PPTA
Plasma Protein Therapeutics Association

Viral Marker Standard

Implemented 1999
Revised 2009

Version 4.1

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IQPP Viral Marker Standard

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I. Viral Marker Standard

The Viral Marker Standard is based on the industry wide viral testing rates and the plasma center collection volume and includes both a composite of viral marker confirmed positives by serology or NAT and an assessment of individual marker positives for HIV, HCV, and HBV. Data collection for the application of this standard commenced with the month of October 1998. NAT test results for HIV and HCV became part of this Standard January 1, 2002 and HBV January 1, 2003. The Standard is as follows:

1. All IQPP certified facilities must participate in the PPTA viral marker data collection program. Data on serology collections and NAT and viral marker test results must be submitted three months after the bleed month. Viral marker data reports must be submitted to PPTA by the 20th of each month.

2. If data have not been reported to the Association within 30 days of the due date, a letter will be sent to the Corporate Board Member or Company Contact via expedited mail informing them that IQPP certification could be withdrawn if data are not reported within 48 hours.

3. All IQPP certified facilities must have qualified confirmed positive viral marker numbers by serology and/or NAT for HIV, HCV, HBV, and a composite of the three markers at or below the PPTA published Viral Marker Alert Limits.

4. Should an IQPP certified plasma center exceed the Viral Marker Alert Limit, the plasma center has 30 days from notification to submit a corrective and preventive action plan (CAPA) to PPTA. The plasma center will have six (6) months following submission of the CAPA to demonstrate a viral marker rate below the Viral Marker Alert Limit or IQPP Certification will be withdrawn.

5. All IQPP certified facilities must have a mechanism for developing CAPAs should the plasma center exceed the Viral Marker Alert Limits. This must include provisions for investigation, performance of root cause analysis, involvement of appropriate staff and records, and development of corrective and preventive action.

II. Viral Marker Alert Limits

The viral marker alert limits are based on Poisson Distribution probability tables. These tables assess the relative probability of any number of confirmed positive donors based on any given number of total donations and the industry wide average viral positive rates for Qualified Donors. Thus, each plasma center can be assessed with the same periodicity using its own collection volume. The use of probabilities as a standard setting tool permits fair comparisons of all plasma centers regardless of the number of total collections for a given period. Appendix I contains the PPTA viral marker alert limits confirmed positive by serology & NAT for HCV, HIV and HBV. It also includes a composite table of the three markers.

III. Probability and Reference Rates

The Alert Limits are set at a probability of 0.01 for the viral marker rate standard composite and a probability of 0.005 for the individual viral markers. This means that a plasma center would fall outside the standard if it had more positive donors than would be expected 99% or 99.5% of the time for a plasma center based on their number of donations for a given period. The actual number of positive donors that would put a plasma center outside the standard will depend on two factors: the number of donations at a plasma center for a given period and the reference rate.

The reference rate refers to the overall industry average viral marker rates that serve as the basis for establishing the probability tables. The industry viral marker prevalence for qualified donors measured during the data collection year of January through December 2000 is the basis for the standard for HCV, HIV and the composite. The industry viral marker prevalence for qualified donors measured during the data collection year of January through December 2001 is the basis for the standard for HBV.

IV. Review Period and Other Timing Issues

Enclosed is a timeline of important events associated with the administration of the standard (Table I).

Table I describes the normal events in the data collection and standard administration process. Data are collected on a monthly basis. An interim report (A) of the data received by PPTA will be provided to member companies for their plasma centers after the first three months of any review period (B). Data evaluations (C) will take place in April and October of each year. The April evaluation will cover the period from July 1 through December 31. The October

evaluation will cover the period from January 1 through June 30. Given the time needed for companies to report data to PPTA and the time needed to generate the six-month statistical analyses for each plasma center, it is anticipated that the individual plasma center evaluations will be completed within 120 days of the close of the evaluation period. Thus, plasma centers will be notified of their compliance status for any given evaluation period within 120 days following the close of the evaluation period.

