Variances Granted for the *30th Edition of Standards Blood Banking and Transfusion Services*

Country	*Facility*	*Accredited Activity*	*Variance Request*	*Rational behind granted request*
Argentina	Hospital Nacional De Pediatria Garrahan	BBTS	5.8.5 – WNV	West Nile Virus testing is not currently required in Argentina and there have not been any reported cases in the country. However, the facility was requested to continue to work with public health authorities that monitor incidence of West Nile Virus in Argentina.
Brazil	Centro Regional de Hemoterapia do HCFMRP - USP – Hemocentro	BBTS	5.8.5, 5.8.6 – WNV	West Nile Virus testing is not required in Brazil and cases of the disease have not been reported. The facility's process in place to screen donors and defer if necessary meets the intent of the standard.
Brazil	Hospital Albert Einstein	BBTS	5.8.5—WNV 5.4.1A, #13—Malaria	West Nile Virus testing is not required in Brazil and cases of the disease have not been reported. The facility was requested to implement a mechanism to collaborate with local health authorities responsible for monitoring the population for cases of West Nile Virus. The facility was also requested to put a process place to ensure proper response to an outbreak of West Nile Virus in the event an outbreak occurs. The facility's screening in place to ensure donors whom have been potentially exposed to malaria are deferred from donation meets the intent of the standard.
China	Daping Hospital	BBTS	5.7.4.18—Volume unit, 5.7.4.21—Volume unit 5.19.2—CMV	The facility's method to collect smaller volume units meets the intent of standards. The People's Republic of China's Ministry of Health inspected the practice and approves of its use. The facility's process to provide clinicians with leuko-reduced blood on demand if needed, in place of performing CMV testing, meets the intent of the standard.
China	Hong Kong Red Cross	BBTS	5.1.4—Use of Materials 5.7.4.18—Platelets 5.8.5 – anti HBC 5.8.5 – WNV NAT 5.8.5 – *T. cruzi* 5.4.1A #1—Whole Blood 5.4.1A, #5B—Requirements for Allogeneic Donor Qualification	The facility's process in place with the inclusion of package insert meet the intent of the standard. The facility's approach to produce whole blood platelets from low volume units is appropriate to meet the intent of the standard. The facility's use of NAT for HBV in place of anti HBC meets the intent of the standard. The facility performs donor screening to ensure donors that have been potentially exposed to West Nile Virus are deferred from donation meets the intent of the standard. The facility's plan in place to defer donors with a history of *T. cruzi* meets the intent of the standard. The facility's validated process in place to extend the expiration time of whole blood as described meets the intent of the Standards. The facility's method in place meets to adjust required hemoglobin levels based on the donor's gender meets the intent of the standard.
Dominican Republic	Referencia Banco de Sangre (BBTS)	BBTS	5.8.5—WNV 5.8.5—*T. cruzi* 5.4.1A #13—Malaria	The facility's approach to screen donors for potential exposure to West Nile Virus, and deferring them accordingly meets the intent of the standard. The facility's approach to screen donors for potential exposure to *T. cruzi*, and deferring them accordingly would meet the intent of the standard. The facility's screening in place to ensure donors who have been potentially exposed to malaria are deferred from donation meets the intent of the standard.
Honduras	Centro Nacional de Sangre, Cruz Roja Hondurena	BBTS	5.8.5—WNV 5.8.5—FDA Requirements	West Nile Virus testing is not currently required in Honduras, and there have not been no reported cases in the country. The facility was requested to continue to work with public health authorities that monitor incidence of West Nile Virus in Honduras and screen and defer donors accordingly.

