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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
2. Antibody Screen (ABS)
3. Syphilis Testing (STS)

VIRAL MARKERS

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

- **Allogeneic**

13. CMV (as required)
14. HLA (as required)
15. DAT (as needed)
16. HGBS (as needed)
17. 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. WB2: HTLV WB

9. WNV: WNV NAT: ID
10. CHA2: Chagas by a 2nd manufacturer
11. 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.
                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
                    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, UPGR)
            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).

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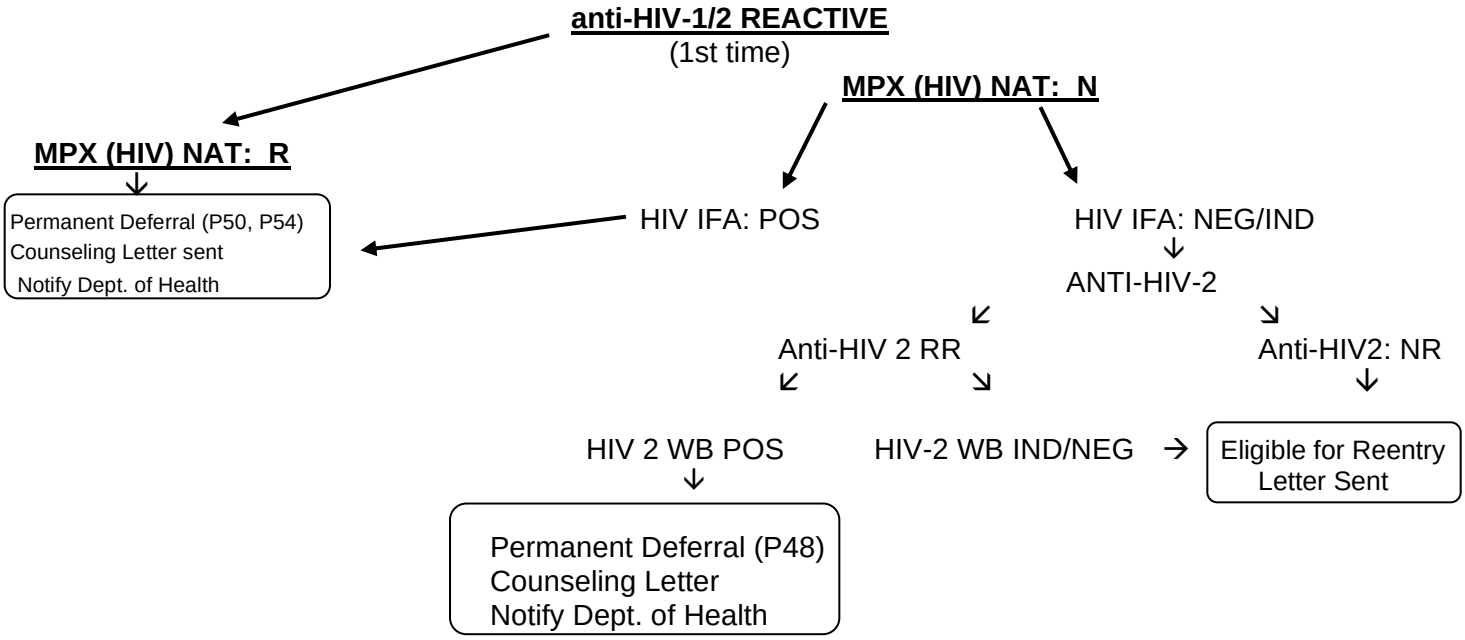
3. The following indicates actions to be taken with computer records, donor notification and reentry protocol:



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

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

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anti-HTLV-I/II
(1st Time) Repeat Reactive
↓
Supplemental/Further test (*Not performed on Autologous units)*

Licensed HTLV I/II Confirmatory

↙ ↘

NEGATIVE/INDETERMINATE
Donor eligible to donate
Comments in Computer

POSITIVE
Permanent Deferral (P44)
Deferral Letter

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

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

↙ ↘

Anti-HBc Reactive → → HBsAg Neutralization

↓ ↙ ↘ ↘

Permanent Deferral
Donor Notification Letter sent

Negative/
Repeat Reactive:NonConfirming
↓
↓
↓
Reentry (PRE)
↓
↓

Positive
No history of HBV Vaccination w/in 28 days prior to donation or received vacc. Due to exposure.
↓
Permanent Deferral
Donor Notification Letter sent
Notify Dept. of Health

Positive
(History of HBV Vaccination w/in 28 days prior to donation)
↓
Donor Reentry
Deactivate deferral

HbsAg DONOR REENTRY >8 WEEKS,
↙ ↘

HBsAg NEGATIVE
Donor Reentry

HBsAg POSITIVE
Permanent Deferral (P09)
Deferral Letter

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.