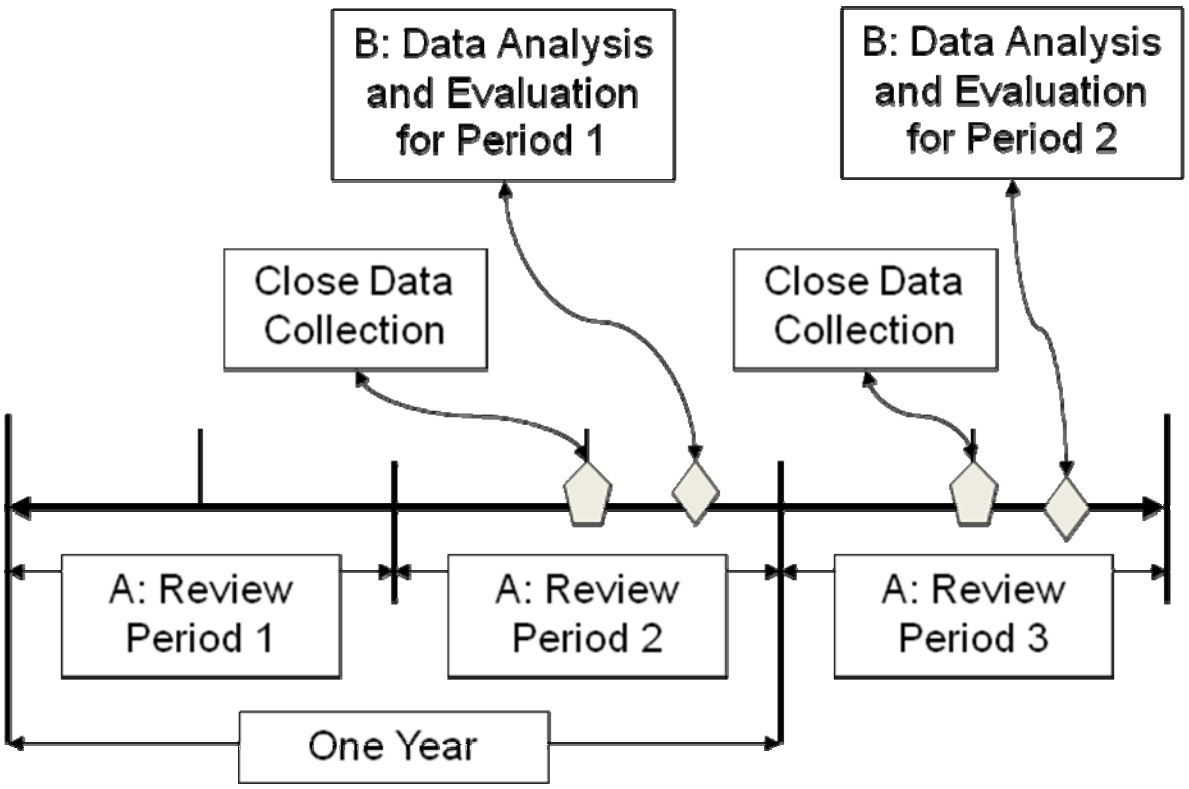
A plasma center that is deemed to be out of compliance for any given evaluation period will be required to submit its CAPA approximately 30 days after receiving notification of their compliance status. Thus, from the close of the evaluation period, plasma centers will have 120 days until their status is determined and, if out of compliance, will have another 30 days to prepare and submit a CAPA.

To demonstrate compliance, a previously out of compliance plasma center must have viral marker rates within the standard for the next six month evaluation period. IQPP status determination will occur following the next six-month evaluation period. If a previously out of compliance plasma center demonstrates compliance with the viral marker standard during that evaluation period, they will maintain their certification. If an out of compliance plasma center does not demonstrate improvement, i.e. viral marker numbers within the acceptable limits, IQPP certification will be revoked.

