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TITLE: TESTING, DEFERRAL & REENTRY REQUIREMENTS

PURPOSE: To outline the required testing on human donor blood, the deferral protocol associated with reactive test results and the requirements for re-entry. All testing will be performed at a CLIA certified, FDA registered laboratory. No testing is performed on therapeutic donors not for transfusion.

FORMS: Donor Lookback/Positive Test Result form
Recall/Market Withdrawal form
Autologous Reactive Result Notification form
Lookback Binder
Test Requisition
Donor Testing Test Request Form
Blood Product Recall/Withdrawal Log ITxM Clinical Services

PROCEDURE:

A. TESTING REQUIREMENTS: To be performed at external testing laboratory

Samples will be prepared and stored according to manufacturer package inserts.

- **Allogeneic and Autologous**

1. ABO and Rh (ABRH)
2. Antibody Screen (ABS)
3. Syphilis Testing (STS)

VIRAL MARKERS

4. Anti-HTLV I/II (HTLV)
5. HBsAg (HBS)
6. Anti-HCV (HCV)
7. Anti-HBc (HBC)
8. Anti-HIV 1/2., Group O (HIVC)
9. MPX NAT: reported as HIVN, HBVN, HCVN
10. WNV NAT (see WNV Testing/Deferral & Reentry Requirements SOP) (WNVN)
11. CHAGAS: (see Chagas Testing/Deferral & Reentry Requirements SOP) (CHAG)
12. ZIKA: (See ZIKA Testing/Deferral and Reentry SOP) (ZIKA)
13. Babesia NAT (BABE)

- **Allogeneic**

14. CMV (as required)
15. HLA (as required)
16. DAT (as needed)
17. HGBS (as needed)
18. WBTI (as needed)

- **Supplemental/Further Testing (Allogeneic and Autologous)**

1. HIVN: HIV NAT: from MPX
2. HCVN: HCV NAT: from MPX
3. HBVN: HBV NAT: from MPX
4. HBSN: HBsAg Neutralization
5. HBC2: Anti HBc by 2nd manufacturer
6. HCV2: Anti-HCV by 2nd manufacturer
7. HIV2: Anti-HIV 2
8. HIV3: Anti-HIV-2 confirmatory

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9. HIV4: Anti-HIV 1 confirmatory
10. WB1: HIV1 WB
11. WB2: HTLV WB
12. WNVN: WNV NAT: ID
13. CHA2: Chagas by a 2nd manufacturer
14. STS2: Captia T. Pallidum -G EIA

B. DEFERRAL REQUIREMENTS

Any donor of human blood and blood components who tests reactive/positive to FDA required donor screening tests must be deferred from future donation except as follows:

1. Donor testing Reactive for anti-HTLV I/II or anti-HBc only one time is permitted to donate again without being deferred unless there is further testing using an approved supplemental test.
2. May serve as an autologous donor.
3. Donor has been re-entered into the donor pool under an FDA approved algorithm. (See separate Re-entry schemes.)

DONOR DEFERRAL ACTIONS:

1. Positive/Reactive Test results
 - a. Technologist committing test results will generate a donor lookback/positive test result form when final testing is complete.
 - i. Complete unit #, donor ID #
 - ii. Date testing was completed
 - iii. Check reactive/positive test result that applies
 - iv. When QA is not available, perform lookback for in-date components.
 - =LA
 - DL, tab, Reactive Unit Number
 - Print Screen or Shift F1 to print the screen
 - Contact any facility for final disposition of in-date components.
 1. If the in-date component is in CBB's inventory or the contacted facility, return the component and discard.
 - a. For POS WBTI- In-date components are restricted to plasma components for transfusion only.
 - b. For Reactive Babesia-It is not necessary to retrieve from consignees the following products: 1) previously distributed cellular blood components that were pathogen reduced using an FDA-approved device according to its instructions for use and 2) frozen acellular blood components (i.e. frozen plasma products). However, these products must be discarded if in-house.
 2. Any components consigned to ITXM (or UPSH, UPGR)
 - a. Complete Blood Product Recall/Withdrawal Log ITxM Clinical Services.
 - Product ID#
 - Product Blood Type, Product Outdate
 - Date/Time of Initial Notification
 - Notified By
 - Reason for Recall/Withdrawal