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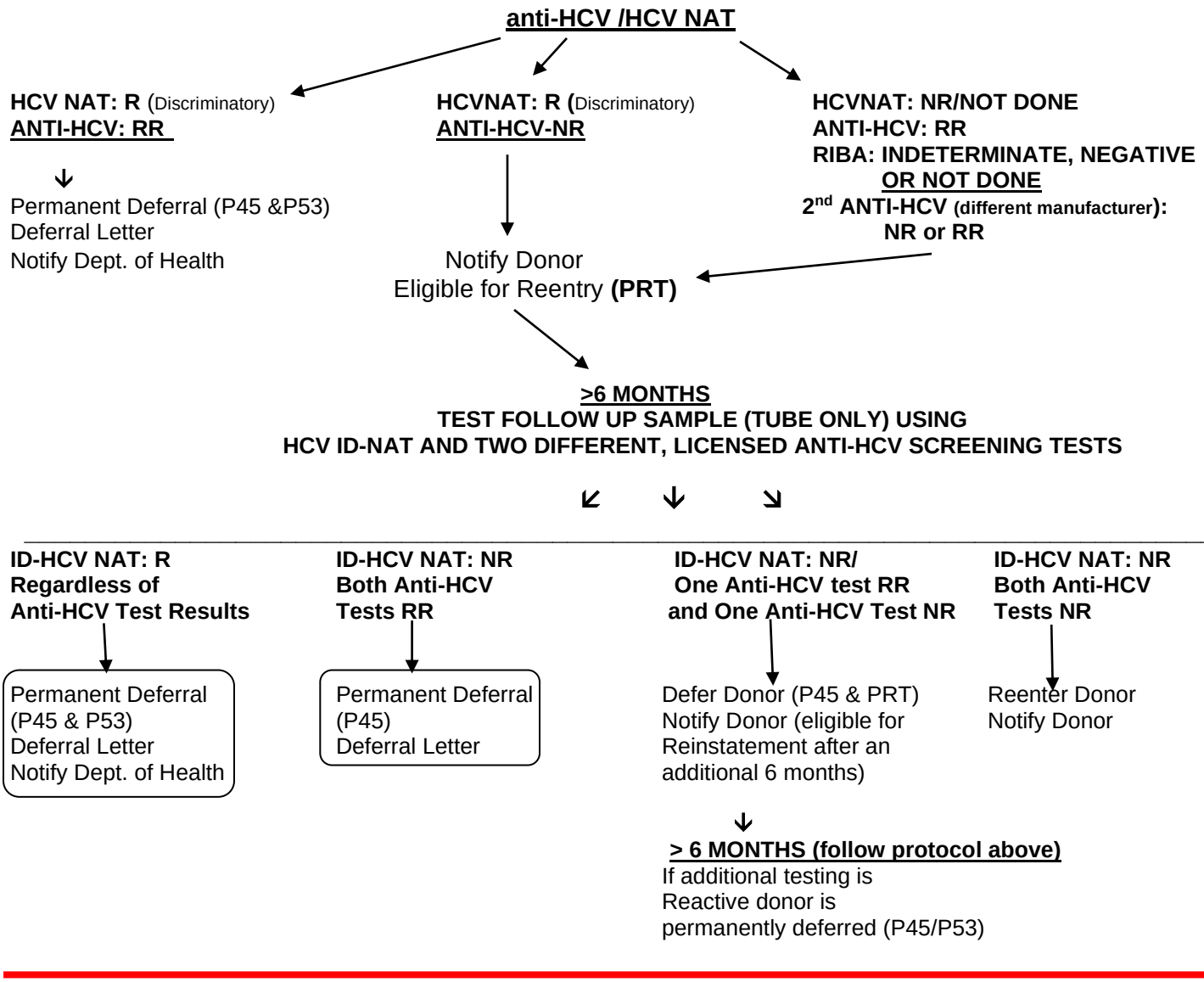

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HBV NAT

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**	

[1]HBsAg 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

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

↓

Positive
Permanent Deferral (P57/PRT)
Deferral Letter
Eligible for Reentry

↓

> 6 Months
Test Follow Up Sample (Tube Only)

↙	↘
Negative Eligible for Reentry Donor Notification	Positive Permanent Deferral (P57) Deferral Letter (No Reentry)

SYPHILIS TESTING
Perform FDA-cleared Treponemal screening test (STS)

↙	↘
Reactive/Positive Defer Donor (P41) Discard Donation	Non-Reactive No Deferral, Release Donation

↘

Confirmatory/Supplemental Test (STS2)
FDA cleared treponemal screening test from different manufacturer on index donation or follow up sample

↙	↘
POSITIVE Indefinite Deferral (P41) Donor NOT eligible for Reentry Deferral Letter to donor Notify Dept. of Health	NEGATIVE Deactivate Deferral Donor May be Reentered Notify Dept. of Health

AUTOLOGOUS DONORS

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-HTLVI/II 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:

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.

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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

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 Effective Date	Revised by	Revision	Supersedes Revision #
9.10.01	D. Pirschel	Computer action/deferral and Reentry requirments 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: 2nd 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 ↙ ↘ POSITIVE NEGATIVE 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 2nd 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)	1.023

		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 and Blood Components based on Screening Tests for Syphilis, Sept.2014 WNV Testing/Deferral & Reentry Requirements SOP 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 **2.0** 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	1.029

		Or Technical Director Added: CHA2: Chagas by a 2nd manufacturer Or designee designee	

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REVIEW/APPROVAL/IMPLEMENTATION			
Department Head	**Name**	**Signature**	**Date**
Collections Management	Jennifer Stephany	Jennifer Stephany	11/26/19
Technical Director	Tracy Collier	Tracy Collier	11-25-19
APPROVED BY:			
Position	**Name**	**Signature**	**Date**
QA Director	Kristin Kramer	Kristin Kramer	11-26-19
Medical Director	Jeffrey A. Richmond MD	J.R. Richmond	12/2/19
IMPLEMENTATION DATE:	JAN 01 2020		

REVIEW			
MEDICAL DIRECTOR	DATE	MEDICAL DIRECTOR	DATE

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RETIRED SOP

SOP RETIRED BY	TITLE	SIGNATURE	DATE RETIRED

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