Community Blood Bank of Erie County
2646 Peach St. Erie, PA 16508

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TITLE: REGISTRY OF ADVERSE REACTIONS TO TRANSFUSIONS

PURPOSE: A registry of all reported cases of adverse reactions to transfusions will be maintained at CBB. These include transfusion-transmitted hepatitis B, hepatitis C, HTLV-I/II infection, HIV-1 or HIV-2 infection, sepsis, Chagas, Syphilis, WNV infection, Babesia infection or TRALI (Transfusion Related Acute Lung Injury) due to blood transfusion.

MATERIALS: Report of Transfusion Transmitted Disease TTD Form
Transfusion Transmitted Disease (TTD) Implicated Donor Report
External Laboratory Test Requisition

Contact Information:

ACL: Associated Clinical Laboratory
BCW (Versiti, Wisconsin): Blood Center of Wisconsin: http://www.bcw.edu/bcw/index.htm
IBC (Versiti, Indiana): Indiana Blood Center

PROCEDURE: When a case of suspected adverse reaction to transfusion is reported to CBB (Community Blood Bank), the following procedure is to be followed:

A. Transfusion Service:
   1. Notify CBB via telephone of a potential transfusion transmitted disease report. Include all product types and unit numbers involved.
      a. Complete a Transfusion Transmitted Disease Form and send it to the CBB Medical Director, QA Director and/or Technical Director via mail, email or fax.
      b. Include on the report:
         i. Unit number (entire ISBT# W0456…..)
         ii. Product code (ISBT #)
         iii. Date Transfused
         iv. Clinical testing performed on recipient/patient that supports diagnosis
         v. Additional pages may be attached with this information
   2. Return any remaining blood product to CBB.

NOTE: Recipient testing will not be performed by or paid for by CBB.

B. CBB
   1. Laboratory/designee
      a. Perform a lookback on each unit number. (=LA, DL)
      b. Quarantine in-date products from each implicated donor until investigation is complete.
   2. QA/designee
      a. Send a donor recall letter to each involved donor asking him/her to report for follow-up testing.
      b. Complete Implicated Donor Report, include:
         i. Date report initiated
         ii. Hospital involved
         iii. Patient name and suspected TTD
         iv. Donor SafeTrace ID #
         v. Donor Name
         vi. Implicated Unit # and date of donation
         vii. Date donor recall letter sent

c. Assign a case number to the documents: date report initiated + hospital + TTD +disease (e.g.: 6.2.00.SV.TTD.HCV)

d. SafeTrace documentation: each involved donor
   i. Defer donor(s)-P40: pending results of the follow-up testing.
      a. Under deferral (=DN, DE) document case number
      b. Under Memo (=DN, MS), document P40 and case number

e. Complete and distribute instructions for laboratory, donor collections and front desk, to include:
   i. Donor name, SafeTrace ID # and last donation location
   ii. Front desk instructions: Notify Collections Management or donor collections staff member that tubes need to be drawn
   iii. Donor Collections staff instructions:
      a. what needs to be completed on requisition,
      b. what tubes to be drawn,
      c. use of ISBT number,
      d. Send/Give tubes and requisition to laboratory
      e. Donor instructions: CBB will contact them by mail of test results and their eligibility as a donor. Until they are contacted, they are deferred from donation. Further questions may be directed to QA, Technical Director and/or Collections Management
   iv. Lab instructions
      a. Specimen requirements
      b. Shipping requirements
      c. Copies of requisition to:
         i. Accounting
         ii. Data Entry/QA
      d. Freeze additional specimen

C. Donor testing:
Donor testing to be performed will be determined by the CBB Medical Director, but may include the following (but not limited to):

	TEST	PERFORMED BY		TEST	PERFORMED BY
Hepatitis	HBsAg	IBC	Bacteremia	Culture with Gram Stain	ACL
	Anti-HBc	IBC	West Nile Virus	WNV NAT	IBC
	HBV NAT	IBC	TRALI	Anti-HLA antibodies	BCW
	Anti-HCV	IBC		Anti-Granulocyte Antibodies	BCW
	Anti-HCV (2nd Mfg)	IBC			
	HCV NAT	IBC	Chagas	Anti-Chagas	IBC
HIV	Anti-HIV 1/2	IBC			
	HIV 1 IFA (WB)	IBC	HTLV I/II	Anti HTLV I/II	IBC
	HIV NAT	IBC		Anti-HTLV I/II (2nd Mfg)	IBC
	Anti-HIV 2	IBC	Babesiosis	Babesia NAT	IBC
	HIV 2 IFA (WB)	IBC			
	Anti-HIV 1	IBC			