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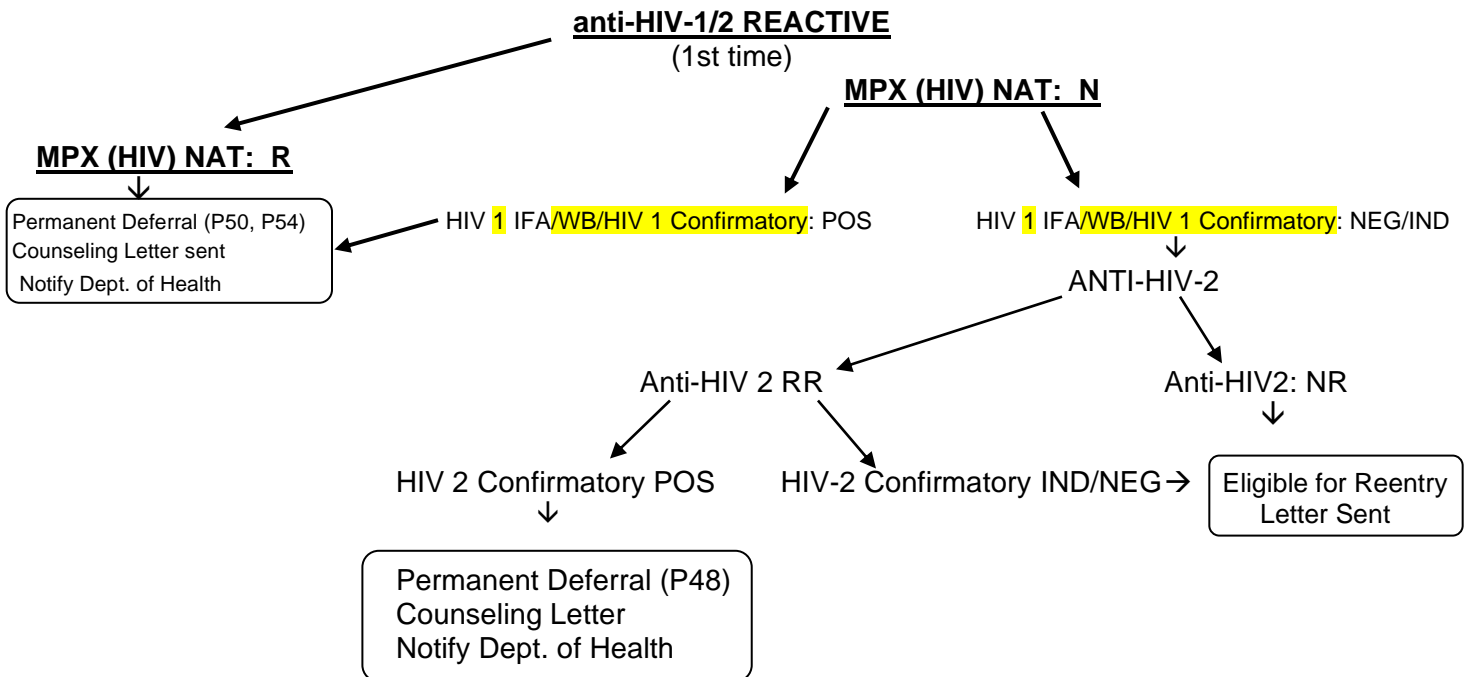
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- b. Fax form to ITxM's Central Transfusion Service (CTS) at:
 - 412-209-7482 or 412-209-7494
- c. Call CTS at 412-209-7460, ask for a manager and let them know the form has been faxed.
 - Complete Market Withdrawal, Lookback form
 1. Attach screen shots
- v. Give documents to QA Department
2. QA Department
 - a. Report results electronically to plasma vendor and/or regulatory agencies as required.
 - b. QA/designee will perform record review using the DV and/or DL screen to determine further action.
 - i. Print screens and attach to Donor Lookback/Positive Test Result form if required
 - ii. Any components consigned to ITXM (or UPSH, UPRG)
 1. Complete Blood Product Recall/Withdrawal Log ITxM Clinical Services.
 - Product ID#
 - Product Blood Type, Product Outdate
 - Date/Time of Initial Notification
 - Notified By
 - Reason for Recall/Withdrawal
 2. Fax form to ITxM's Central Transfusion Service (CTS) at:
 - 412-209-7482 or 412-209-7494
 - iii. Call CTS at 412-209-7460, ask for a manager and let them know the form has been faxed
 - c. If needed, QA or designee will complete a donor notification form and send donor deferral notification letters (see Donor Notifications SOP).