IQPP Certification will be revoked from any plasma center exceeding their acceptable limits more than three times in a three year period.

Companies will be invited to appeal their certification revocation to the PPTA Source Board.

Table 1. Data Review Timeline



Data Reporting Requirements:
Serology and NAT Data – 3 months after reporting month
(Aug. 2004 data due 11/20/04)

APPENDIX I – PPTA Viral Marker Alert Limits

Virus type = Composite Confirmed Positives by Serology or NAT (HBV, HCV and HIV combined)

Alert limits are based on observed qualified donor prevalence (reference rate) of 8 per 100,000 donations and will be applied for a given six-month period.

TOTAL NUMBER OF DONATIONS		MAXIMUM NUMBER OF CONFIRMED POSITIVE DONORS
FROM	TO	
0	1856	1
1857	5450	2
5451	10290	3
10291	15988	4
15989	22316	5
22317	29127	6
29128	36326	7
36327	43843	8
43844	51627	9
51628	59640	10
59641	67852	11
67853	76238	12
76239	84779	13
84780	93459	14
93460	102263	15
102264	111182	16
111183	120000	17

Last Revision: January 2003

PPTA Viral Marker Alert Limits
Virus type = HCV Confirmed Positives by Serology or NAT

Alert limits are based on observed qualified donor prevalence (reference rate) of 4 per 100,000 donations and will be applied for a given six-month period.

TOTAL NUMBER OF DONATIONS		MAXIMUM NUMBER OF CONFIRMED POSITIVE DONORS
FROM	TO	
0	2699	1
2700	8799	2
8800	17699	3
17700	28499	4
28500	40799	5
40800	54199	6
54200	68599	7
68600	83699	8
83700	99399	9
99400	115699	10
115700	132499	11
132500	149599	12
149600	167199	13
167200	184999	14

Last Revision: January 2003

PPTA Viral Marker Alert Limits
Virus type = HIV Confirmed Positives by Serology or NAT

Alert limits are based on observed qualified donor prevalence (reference rate) of 1 per 100,000 donations and will be applied for a given six-month period.

TOTAL NUMBER OF DONATIONS		MAXIMUM NUMBER OF CONFIRMED POSITIVE DONORS
FROM	TO	
0	10699	1
10,700	35199	2
35,200	70599	3
70,600	113899	4
113,900	162999	5

Last Revision: January 2003

PPTA Viral Marker Alert Limits
Virus type = HBV Confirmed Positives by Serology or NAT

Alert limits are based on observed qualified donor prevalence (reference rate) of 3 per 100,000 donations and will be applied for a given six-month period.

TOTAL NUMBER OF DONATIONS		MAXIMUM NUMBER OF CONFIRMED POSITIVE DONORS
FROM	TO	
0	3449	1
3450	11262	2
11263	22406	3
22407	35930	4
35931	51230	5
51231	67911	6
67912	85703	7
85704	104413	8
104414	120000	9

Last Revision: January 2003

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Revision History

Date	Version	History
Nov 1999		
Sept 2000		Text “internationalized.” [9/2000]
Oct 2001		Changes made (1) to accurately reflect use of numbers, not rates, for assessing viral marker compliance and
		(2) to correct interpretation of table from donations to donors. [10/15/01]
Feb 2002		Changes made to reflect merger/name change PPTA Source [2/14/02]
Oct 2002		Incorporation of NAT and HCV [10/1/02]
Jan 2003		Incorporation of NAT for HBV [1/1/03]
Dec 2003		Changes made to reflect name change PPTA Source to PPTA [12/18/03]
Oct 2004		Change reporting of serology data to 3 months prior instead of 2 [10/26/04]
April 2006	4.0	Changes made to clarify definitions and reporting requirements.
Jan 2009	4.1	Changed Corrective Action period to align with Evaluation Period. Clarified allowance for appeals process. Set maximum limit for going on Alert List in a 3 year time period.
Jan 2013	4.1	Document format change ONLY