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TITLE: CHAGAS (TRYPANOSOMA CRUZI) TESTING: SELECTION, LOOKBACK & DEFERRAL

PURPOSE: To outline the procedure to determine what donors are required to be tested for Chagas and how to handle components.
To determine the lookback and deferral process to be used with donor's testing positive for Chagas.

SPECIMENS REQUIRED : Serum Tube (Red Top)

MATERIALS/FORMS:

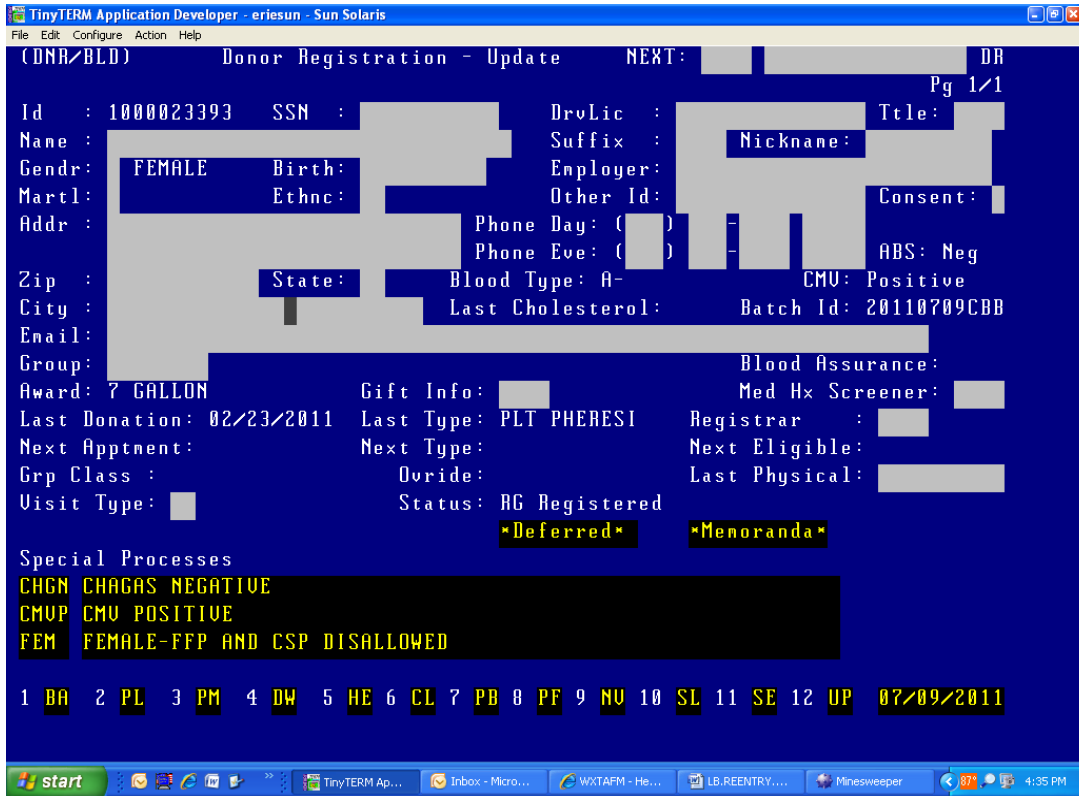
- Crystal Report
- SOP: Chagas Testing Report
- Donor Blood Testing Review.
- Letters: Donor Notification-Chagas.

PROCEDURE: All donors (including Autologous) will be tested one time for Trypanosoma Cruzi (Chagas)

A. SPECIMEN SELECTION

1. Donor Collections Staff

- a. In SafeTrace in the DN subsystem, DR screen- donors who have had previous Chagas Negative Testing will have the Special Process "CHGN" Chagas Negative. Mark the Donor History Questionnaire: CHGN.



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- b. When looking donors up on the Donor Eligibility flash drives used in mobile locations, the donor will have CHGN if they have been tested- Mark the Donor History Questionnaire: CHGN