3. The following indicates actions to be taken with computer records, donor notification and reentry protocol:

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HIV DONOR REENTRY >8 WEEKS,
 TEST FOLLOW UP SAMPLE (TUBE ONLY) USING
 HIV -1 ID NAT AND ANTI-HIV 1/2 TEST

<p>HIV NAT REACTIVE from MPX ANTI HIV 1/2: RR</p> <p>↓</p> <p>Permanent Deferral Counseling Letter Notify Dept. of Health</p>	<p>HIV NAT REACTIVE from MPX ANTI-HIV 1/2: NR</p> <p>↓</p> <p>Permanent Deferral Counseling Letter Notify Dept. of Health</p>	<p>HIV NAT NR from MPX ANTI-HIV 1/2: RR</p> <p>↓</p> <p>Defer Donor (Eligible for reinstatement after an additional 8 week period) Notify Donor</p>	<p>HIV NAT NR from MPX ANTI HIV- 1/2: NR</p> <p>↓</p> <p>Reenter Donor Notify Donor</p>
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>8 WEEKS (repeat testing protocol above)
 If additional testing is reactive, donor is permanently deferred

anti-HTLV-I/II
(1st Time) Repeat Reactive

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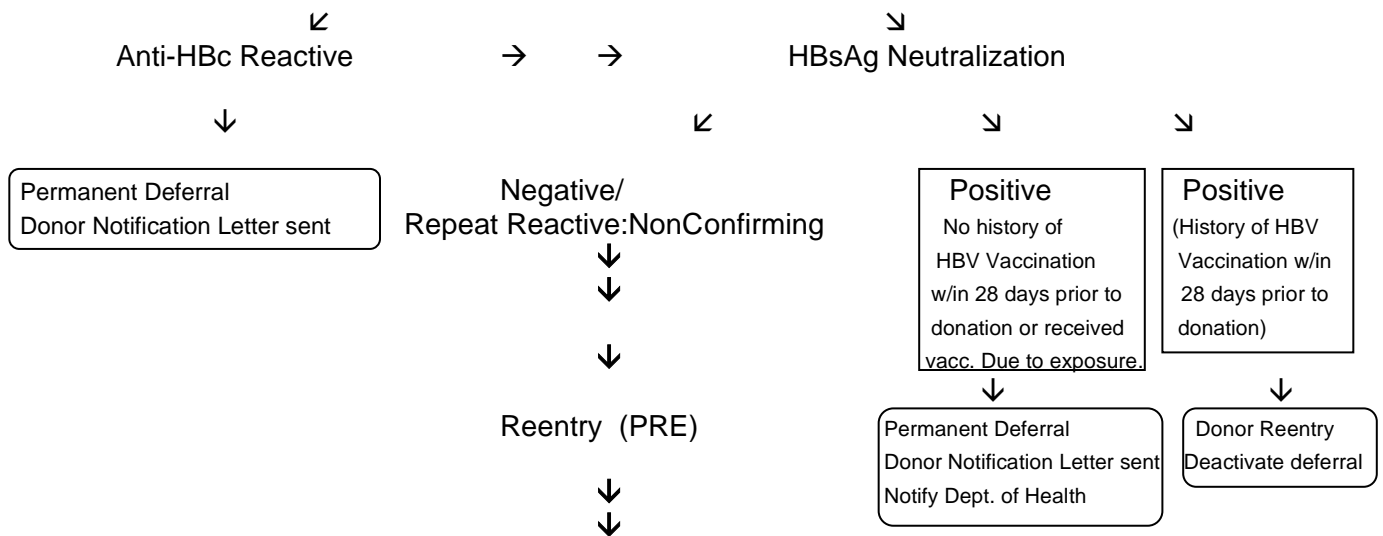
↓
Supplemental/Further test (Not performed on Autologous units)

Licensed HTLV I/II Confirmatory



REPEAT REACTIVE 2ND TIME → Permanent Deferral (P44), No Re-entry
 Deferral Letter

HBsAg (1st Time) Reactive (consult HBV NAT algorithm)



HBsAg DONOR REENTRY >8 WEEKS,



Note: When Hepatitis B Vaccination is given as prophylaxis following a specific incident of potential exposure:

Donor Reentry may occur after

1. It is determined that the donor received the vaccine w/in 28 days of the donation
 2. 12 months after the potential exposure, draw tubes for reentry testing (HBsAg, anti-HBc, and individual donor HBV NAT- all must be negative for reentry.
-

anti-HCV /HCV NAT

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HCV NAT: R (Discriminatory)
ANTI-HCV: RR