			5.4.1A #13—Malaria	The facility's use of the ABBOTT Architect system adequately meet the intent of the standard to test for infectious diseases in a manner that meets FDA criteria. The facility's process described to defer potential and confirmed malaria positive donors adequately meets the intent of the standard.
Kuwait	Kuwait Central Blood Bank	BBTS	5.8.5, 5.8.6, 5.4.1A – *T. Cruzi*	The facility is not required to perform *T. cruzi* testing of your allogeneic donor population. The facility was requested to implement donor screening measures to capture potential donors who may have travelled to a *T. cruzi* endemic region. The facility was also encouraged to work with their health authorities to develop a plan to respond to any potential outbreaks of *T. cruzi* or other infectious diseases.
			5.8.5, 5.8.6, 5.4.1A – WNV	The facility's process in place to screen all potential donors for WNV exposure is sufficient to the meet the intent of the standard.
			5.8.4, 5.4.1A – Anti-HBc	The facility is meeting the requirement of the standard but has been requested to move towards implementing HBV DNA testing in the future to meet the intent of standard without the need of a variance.
			5.1.6A, #14, 15 – Donor Unit Labeling	The facility does not label Apheresis units collected from paid donors as "Paid" as it is contrary to the regulations put forth by the Kuwaiti Ministry of Health.
			5.4.1A, #13 – Malaria	Malaria testing is not required in Kuwait however donors are deferred if they are suspected of being positive for the disease.
Mexico	Centro Estatal de la Transfusion Sanguinea	BBTS	5.8.5 – anti HTLV I/II	The facility does not perform anti HTLV I/II testing as it is not required by the Mexican Ministry of Health, however they do screen donors for the disease and defer those that could potentially provide virulent units.
			5.8.5 – WNV	The facility does not perform WNV RNA testing as it is not required by the Mexican Ministry of Health. The facility does screen donors based on their travel history to ensure that those donors that have visited countries where the disease is present are deferred accordingly.
			5.19.4 – Hemoglobin S Testing	The facility does not perform Hemoglobin S testing as it is not required by the Mexican Ministry of Health, however they are complying with the standard to have a policy in place should a donor be a potential carrier of the disease.
Saudi Arabia	King Abdul Aziz Medical City—Jeddah	BBTS	5.8.5— WNV; *T. cruzi* testing	The facility's plan in place to meet the requirements of the standard is adequate. It was recommended that the facility continue to perform donor screening to capture potential donors who may have travelled to a *T. cruzi* or West Nile Virus endemic region.
Saudi Arabia	King Abdulaziz Medical City – Riyadh	BBTS	5.8.5— *T. cruzi*	Saudi Arabia is not endemic for *T.cruzi*. As evidence is a Memorandum by the Kingdom of Saudi Arabic National Guard Health Affairs, the facility's local regulation does not require testing for *T.cruzi*. In lieu of *T. cruzi* testing of their allogeneic donor population, the facility was requested to implement donor screening measures to capture potential donors who may have travelled to a *T. cruzi* endemic region.
			5.8.5—WNV	Saudi Arabia is not endemic area for WNV. As evidence in a Memorandum by the Kingdom of Saudi Arabic National Guard Health Affairs, the facility's local regulation does not require testing for WNV RNA. In lieu of WNV RNA testing, the facility was requested to have a mechanism to collaborate with local health authorities responsible for monitoring the population for cases of West Nile Virus and to have a plan to respond to an outbreak of West Nile Virus in the event an outbreak occurs.
			5.1.8A, #17—Platelet concentrates, Leukoreduced	The facility's process meets the intent of the standard. Platelet concentrates are derived from pooled buffy coat that are pre-stored in a leukoreduced in a closed system, and the process in place has been validated to ensure that these units can be issued for transfusion up to midnight on the fifth calendar day of storage.
Saudi Arabia	King Abdul Aziz Medical City—University Hospital	BBTS	5.8.5— WNV; *T. cruzi* testing	The facility's plan in place to meet the requirements of the standard is adequate. It was recommended that the facility continue to perform donor screening measures to capture potential donors who may have travelled to a *T. cruzi* or West Nile Virus endemic region.
Saudi Arabia	Saad Specialist	BBTS	5.8.5—WNV; *T. cruzi* testing	The facility's plan in place to meet the requirements of the standard is adequate. It was recommended that the facility continue to perform