	A	B	C	D	E	F	G	H	I	J	K
7918	HORCHEN, JEFFREY F	B	+		1000062255		08/13/1956		20011220		
7919	HORCHEN, RAMONA	O	+		1000065873		01/08/1960		20110622		FEM
7920	HORDOSKY, JOAN	B	+		1000093036		10/18/1956		20111111		AG
7921	HORDOSKY, JOAN	B	+		1000093036		10/18/1956		20111111		FEM
7922	HORDUSKY, COURTNEY L	O	+		1000087327		11/23/1987		20060105		
7923	HORDUSKY, ERIN M	B	+		1000055156		06/24/1981		19990506		
7924	HORDUSKY, JOAN	B	+		1000093036		10/18/1956		20111111		AG
7925	HORDUSKY, JOAN	B	+		1000093036		10/18/1956		20111111		FEM
7926	HORDUSKY-RICHARDSON, MADELINE	A	+		1000064374		10/01/1980		20010621		
7927	HORDYCH, GERALD				1000088112		02/18/1952				
7928	HORDYCH, JACOB T				1000056589		09/04/1981		19990402		
7929	HORDYCH, KYLIE A	O	-		1000000236		10/10/1978		19970604		
7930	HOREJS, THOMAS A	O	+		1000027314		12/18/1952		19941101		
7931	HORELL, JOSEPH P	O	+		1000119540		10/25/1965		20101215		
7932	HORGAN, MELODY				1000075253		11/09/1972		20050331		
7933	HORGAS, ROBERT	O	+		1000050224		01/09/1965		19851225		
7934	HORIHAN, NORA A	A	-		1000023393		09/15/1956		99999999		CHGN
7935	HORIHAN, NORA A	A	-		1000023393		09/15/1956		99999999		CMVP
7936	HORIHAN, NORA A	A	-		1000023393		09/15/1956		99999999		FEM
7937	HORL, AMY E	A	+		1000059871		04/10/1974		20030701		
7938	HORM, CANDACE L	O	-		1000042556		08/26/1952		20090601		FEM
7939	HORN, BETTY	A	+		1000010650		11/18/1939		99999999		
7940	HORN, BILL	**			1000047814		02/21/1955		19900417		
7941	HORN, BRIAN J	A	+		1000013297		08/06/1958		20090609		AG
7942	HORN, BRIAN J	A	+		1000013297		08/06/1958		20090609		CMVN
7943	HORN, DORIAN K	O	+		1000084519		02/18/1940		20110714		AG
7944	HORN, FRANK W	A	+		1000117198		04/26/1949		20110209		
7945	HORN, JADE M	O	+		1000060489		02/21/1983		99999999		
7946	HORN, JANE	O	+		1000004970		07/19/1962		20110511		AG
7947	HORN, JANE	O	+		1000004970		07/19/1962		20110511		FEM
7948	HORN, JODY L	A	+		1000087687		01/25/1965		20110419		FEM
7949	HORN, KARA	**			1000049925		03/04/1975		19950302		

B. CHAGAS RESULT ENTRY

1. When the Chagas Screening test result is **Negative**:
 - a. The Review/commit staff member doing testing review will review and commit test result per “Donor Blood Testing Review” and Chagas Testing Report SOP.
 - b. A special process “CHGN” will automatically post to the DN system when a negative Chagas test result is committed in the LA system.
2. When the Chagas Screening test is reactive, external testing laboratory will have 2nd Chagas by a different manufacturer performed. The Review/commit staff member will:
 - a. Complete Donor Lookback form and complete lookback for in-date products.
 - i. Give form to QA department to review and complete lookback and notification. (see step C)
 - b. When 2nd Chagas result is received:
 - i. Enter result into SafeTrace (ET-CHA2)
 - ii. Give completed results to QA Department
 - c. QA will send donor notification
 - i. Negative: Indefinite Deferral (P58). Letter sent.
 - ii. Positive: Indefinite Deferral (P58). Letter sent

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C. LOOKBACK

Within 3 calendar days: Notify Consignee of in-dates. Lookback will extend 10 years from date of current donation or 12 months from the last negative Chagas test.

1. Product Management
 - a. Repeat Reactive Index donations
 - i. Quarantine and destroy all components from the reactive donation
 - ii. Retrieve and destroy all in-date prior donations from the donor.
 - iii. Perform consignee notification
2. Lookback (product retrieval and Consignee notification): Within 3 calendar days after a donor tests repeatedly reactive by a licensed test for *T. cruzi*:
 - a. Identify all in-date blood and blood components previously donated by the donor, going back 10 years (or indefinitely where electronic records are available) or else, in a previously tested donor, 12 months prior to the donor's most recent negative test result with a licensed test for *T. Cruzii*, whichever is the lesser period.
 - b. Quarantine all previously collected in-date blood and blood components held at CBB.
 - c. Notify consignees of all previously collected in-date blood and blood components to quarantine and return the blood and blood components to CBB or to destroy them.
 - d. When a donor tests repeat reactive on the Chagas screening test and positive on a licensed supplemental test (if available), or there is information that the donor or donor's mother resided in an area endemic for Chagas disease (Mexico, Central and South America) or there is other testing indicating a *T. cruzi* infection:
 - i. Notify consignees of all previously distributed blood and blood components collected during the lookback period
 - ii. If blood or blood components was transfused, encourage consignees to notify the recipient's physician of a possible increased risk of *T. cruzi* infection.
 - iii. Notification must be made within 12 weeks of obtaining the repeatedly reactive test result.
3. Autologous Donations
 - a. Blood and blood components from autologous donors that test repeat reactive by a licensed test for *T. cruzi* antibody may be released to hospitals with approval from the autologous donor's referring physician. Collection/testing facilities will provide the results of additional testing as available to the autologous donor's referring physician
 - b. Units will be marked with a Biohazard sticker.