↓
Permanent Deferral (P45 & P53)
Deferral Letter
Notify Dept. of Health

HCVNAT: R (Discriminatory)
ANTI-HCV-NR

↓
Notify Donor
Eligible for Reentry (**PRT**)

HCVNAT: NR/NOT DONE
ANTI-HCV: RR
RIBA: INDETERMINATE, NEGATIVE
OR NOT DONE
2nd ANTI-HCV (different manufacturer):
NR or RR

↓
>6 MONTHS
TEST FOLLOW UP SAMPLE (TUBE ONLY) USING
HCV ID-NAT AND TWO DIFFERENT, LICENSED ANTI-HCV SCREENING TESTS



ID-HCV NAT: R
Regardless of
Anti-HCV Test Results

↓
Permanent Deferral
(P45 & P53)
Deferral Letter
Notify Dept. of Health

ID-HCV NAT: NR
Both Anti-HCV
Tests RR

↓
Permanent Deferral
(P45)
Deferral Letter

ID-HCV NAT: NR/
One Anti-HCV test RR
and One Anti-HCV Test NR

↓
Defer Donor (P45 & PRT)
Notify Donor (eligible for
Reinstatement after an
additional 6 months)

ID-HCV NAT: NR
Both Anti-HCV
Tests NR

↓
Reenter Donor
Notify Donor

↓
> 6 MONTHS (follow protocol above)
If additional testing is
Reactive donor is
permanently deferred (P45/P53)

HBV NAT

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HBVN RESULT	HBsAg RESULT ¹	ANTI-HBC RESULT	DONOR AND UNIT
Positive	Reactive/ Confirmed Positive	NR	Discard Unit Donor: Permanent Deferral Donor Not Eligible for Reentry Notify Department of Health
Positive	Reactive/ Confirmed Positive	REACTIVE	
Positive	Reactive/ Not Confirmed	REACTIVE	
Positive	NR	REACTIVE	Discard Unit Donor: Indefinite Deferral Donor May Be Eligible for Reentry
Positive	NR	NR	
Positive	Reactive/ Not Confirmed	NR	

¹HBsAg Neutralization used for confirmatory

HBVNAT REENTRY: >6 MONTHS FROM INITIAL REACTIVE SPECIMEN,

COLLECT TUBES



TEST FOR HBVNAT (from MPX), HBSAG AND ANTI-HBC

HBV NAT	HBSAG AND ANTI-HBC RESULT	DONOR
Positive	Any test result	Permanently defer and notify
Negative	Non-reactive	Donor may be reentered
Negative	Repeat reactive	Follow reentry protocol for HBsAg and anti-HBc

ANTI-HBc (1st Time)

(consult HBV NAT algorithm also)

N
↙

No Action

R
↘

Permanent Deferral (P21), Comments



ANTI-HBc (by 2ND Mfg)

R
↙

Permanent Deferral (P21)
Eligible for Reentry (PRT)
Deferral Letter



N
↘

No Action
Deactivate Deferral

REENTRY VISIT (≥8 WEEKS AFTER SECOND POSITIVE ANTI-HBc)

DRAW TUBES ONLY AND TEST FOR ANTI-HBC, HBSAG, AND ID HBVNAT

N (ANTI-HBC, HBSAG AND HBVN)



Reentry
Donor Letter

R (ANTI-HBC, HBSAG AND/OR HBVN)



Permanent Deferral (P21)—No Reentry
Deferral Letter

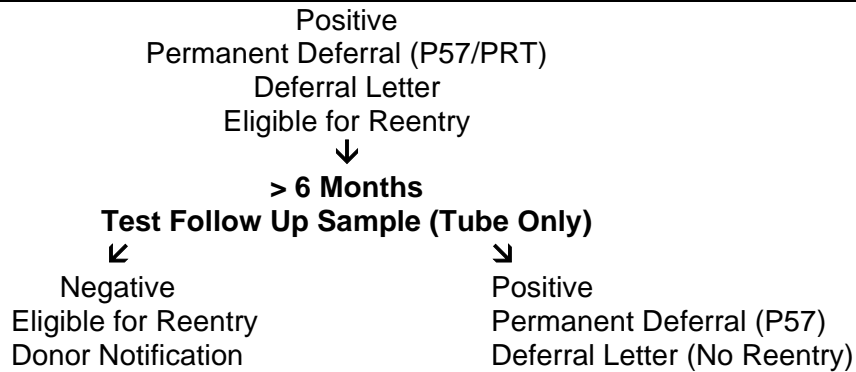
Any time the anti-HBc is reactive in conjunction with the HBsAg, the donor will be permanently deferred.