	Hospital (BBTS)			donor screening measures to capture potential donors who may have travelled to a *T. cruzi* or West Nile Virus endemic region. The facility was encouraged to work with local health authorities to develop a plan for a potential outbreak of either infectious disease.
Singapore	Health Sciences Authority	BBTS	1.5—Communication of Concerns	The facility's process in place including publishing AABB's contact information along with the contact information of local authorities meets the intent of the standard.
			5.1.8A, #1—Whole Blood Storage, Transport, and Expiration	The facility's validated process in place to extend the expiration time for whole blood meets the intent of the Standards.
			5.4.1A, #13—Malaria	The facility's process in place to screen donors and test units that are potentially virulent meets the intent of the standard.
			5.7.4.4—Deglycerolized Red Blood Cells	For all units collected after 2007, facility's quality control monitoring for deglycerolization red cells for release is based on total hemoglobin and supernatant hemoglobin of deglycerolized red cells instead of the stipulated mean recovery of ≥ 80% of the preglycerolization red cells following deglycerolization. For units collected before 2007, the facility was requested to put a process in place to ensure that these units are labeled as not meeting the > 80% recovery and that they only be released under the direction of the medical director in times of urgent need.
			5.7.4.15—Cryoprecipitated AHF	The facility's labeling process in place to label the units in question for "fibrinogen replacement only" meets the intent of the standard as an international variance request. However, any units that would be labeled and tested could not be shipped to the United States without appropriate biohazard labeling.
			5.8.5, 5.8.6—anti HTLV I/II	The facility is not required to perform anti HTLV I/II testing due to the extremely low prevalence of the disease in Singapore.
			5.8.5, 5.8.6—Anti HBc	The facility's use of HBV NAT in place of anti-HBc testing meets the intent of the standard.
			5.8.5, 5.8.6—WNV	The facility's process in place to test donors that have traveled to WNV endemic countries with WNV RNA meets the intent of the standard.
			5.8.5, 5.8.6— *T. cruzi*	The facility's plan in place to permanently defer all donors that have been exposed to *T. cruzi* or traveled to areas endemic for the disease meets the intent of the standard.
United Arab Emirates	Abu Dhabi Blood Bank	BBTS	5.8.5/5.8.6 – *T. cruzi*	The facility's process in place to respond to a potential outbreak satisfies the standard in question. The implementation of a plan to screen all potential donors for exposure to Chagas was encouraged in lieu of mandatory testing. Chagas disease testing is not required in the United Arab Emirates, and cases of the disease have not been reported. Any outbreak of the disease will be investigated by and communicated to blood bank facility.
			5.8.5/5.8.6 – WNV (West Nile Virus)	The facility was requested to implement donor screening for all donors who have potentially been exposed to West Nile Virus in lieu of mandatory testing of West Nile Virus.
United Arab Emirates	Dubai Blood Donation Centre	BBTS	5.8.5/5.8.6 – *T. cruzi*	The facility's process in place to respond to a potential outbreak satisfies the standard in question. The plan in place to screen all potential donors for exposure to *T. cruzi* was accepted in lieu of mandatory testing.
			5.8.5/5.8.6 – WNV (West Nile Virus)	The facility's donor screening process for all donors who have potentially been exposed to West Nile Virus was accepted in lieu of mandatory testing of West Nile Virus.
			5.4.1A, #13 - Malaria	The facility's process described to defer potential and confirmed malaria positive donors adequately meets the intent of the standard.
United Arab Emirates	Sharjah Blood Transfusion and Research Center	BBTS	5.8.5/5.8.6 – *T. cruzi*	Testing for *T. cruzi* is not required in the United Arab Emirates. In this facility, this testing's place, donor screening is performed to ensure the capture of any potentially virulent units.
			5.8.5/5.8.6 – West Nile Virus	The facility's donor screening process for all donors who have potentially been exposed to West Nile Virus was accepted in lieu of mandatory testing of West Nile Virus.

USA—AZ	Blood Systems	BBTS	5.1.6.3.1 – ISBT 128 labeling of blood and blood components, 5.1.6.5.2 –ISBT labeling & ABO/Rh code	The facility's plan to continue to label in Codabar is deemed acceptable with the understanding that the facility be fully compliant with the *Standards* by August 1, 2016.
USA—ID	Medical Regional Blood Center	BBTS	5.1.6.3.1, #1—ISBT 128 labeling of blood and blood components	The facility has agreed to develop a revised ISBT 128 labeling plan for products previously labeled in Codabar, achieving conformance to the Standards by September 28, 2016.
USA- MN	Mayo Clinic	BBTS	5.1.5.1, 5.1.8A, #20, 21 – Testing of platelet components	The facility can now store platelets for a maximum of three days without agitation at 1-6 Celsius. The variance is limited to apheresis platelets collected using the TerumoBCT Trima Accel automated blood collection systems and intended for use in the resuscitation of actively bleeding trauma patients.
			5.14.1, 5.27.1 – Use of O Group Whole Blood	The facility can now use group O non-leukocyte reduced platelet preserved whole blood in trauma situations when the recipient's ABO group is not known.
USA – NJ	Cooper Medical System	BBTS	5.27.1—Use of O Group Whole Group	The facility received a variance to give uncrossmatched group O whole blood to male patients in trauma settings, with the patients receiving no more than 2 units per patient. The facility will perform follow up monitoring on all patients based on defined outcome measures.
USA—OH	LifeShare Community Blood Services	BBTS	5.6.1– Blood collection in a sterile closed system	The facility's collection of plasma using the Haemonetics PCS2 device, meets the intent of the standard.

