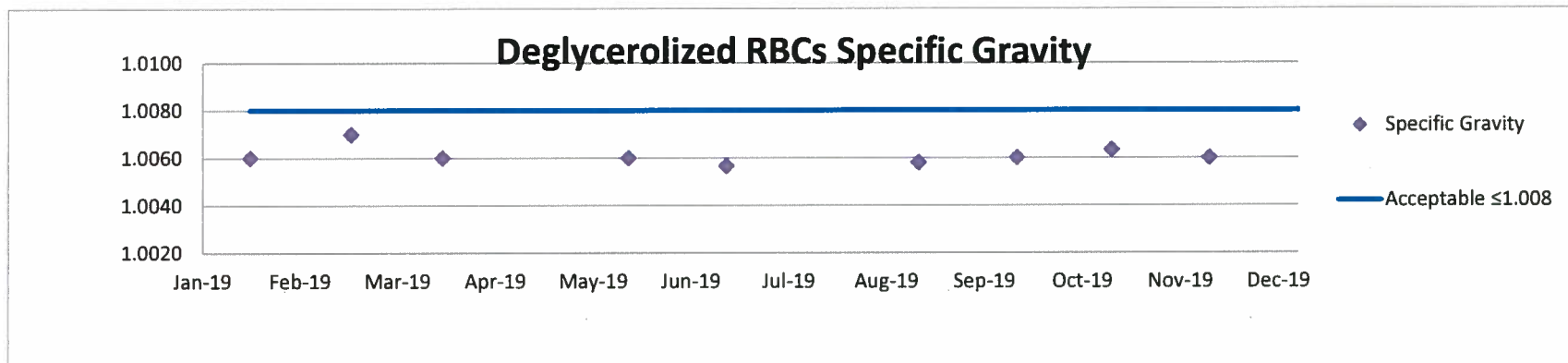


Per AABB standards and FDA guidelines, at least 90% of platelets tested shall have a pH of ≥ 6.2 . Any product with a pH of < 6.2 is discarded.

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Deglycerolized RBCs

<u>Specific Gravity (CP301-05.1)</u>		<u>Hemolysis Check (CP301-05.1)</u>	<u>% Recovery (CP803-01.1)</u>
(Accept. ≤ 1.0080)		Target = No Hemolysis (Hemolysis ≤ 4)	Accept. $\geq 80\%$ (Performed Quarterly)
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%
Oct-19	1.0063	3	NA
Nov-19	1.0060	4	90.9%
Dec-19	1.0060	4	89.7%



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.

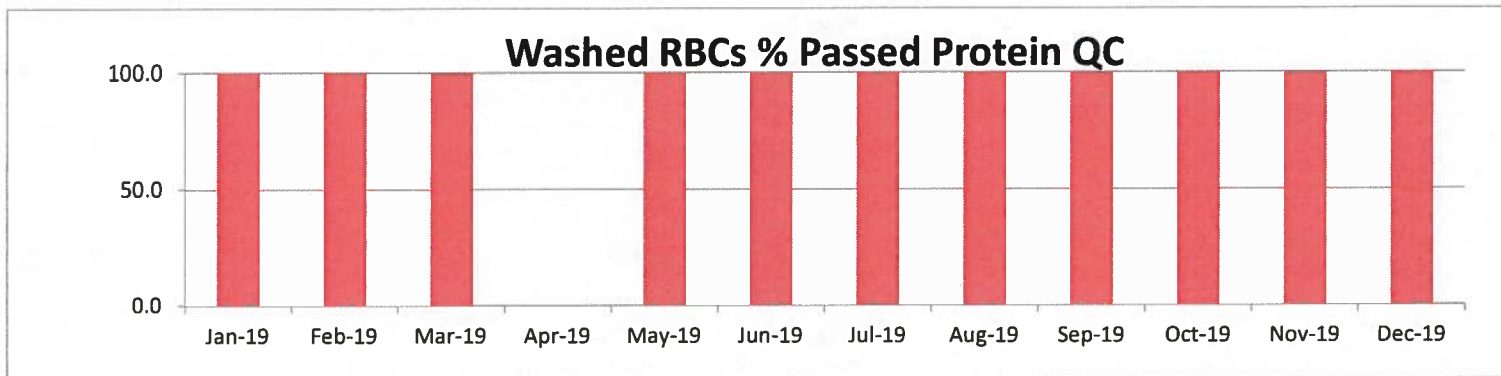
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Washed RBCs (CP310-05.1)

% Passed Protein QC

(Target = 100%)

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
Oct-19	100.0
Nov-19	100.0
Dec-19	100.0

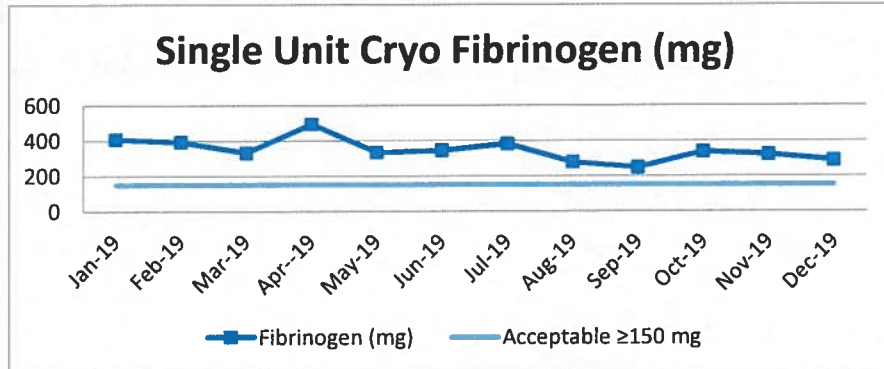
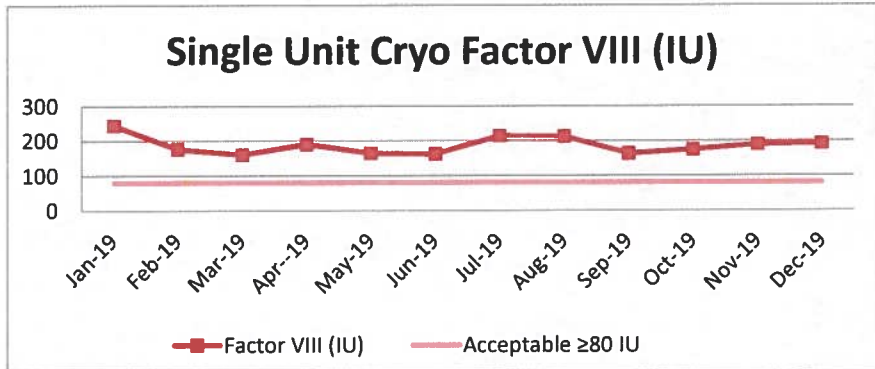


Per AABB standards, washed red blood cells shall be prepared by a method known to ensure that the red cells are washed with a volume of compatible solution that will remove almost all of the plasma. This is determined by testing each product for residual supernatant protein.

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Cryoprecipitate Single Unit (CP806-01.1)

	Factor VIII (Acceptable ≥ 80 IU)	Fibrinogen (Acceptable ≥ 150 mg)
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
Oct-19	174	338
Nov-19	189	321
Dec-19	191	289



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

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
Oct-19	None tested
Nov-19	None tested
Dec-19	None tested

Passing Rate (for 12 months)

(Accept. > 75% Passing)

100
100
100
100