HOSPITAL REPORT OF DAT



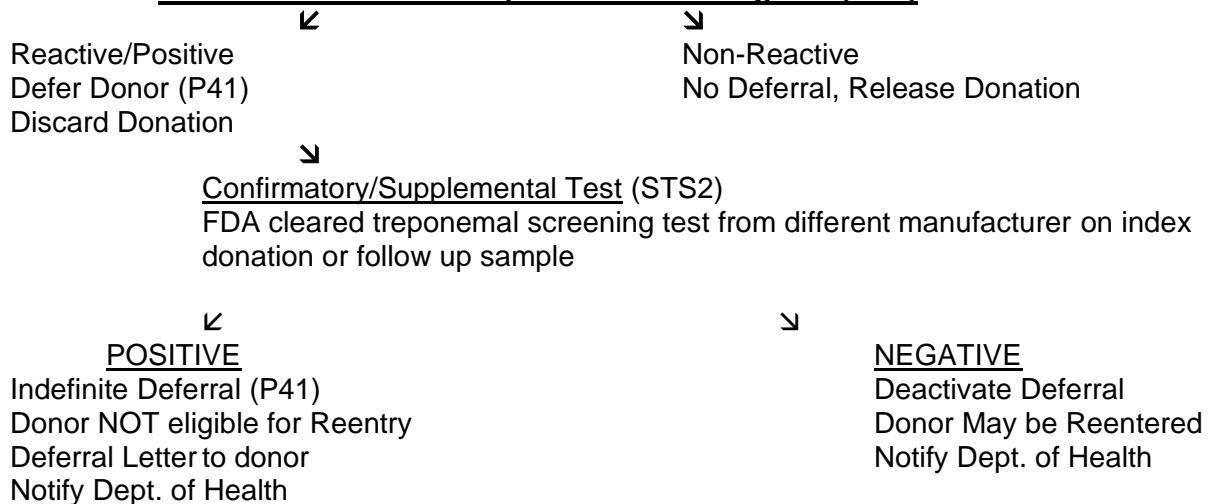
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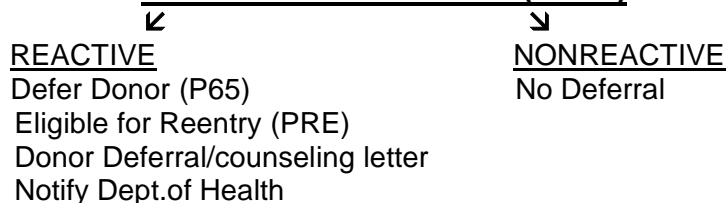
SYPHILIS TESTING

Perform FDA-cleared Treponemal screening test (STS)



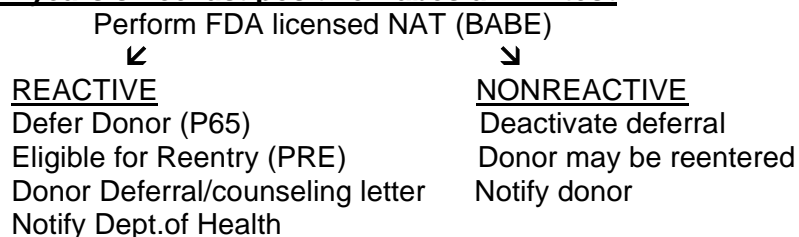
BABESIA TESTING

Perform FDA licensed NAT (BABE)



REENTRY VISIT (PRE)

>2 years since last positive Babesia NAT test



AUTOLOGOUS DONORS

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Autologous donors will be handled in the same manner as allogeneic donors with the following exceptions:

1. Notification will be made to referring physician as well as the donor (See Deferral Notification SOP).
2. The Transfusion Service will be notified of positive test results using the Autologous Reactive Result Notification form.
3. Units may be released for autologous use only after authorization is received from the referring physician and Transfusion service approval is on file.
4. Confirmatory test is only performed on 1st donation in a 30-day period. If confirmatory is positive, no further confirmatory testing is done.
5. First time anti-HBc and Anti-HTLV/III reactive donors will not have the deferral deactivated

C. DONOR RE-ENTRY:

1. Donor Collections:
Any donor with an active permanent deferral will not be drawn without further investigation by the screener.