Variances Granted for the 7th Edition of Standards for Cellular Therapy Services

Country	*Facility*	*Accredited Activity*	*Variance Request*	*Rationale behind Granted Variance*
Brazil	Centro Regional de Hemoterapia do HCFMRP - USP – Hemocentro	Cord Blood, AABB Accredited Hematopoietic Progenitor Cell (HPC), Somatic Cell	5.11B, C, D – West Nile Virus	The facility performs donor screening to ensure that donors with a travel history indicating a trip to an area where West Nile Virus is endemic, would be deferred.
China	Beijing Cord Blood Bank	Cord Blood	5.11.3.6 – HTLV I/II Testing	Facility does not need to perform infectious disease testing for HTLV I/II because "Blood Donor Screening Requirement" and “Umbilical Cord Blood Hematopoietic Stem Cell Bank Technical Manual” policies by the People’s Republic of China’s Ministry of Health do not require HTLV I/II testing, and there is no laboratory available to perform HTLV I/II testing.
Greece	Biohellenika	Cord Blood	5.11.3.6— HTLV I/II Testing 5.11.3.6 - 5.11D— HCV, HIV, HTLV I/II, CMV Testing 5.18.2.1— Cryopreservation	Facility does not need to perform infectious disease testing for HTLV I/II because the Greek Ministry of Health does not mandate it as it is not endemic to Greece. Facility uses PCR methodology to perform testing for HCV, HIV, and CMV rather than screening for antibodies. Greek legislation requires that all tests for infectious diseases be performed by either ELISA or PCR methodology. The facility has an alternative process to ensure that cord blood segments remain integrally attached to the original product.
Hungary	Krio Institute	Cord Blood	5.11.3.6– HTLV I/II Testing	The facility performs donor screening to determine if any potential donors may be carriers of HTLV I/II are identified before donation.
Poland	Polish Stem Cell Bank	Cord Blood	5.11.3.6— HTLV I/II Testing	Facility does not need to perform infectious disease testing for HTLV I/II because the Polish Ministry of Health does not mandate it as it is not endemic to Poland. The donor screening in place to determine if any potential donors have been exposed to the disease before donation meets the intent of the standard.
Portugal	Crioestaminal	Cord Blood	5.11.3.6—HTLV I/II	The facility does not perform infectious disease testing for HTLV I/II on all donors as the Portuguese Ministry of Health does not require it. The facility assesses the risk for potential exposure through the donor screening process and defers donors as needed.
Singapore	Health Sciences Authority	Cord Blood	5.11.3.6 – anti HTLV I/II	The facility does not perform infectious disease testing for HTLV I/II as the Ministry of Health does not require it.
South Africa	Cryo-Save	Cord Blood	5.11.3.6—HTLV I/II	The facility does not perform infectious disease testing for HTLV I/II on all donors as the test is not mandated by the South African Ministry of Health.
South Africa	Netcells Cryogenics	Cord Blood	5.11.3.6 – HTLV I/II	The facility does not perform infectious disease testing for HTLV I/II; as it is not required by the South African Ministry of Health.
Taiwan	Bionet Corporation	Cord Blood	5.18.2.1—Cryopreservation	The facility has an alternative process to ensure that cord blood segments remain integrally attached to the original product.

Thailand	Cryoviva	Cord Blood	5.11.3.6—HTLV I/II 5.11.3.6—CMV Testing	The facility does not perform infectious disease testing for HTLV I/II on all donors as the Competent Authority in Thailand does not require it. The facility does not test for anti CMV (IgM) testing on potential donors unless the initial test for anti-CMV (IgG) is negative.

Variances Granted for the *9th Edition of Standards for Immunohematology Reference Laboratories*

Kuwait	Kuwait Central Blood Bank	IRL	2.2.1, 2.2.2, 2.2A, 2.2B	The facility has received conditional accreditation as they work towards full compliance with the required percentages as described in standards 2.2.1 (95%) and 2.2.2 (50%). Their accreditation will be re-evaluated once the 10th edition of *Standards for Immunohematology Reference Laboratories* becomes effective in January of 2018.