D. DONOR DEFERRAL

1. All donors who test repeat reactive by the licensed test for *T. cruzi* antibody and/or reactive or non-reactive to a licensed test for *T. cruzi* by a 2nd manufacturer will be indefinitely deferred (P58)
2. Donor Notification Letter will be sent with a recommendation to donor to have personal physician follow up in the absence of a confirmatory test

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E. CONTROLS:

1. The Review/commit staff member will review Chagas units tested vs. Chagas units requiring testing using the Chagas Crystal report.
 - a. Donors requiring testing that were not tested that day will have a T81 placed on their donation. Review of test results will be required prior to release of product.
2. Donors testing positive to Chagas will have a permanent deferral code (P58) automatically generated by SafeTrace

F. REPORTING AND INTERPRETING:

1. Donors testing positive to the screening test for Chagas will be indefinitely deferred
2. Donor Notification letters will be sent in accordance with the "Donor Notification" SOP.


REFERENCE:

FDA Guidance for Industry: Use of Serological Tests to Reduce the Risk of Transmission of Trypanosoma cruzi infection in Whole Blood and Blood Components Intended for Transfusion, Dec. 2010

Original Effective Date	Revised by	Revision	Supersedes Revision #
5.1.07	D. Pirschel	Updated in accordance with FDA Guidance. Added: Review with Crystal Report	1.000
	D. Pirschel	Remove BRD Union Square address	1.001
	J. Vieyra	Change from CD to flash drive Deleted Laboratory staff running the Prism will review Chagas Testing list generated daily using Crystal reports to determine which tubes do or do not need to be tested.	1.002
	D. Pirschel	Deleted: RIPA (CRIP-SafeTrace Designation) RIPA- Indeterminate: Indefinite Deferral (P58). Letter sent Added: Send specimen for Chagas screening test by a different manufacturer (CHG2-SafeTrace designation) Negative: Indefinite Deferral (P58). Letter sent. Positive- Indefinite Deferral (P58). Letter sent	1.003
	D. Pirschel	Deleted: Prism Testing staff: Perform Prism Chagas testing on all donors who have blue marking on red top tube. NOTE: See Chagas Testing Report SOP for additional process. and sent for supplemental testing. Added: When the Chagas Screening test is reactive, external testing laboratory will have 2 nd Chagas by a different manufacturer performed. The Review/commit staff member will: Complete Donor Lookback form and complete lookback for in-date products. Give form to QA department to review and complete lookback and notification. When 2 nd Chagas result is received: Enter result into SafeTrace (ET-CHA2) Give completed results to QA Department QA will send donor notification Negative: Indefinite Deferral (P58). Letter sent. Positive: Indefinite Deferral (P58). Letter sent	1.004

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	T. Wurst	<p>Deleted: Blue Marker (e.g. Sharpie) Donors who DO NOT have the CHGN special process On the RED TOP tube, mark the tube using a blue magic marker. DO NOT place blue markings over the DIN number (see example)</p> 	1.005
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REVIEWED BY:			
Department Head	Name	Signature	Date
QA Auditor	Kathryn Bell	<i>Kathryn Bell</i>	5-13-21
IT Specialist	Jason Radel	<i>J. Radel</i>	5-13-21
Technical Director	Shelley West	<i>Shelley West</i>	5/14/21
Collections Management	Jennifer Stephany	<i>Jennifer Stephany</i>	5-17-2021
APPROVED BY:			
Position	Name	Signature	Date
QA Director	Kristin Kramer	<i>Kristin Kramer</i>	5/14/21
Medical Director	Jeffrey A. Richmond, M.D.	<i>J. Richmond</i>	5-17-21
IMPLEMENTATION DATE:		JUN 01 2021	

MEDICAL DIRECTOR REVIEW							
MEDICAL DIRECTOR	DATE	MEDICAL DIRECTOR	DATE	MEDICAL DIRECTOR	DATE	MEDICAL DIRECTOR	DATE

COPIES: Donor Collections Manuals, Laboratory Manual, WEBSITE

RETIRED SOP

SOP RETIRED BY	TITLE	SIGNATURE	DATE RETIRED

COPIES RECEIVED

CBB	VAN	MASS	BRDM
	WNYM	WNYV	LAB