Donors eligible for re-entry will be denoted in the computer by PRE or PRT.
 - **PRT** indicates draw tubes only per the laboratory staff instructions. A special notation on the DR screen will state "Draw tubes for testing - see "DE" for date".
 - a. Collect tubes per "Collection of Tubes for Additional Donor Testing" SOP.
 - b. Complete Test Requisition and check appropriate Reentry Testing.
 - c. Return tubes and requisition to Laboratory.
 - d. Laboratory tech will complete test result section and give completed form to supervisor performing review.
 - e. Upon completion of review, requisition will be given/sent to QA.
 - f. QA or designee will determine reentry after review of results.
 - g. QA or designee will deactivate deferral code if required.
 - **PRE** indicates donor is eligible to be drawn for re-entry.
 - Donor re-entry may occur after all appropriate testing is completed per individual re-entry protocol.
2. Laboratory: when tubes are collected
 - a. Complete Donor Testing Test Request Form or order in the Surround Web Interface, as applicable. See Surround Web Interface: Accessioning SOP

CONTROLS:

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1. A monthly review of the Discard Log is performed by the Technical Director to look for appropriate and complete discards.
2. The QA Director/designee will review the same log to verify that appropriate donor action has occurred (deferral code, info comments, letters, etc.).
3. The QA Director/designee will also review all Unit Lookback and Recall/Market Withdrawal forms for appropriate action.
4. QA Director/designee performs a daily check of previous day's deferrals (see Daily Quality Audits).

REPORTING & INTERPRETING RESULTS:

1. Reactive/Positive Results will generate a Donor Lookback Form, which will be filed in the QA Office.
2. Recall/Market Withdrawal Forms will be attached to the Donor Unit Lookback form.
3. Deferral Notification, if appropriate, will take place per Donor Notification SOP.
4. Confirmatory/Supplemental Results are kept on file in the Laboratory.

References:

FDA Guidance for Industry:

- Recommendations for Donor Screening, Deferral and Product Management to Reduce the Risk of Transfusion Transmission of Zika Virus
- Lookback[®] for Hepatitis C Virus (HCV): Product Quarantine, Consignee Notification, Further Testing, Product Disposition, and Notification of Transfusion Recipients Based on Donor Test Results Indicating Infection with HCV, Rev. 12/10
- Nucleic Acid Testing (NAT) for Human Immunodeficiency Virus Type 1 (HIV-1) and Hepatitis C Virus (HCV): Testing, Product Disposition, and Donor Deferral and Reentry, 12/2017
- Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products
- Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease and Variant Creutzfeldt-Jakob Disease by Blood and Blood Products
- Recommendations for Assessment of Donor Suitability and Blood and Blood Product Safety in Cases of Possible Exposure to Anthrax
- Recommendations for Deferral of Donors and Quarantine and Retrieval of Blood and Blood Products in Recent Recipients of Smallpox Vaccine (Vaccinia Virus) and Certain Contacts of Smallpox Vaccine Recipients
- Recommendations for the Assessment of Donor Suitability and Blood Product Safety in Cases of Suspected Severe Acute Respiratory Syndrome (SARS) or Exposure to SARS
- Revised Recommendations for Reducing the Risk of Zika Virus Transmission by Blood and Blood Components, 8.16
- FDA Guidance for Industry: Recommendations for Screening, Testing and Management of Blood Donors and Blood and Blood Components based on Screening Tests for Syphilis, Sept.2014
- FDA Guidance for Industry: Recommendations for Reducing the Risk of Transfusion-Transmitted Babesiosis, May 2019

SOP:

- WNV Testing/Deferral & Reentry Requirements SOP
- Chagas Testing/Deferral & Reentry Requirements SOP
- ZIKA Testing/Deferral and Reentry SOP
- Surround Web Interface: Accessioning SOP
- Collections of Tubes for Additional Donor Testing SOP
- Donor Notification SOP
- Donor Reentry SOP

