ADULT AND PEDIATRIC BLOOD AND MARROW TRANSPLANT PROGRAM

**DOCUMENT NUMBER:** APBMT-COMM-004

**DOCUMENT TITLE:**
Collection of Donor Blood Samples for Infectious Disease Testing

**DOCUMENT NOTES:**

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**Document Information**

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APBMT-COMM-004
COLLECTION OF DONOR BLOOD SAMPLES FOR INFECTIOUS DISEASE TESTING

1 PURPOSE
1.1 To define the steps for sending donor blood samples to a Food and Drug Administration (FDA) accredited laboratory for infectious disease testing and other physician driven screening tests.

2 INTRODUCTION
2.1 Adult and Pediatric autologous and allogeneic cellular therapy donors must have blood samples drawn prior to donation which will test for the presence of infectious diseases. Additional testing may be performed per physician request. Refer to APBMT-COMM-001 Donor Selection, Evaluation and Management.

3 SCOPE AND RESPONSIBILITIES
3.1 This procedure lists the infectious disease tests and other physician driven screening tests that shall be drawn on autologous or allogeneic cellular product donors in the Adult and Pediatric Blood and Marrow Transplant (APBMT) Programs.
3.2 Nurse Coordinators/Clinicians, Advance Practice Providers (APP), Apheresis Nurse(s) and phlebotomists are responsible for sending blood samples for testing.

4 DEFINITION/ACRONYMS
4.1 AB Antibody
4.2 AG Antigen
4.3 APBMT Adult and Pediatric Blood and Marrow Transplant
4.4 APP Advance Practice Provider
4.5 CFR Code of Federal Regulations
4.6 CMV Cytomegalovirus
4.7 DUHS Duke University Health System
4.8 EDTA Ethylenediaminetetraacetic acid
4.9 FACT Foundation for the Accreditation of Cellular Therapies
4.10 FDA Food and Drug Administration
4.11 HEP Hepatitis
4.12 HBV Hepatitis B
4.13 HCV Hepatitis C Virus
4.14 HIV Human Immunodeficiency Virus
4.15 HTLV Human T-Lymphotropic Virus
4.16 IgM Immunoglobulin M
4.17 IVIG  Intravenous Immunoglobulin G
4.18 mL  Milliliters
4.19 NAT  Nucleic Acid Test
4.20 PCR  Polymerase Chain Reaction
4.21 PPT  Plasma Preparation Tube
4.22 PST  Plasma Separator Tube
4.23 RPR  Rapid Plasma Reagin
4.24 SST  Serum Separator Tube
4.25 Toxo IgG  Toxoplasmosis Immunoglobulin G
4.26 VZV  Varicella Zoster Virus

5  MATERIALS
5.1 Donor Referral Panel-Viromed package of blood tubes for infectious disease testing.
5.2 Blood tubes for other donor testing not sent to Viromed.

6  EQUIPMENT
6.1 N/A

7  SAFETY
7.1 Follow all safety related Standard Operating Procedures and wear all necessary Personal Protective Equipment (PPE) when handling potentially hazardous blood and body fluids. PPE includes but is not limited to gloves, surgical mask, face shield and/or goggles. Hand hygiene will be performed before and after patient contact.

8  PROCEDURE
8.1 Collect the appropriate tubes as outlined below for infectious disease testing using the Donor Referral Panel-Viromed Collection Kit.

8.1.1 Donor Referral Panel-Viromed: Testing Components

- Hepatitis B Surface Antigen (HBs-Ag)
- Hepatitis B Core Antibody (HBC-Ab)
- Hepatitis C Virus Antibody (HCV-Ab)
- Treponema pallidum (syphilis) Antibody Screen
- Cytomegalovirus CMV Total Antibody
- HIV1/0/2 Antibody test (Anti HIV to 1/0/2)
- HIV/HCV/HBV NAT
- HTLV I/II/ Antibody Qualitative (HTLV I/II)
- Zika Virus NAT
• West Nile Virus NAT (WNV)
• Trypanosoma cruzi (Chagas) Antibody

8.1.2 Donor Referral Panel-Viromed: Testing Components
(Donor < 6 months of age or any donor having received IVIG)
• Hepatitis B Surface Antigen (HBs-Ag)
• Treponema pallidum (syphilis) Antibody Screen
• HIV/HCV/HBV NAT
• Zika Virus NAT
• West Nile Virus NAT (WNV)

8.2 Collect the appropriate tubes as outlined below for additional testing, if requested by the physician, and send to DUHS Clinical Laboratory.

Note: Not all testing may be required for every donor.

8.2.1 Donor in Adult BMT
• Toxoplasma gondii IgG Antibody
• Toxoplasma gondii IgM Antibody
  ○ Draw only if IgG is positive
• EBV IgG, EBV IgM, EBV EBNA, and EBV EA IgG Antibodies
• Herpes Simplex IgG Antibody
• Varicella-Zoster IgG Antibody
• CMV DNA (PCR, quantitative; if CMV is positive)
• Type and Screen/Blood Type (ABO/Rh)
  ○ Includes Red Blood Cell Antibody drawn on all donors/recipients
• Anti-HLA Antibody Screen
• Serum Protein Electrophoresis Panel (SPEP)
• Hepatitis B Surface Antibody
• Hepatitis A IgM Antibody
• HGB Electrophoresis Panel (HEP)
  ○ Draw if donor or recipient is positive
• HLA Class I High Resolution Typing
• HLA Class II High Resolution Typing

8.2.2 Donor in Pediatric BMT ≥ 6 month of age
• Toxoplasma gondii IgG Antibody
• Toxoplasma gondii IgM Antibody
• EBV IgG, EBV IgM, EBV EBNA, and EBV EA IgG Antibodies
• Herpes Simplex IgG Antibody
• Varicella Zoster IgG Antibody
• CMV DNA (PCR, quantitative)
• Type and Screen/Blood Type (ABO/Rh)
  o Includes Red Blood Cell Antibody drawn on all donors/recipient
• Anti-HLA Antibody Screen
• HGB Electrophoresis Panel (HEP)
  o Draw if donor or recipient is positive
• HLA Class I High Resolution Typing
• HLA Class II High Resolution Typing

8.2.3 Donor in Pediatric BMT < 6 month of age or having received IVIG

• EBV (PCR, quantitative)
• CMV (PCR, quantitative)
• Type and Screen/Blood Type (ABO/Rh)
  o Includes Red Blood Cell Antibody drawn on all donors/recipient
• Anti-HLA Antibody Screen
• HGB Electrophoresis Panel (HEP)
  o Draw if donor or recipient is positive
• HLA Class I High Resolution Typing
• HLA Class II High Resolution Typing

9 RELATED DOCUMENTS/FORMS
9.1 APBMT-COMM-001 Donor Selection, Evaluation and Management
9.2 APBMT-COMM-001 FRM2 Summary of Donor Eligibility and Infectious Disease Testing (PBMT)
9.3 APBMT-COMM-001 FRM3 Summary of Donor Eligibility and Infectious Disease Testing (ABMT)

10 REFERENCES


10.3 Food and Drug Administration. Proposed FDA regulations: 21 CFR 1270, Human Cellular and Tissue-Based Products.
### 11 REVISION HISTORY

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<td>06</td>
<td>M. Christen</td>
<td>- Removed all tables and transitioned to new format.</td>
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<td>- Updated names of testing according to FDA requirements and in comparison to APBMT-COMM-001 and associated forms.</td>
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