1. Collect donor specimen per instruction and requirements
2. Process and ship specimens per instructions and requirements.
   a. Consult Surround Web Interface: Accessioning SOP for additional specimen/shipping information
3. When results completed/received give results to QA.
4. QA or designee will perform the following:
   a. Entry or documentation of test results in SafeTrace: =DN, DE, & MS
   b. Documentation of Test Results on Implicated Donor report
   c. Deactivation of deferral (if indicated).
   d. Letter to donor
   e. Additional Lookback if required
   f. Letter to Transfusion Service upon completion of all donors
   g. Notification to appropriate department of health if required
   h. Notification to appropriate other agencies if required (FDA, CDC, etc)
5. Medical Director:
   a. Review of implicated donor report to determine donor eligibility
   b. Review of transfusion service report(s)

D. If a donor is the only source of transfusion for a patient with transfusion-transmitted hepatitis, that donor will be permanently deferred. Permanent deferral also occurs if a donor is implicated in two cases of transfusion-transmitted hepatitis where multiple donors are involved.

REPORTING & INTERPRETING RESULTS:

1. Complete:
   a. Report of Transfusion Transmitted Disease – Hospital Transfusion Service
   b. Implicated Donor Report

2. The Medical Director will review completed reports and determine donor eligibility.

References:
21 CFR, 606.170
AABB Standards for Blood Banks and Transfusion Services, current edition, STD: 7.5.2, 7.5.4, 7.5.5
Surround Web Interface: Accessioning SOP

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Original Effective Date	Revised by	Revision	Supersedes Revision #
9.12.1991	D. Pirschel	REMOVED UNYTS	1.001
	D. Pirschel	Remove BRD Union Square address	1.002
	D. Pirschel	Added:testing laboratory information Added: additional information on entry into SafeTrace and responsibilities by department	1.003
	J. Vieyra	Added: Anti-HCV (2nd mfg) and Anti-HTLV I/II (2nd mfg)	1.004
	D. Pirschel	Deleted: GCRBC: Gulf Coast Regional Blood Center: http://yourlab.giveblood.org Chagas RIPA Added: IBC: Indiana Blood Center	1.005
	D. Pirschel	Deleted: Director, Donor Operation Added: GCRBC: Gulf Coast Regional Blood Center Collections Management Zika | Per IND protocol | GCRBC/Roche	1.006
	T. Collier	Deleted: GCRBC: Gulf Coast Regional Blood Center GCRBC/Roche "Specimen Shipment To External Testing Laboratory" SOP and/or References: Specimen Shipment To External Testing Laboratory" SOP Added: IBC/Roche	1.007
	D. Pirschel	Deleted: Roche Per IND protocol Added: Zika Virus Test	1.008
9.12.1991	K. Kramer	Added: Syphilis, WNV infection, Babesia infection TTD Form Transfusion Transmitted Disease (TTD) Babesiosis Babesia NAT IBC	1.009
9.12.1992	K. Kramer	Deleted: , ZIKA Virus infection Zika Zika Virus Test IBC Added: (Versiti, Wisconsin) (Versiti, Indiana) Anti-HIV 1 IBC	1.010

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REVIEWED BY:			
Department Head	**Name**	**Signature**	**Date**
Technical Director	Shelley West	Shelley West	10/28/21
APPROVED BY:			
Position	**Name**	**Signature**	**Date**
QA Director	Kristin Kramer	Kristin Kramer	6/28/21
Medical Director	Jeffrey A. Richmond MD	JR:MD	6.28.21
IMPLEMENTATION DATE:	AUG 16 2021		

REVIEW			
MEDICAL DIRECTOR	DATE	MEDICAL DIRECTOR	DATE

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RETIRED SOP

SOP RETIRED BY	TITLE	INITIALS	DATE RETIRED	COPIES RECEIVED
				LAB