21 CFR 610.46-48, 42 CFR 482.27(c)

AABB Standards for Blood Banks and Transfusion Services, 7.4.6, 7.4.6.1

Original	Revised	Revision	Supersedes
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Effective Date	by		Revision #
9.10.01	D. Pirschel	Computer action/deferral and Reentry requirements updated for HIV, HCV, anti-HBc in accordance with FDA Guidance	1.010
	D. Pirschel	Remove BRD Union Square address Deleted CUE information	1.011
	D. Pirschel	Include HBVN per FDA Guidance: Use of NAT tests to reduce risk of HBV	1.012
	D. Pirschel	Added: 2 nd ANTI-HCV (different manufacturer): NR to HCV flowchart and list of confirmatory/supplemental tests	1.013
	D. Pirschel	Deleted: FTA/Captia G Syphilis and HTLV WB Added: RPRC: TP-PA, HT2: anti-HTLV I/II by different manufacturer	1.014
	J. Vieyra	Deleted: Reactive RPR: mark DILs Change from bi-weekly to monthly review of Discard log	1.015
	D. Pirschel	Deleted: CRIP: Chagas RIPA (unlicensed) Added: CHA2: Chagas by a different manufacturer	1.016
	D. Pirschel	Deleted RPR (alternate NAT & IgM) Technologist performing testing Added: To be performed at external testing laboratory Syphilis Testing (treponemal test) with updated flow chart Technologist committing test results Complete Market Withdrawal, Lookback form Laboratory Complete Indiana Blood Center Client Supplemental Test Request Document: Draw Date Sample ID number Place an X under the desired test. HCV- mark Prism HCV and Donor Reentry HCV HBC- mark Prism HBC, Prism HBs and Donor Reentry HBV (x3) HBsAg- mark Prism HBs and HBs Neut HIV- mark Prism HIV and Donor Reentry HIV	1.017
	T. Collier	Added: When QA is not available	1.018
	D. Pirschel	Deleted: RPRC: TP-PA Perform FDA cleared non-treponemal screening test ↙ <u>POSITIVE</u> ↘ <u>NEGATIVE</u> Added; TPHA: Treponemal Hemagglutination test (for Syphilis)	1.019
	D. Pirschel	Added donor reentry for HBsAg, HBSN due to HBV vaccination in accordance with FDA Guidance: Requalification Method for reentry of donors who test HBsAg positive following a recent vaccination against Hepatitis B Virus Infection, 11/11	1.020
	D. Pirschel	Deleted: ID and Discriminatory MPX flow chart Added: MPX 2.0 NAT : reported as HIVN, HBVN, HCVN from MPX 2.0	1.021
	D. Pirschel	Deleted; HTL2: anti-HTLV I/II by different manufacturer Anti-HTLV-I/II by a different manufacturer Added: Supplemental/Further Testing HBC2: Anti HBc by 2 nd manufacturer WB2: HTLV WB Licensed HTLV I/II Confirmatory ANTI-HBc (by 2ND Mfg) ZIKA: (See ZIKA Testing/Deferral and Reentry SOP or order in the Surround Web Interface, as applicable. See Accessioning SWI SOP	1.022
T. Collier	Added: ZIKA: (See ZIKA Testing/Deferral and Reentry SOP CRIP: Chagas RIPA STS2: Captia T. Pallidum -G EIA (STS2) or order in the Surround Web Interface, as applicable. See Accessioning SWI SOP FDA Guidance for Industry: Recommendations for Screening, Testing and Management of Blood Donors and Blood Components based on Screening Tests for Syphilis, Sept.2014 WNV Testing/Deferral & Reentry Requirements SOP	1.023	

