A Comparison: CPR standards versus regulatory requirements

No.	Description	Canadian Plasmapheresis Regulations	CPR's Standard (Based on Canadian, IQPP and FDA regulations)
Donor Selection and Qualification process:			
01	Community-based donors		
	▪ *Donors applicants must reside within a defined radius from the Plasma Center*	No	Yes (100km radius)
	▪ *Donor address must be checked against a recruitment area map (homeless shelters, hotels, motels or missions are not acceptable)*	No	Yes
02	Elimination of high risk donors and test-seekers		
	▪ *Number of acceptable medical screenings and viral testing required to become a qualified donor*	1	2 separate within 16 weeks
03	Donor age limit	17 years or older	Between 17 to 61
04	National Donor Deferral Registry (NDDR) program		
	▪ *Donors are checked against the NDDR*	No	Yes
	▪ *Reactive donors are entered in the NDDR*	No	Yes
05	Re-entry program for indefinitely deferred donors upon receiving negative confirmatory test results for HIV, Hepatitis B (HBV) and Hepatitis C (HCV)	Possible	Not possible
06	Issuance of "Certificate of good health"	Is not required	Required
Medical Examination:			
07	Allowable time limit between medical examinations and donation	Up to 30 days	Same day
08	Frequency of full medical examination	Once a year	Every 16 weeks
09	Minimum physical examination requirements	Not defined	Defined (as per FDA recommendations)
Transmissible Disease Marker Testing performed every donation:			
10	Antibody Testing		
	▪ *HIV types 1 and 2*	Yes	Yes
	▪ *HCV*	Yes	Yes
	▪ *Hepatitis B Virus Surface Antigen (HbsAg)*	Yes	Yes
11	Nucleic Acid Testing (NAT)		
	▪ *HIV types 1 and 2*	Yes	Yes
	▪ *HCV*	Yes	Yes
	▪ *HBV*	No	Yes
	▪ *Hepatitis A Virus (HAV)*	No	Yes
	▪ *Parvovirus B19*	No	Yes

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No.	Description	Canadian Plasmapheresis Regulations	CPR's Standard (Based on Canadian, IQPP and FDA regulations)
Transmissible Disease Marker Testing performed every donation (cont'd):			
12	*Serological Testing*		
	▪ *Syphilis*	Yes	Yes
Product Safety:			
13	Number of donated units tested before a plasma unit from an applicant donor is released?	1	2
14	QSEAL standard: 60 day inventory hold from the time of collection to fractionation for easy retrieval of units in case of a look-back	Not required	required
15	Plasma centres must meet the viral marker alert limits for the number of positive test results	Not required	Under or equal to the limit
Product Quality:			
16	Allowable time limit from plasma collection to downfreezing	Not specified	Maximum 4 hours
17	Defined conditions for plasma downfreezing	Not specified	Plasma core must reach -25°C within 8 hours