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		Chagas Testing/Deferral & Reentry Requirements SOP ZIKA Testing/Deferral and Reentry SOP Accessioning SWI SOP	
	D. Pirschel	Added: Blood Product Recall/Withdrawal Log ITxM Clinical Services. Any components consigned to ITXM (or UPSH, UPGR) Complete Blood Product Recall/Withdrawal Log ITxM Clinical Services. Product ID# Product Blood Type, Product Outdate Date/Time of Initial Notification Notified By Reason for Recall/Withdrawal Fax form to ITxM's Central Transfusion Service (CTS) at: 412-209-7482 or 412-209-7494 Call CTS at 412-209-7460, ask for a manager and let them know the form has been faxed	1.024
9.10.01	D. Pirschel	Deleted: from MPX 2.0 ANTI HCV: RR Added: Regardless of Both Anti-HCV One Anti-HCV test RR Both Anti-HCV Anti-HCV Test Results Tests RR and One Anti-HCV Test NR Tests NR Nucleic Acid Testing (NAT) for Human Immunodeficiency Virus Type 1 (HIV-1) and Hepatitis C Virus (HCV): Testing, Product Disposition, and Donor Deferral and Reentry, 12/2017 AND Ortho	1.025
9.10.01	D. Pirschel	Deleted: Indiana Blood Center (IBC) Client Supplemental Test Request & Labeling Other Than Indiana Blood Center Client Supplemental Test Request Document: Draw Date Sample ID number Place an X under the desired test. HCV- mark Prism AND Ortho HCV and Donor Reentry HCV HBC- mark Prism HBC, Prism HBs and Donor Reentry HBV (x3) HBsAg- mark Prism HBs and HBs Neutralization HIV- mark Prism HIV and Donor Reentry HIV SWI Added: Donor Testing Test Request Form Additional SOP Donor Testing Test Request Form Surround Web Interface: Accessioning SOP Surround Web Interface Collections of Tubes for Additional Donor Testing SOP Donor Notification SOP Donor Reentry SOP	1.026
9.10.01	T. Collier/K. Kramer	Deleted: 2.0 2.0 <u>2.0</u> 2.0 2.0 2.0 & P53) 2.0 Added:)	1.027
9.10.01	T. Collier	Added: HGBS (as needed) WBTI (as needed) For POS WBTI- In-date components are restricted to plasma components for transfusion only.)	1.028
9.10.01	K. Kramer	Deleted: CRIP: Chagas RIPA DBA Or Technical Director Added: CHA2: Chagas by a 2 nd manufacturer	1.029

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		Or designee designee	
9.10.01	K. Kramer	<p>Added: Babesia NAT WB1: HIV1 WB WB3: HIV2 WB</p> <p>For Reactive Babesia-It is not necessary to retrieve from consignees the following products: 1) previously distributed cellular blood components that were pathogen reduced using an FDA-approved device according to its instructions for use and 2) frozen acellular blood components (i.e. frozen plasma products). However, these products must be discarded if in-house. Deactivate deferral</p> <pre> graph TD A[BABESIA TESTING] --> B[Perform FDA licensed NAT (BABE)] B --> C[REACTIVE] B --> D[NONREACTIVE] C --> E[Defer Donor (P65)] C --> F[Eligible for Reentry (PRE)] C --> G[Donor Deferral/counseling letter] C --> H[Notify Dept.of Health] D --> I[No Deferral] J[REENTRY VISIT (PRE)] --> K[>2 years since last positive Babesia NAT test] K --> L[Perform FDA licensed NAT (BABE)] L --> M[REACTIVE] L --> N[NONREACTIVE] M --> O[Defer Donor (P65)] M --> P[Eligible for Reentry (PRE)] M --> Q[Donor Deferral/counseling letter] M --> R[Notify Dept.of Health] N --> S[Deactivate deferral] N --> T[Donor may be reentered] N --> U[Notify donor] </pre> <p>FDA Guidance for Industry Recommendations for Reducing the Risk of Transfusion-Transmitted Babesiosis, May 2019</p>	1.030
9.10.01	K. Kramer	<p>Added: (ABRH) (HTLV) (HBS) (HCV) (HBC) (HIVC) (WNVN) (CHAG) (ZIKA) (BABE) N</p>	1.031
9.10.01	K. Kramer	<p>Deleted: WB3: HIV2 WB WB</p> <p>Added: HIV3: Anti-HIV-2 confirmatory Confirmatory</p>	1.032
9.10.01	K. Kramer	<p>Added: HIV4: Anti-HIV 1 confirmatory 1 /WB/HIV 1 Confirmatory</p>	1.033

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REVIEW/APPROVAL/IMPLEMENTATION			
Department Head	Name	Signature	Date
Collections Management	Jennifer Stephany	<i>Jennifer Stephany</i>	5-5-21
Technical Director	Shelley West	<i>Debra Helmer Shelley West</i>	5-3-21
APPROVED BY:			
Position	Name	Signature	Date
QA Director	Kristin Kramer	<i>Kristin Kramer</i>	4-29-21
Medical Director	Jeffrey A. Richmond MD	<i>J.A.R.</i>	5-10-21
IMPLEMENTATION DATE:		JUN 01 2021	

REVIEW			
MEDICAL DIRECTOR	DATE	MEDICAL DIRECTOR	DATE

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RETIRED SOP				
SOP RETIRED BY	TITLE	SIGNATURE	DATE RETIRED	
COPIES RECEIVED				
LAB	CBB	VAN	MASS	WNYV
BRDM		WNYM	ITS	