DukeMedicine
Division of Cellular Therapy

ADULT AND PEDIATRIC BLOOD AND MARROW TRANSPLANT PROGRAM

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Collection of Donor Blood Samples for Infection Disease Testing JA2

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APBMT-COMM-001 JA2
COLLECTION OF DONOR BLOOD SAMPLES FOR INFECTIOUS DISEASE TESTING

1 PURPOSE

1.1 To define the steps for collecting and 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 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.

2.2 Some autologous cellular therapy donors may have blood samples drawn prior to donation which will test for the presence of infectious disease. Additional testing may be performed per physician request.

3 SCOPE AND RESPONSIBILITES

3.1 This procedure lists the infectious disease tests and other physician driven screening tests that may be drawn on autologous or allogeneic cellular product donors in the Adult and Pediatric Blood and Marrow Transplant (APBMT) Programs.

3.2 Nurse Coordinators (NC), Transplant Coordinators (TC), Advance Practice Providers (APP), Registered Nurse (RN) 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	HGB Electrophoresis Panel
4.12	HBV	Hepatitis B Virus
4.13	HCV	Hepatitis C Virus

4.14	HIV	Human Immunodeficiency Virus
4.15	HTLV	Human T-Lymphotropic Virus
4.16	IgG	Immunoglobulin G
4.17	IgM	Immunoglobulin M
4.18	NAT	Nucleic Acid Test
4.19	NC	Nurse Coordinator
4.20	PCR	Polymerase Chain Reaction
4.21	PST	Plasma Separator Tube
4.22	RN	Registered Nurse
4.23	RPR	Rapid Plasma Reagin
4.24	SST	Serum Separator Tube
4.25	TC	Transplant Coordinator
4.26	Toxo IgG	Toxoplasmosis Immunoglobulin G
4.27	Toxo IgM	Toxoplasmosis Immunoglobulin M
4.28	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, which may include:

5.2.1 Lavender Top: Ethylenediaminetetraacetic acid (EDTA)

5.2.2 Light-Blue Top: Sodium Citrate

5.2.3 Dark-Yellow Top: Serum Separator Tube (SST)

5.2.4 Mint-Green Top: Plasma Separator Tube (PST)

5.2.5 Dark-Green Top: Sodium Heparin

5.2.6 Gray Top: Sodium Fluoride/Potassium Oxalate

5.2.7 Red Top: Inert Clot Activator

5.2.8 Light-Yellow Top: ACD, Solution A/B

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 Not all donors will require all the testing below due to type of collection, their age and size specification, and/or immunology status.

8.1.1.1 <u>Donor Referral Panel-Viromed: Testing Components</u>

- Hepatitis B Surface Antigen (HBs-Ag)
- Hepatitis B Core Total 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 (HTLV I/II)
- West Nile Virus NAT (WNV)
- Trypanosoma cruzi (Chagas) Antibody
- Zika Virus (collection based on potential risk factors)

8.2 Additional testing, if requested by the physician, may be collected prior to the donor's collection. Testing may be sent to DUHS Clinical Laboratory or another accredited laboratory.

8.2.1 The Standard Donor Testing completed for the APBMT programs includes, but not limited to the lab tests below.

- Type and Screen/Blood Type (ABO/Rh)
  - Includes Red Blood Cell Antibody
- HLA Class I High/Low Resolution Typing
- HLA Class II High/Low Resolution Typing
- EBV IgG, EBV IgM, EBV EBNA, and EBV EA IgG Antibodies
- EBV (PCR, quantitative)
- Herpes Simplex IgG Antibody
- Varicella-Zoster IgG Antibody
- CMV DNA (PCR, quantitative)
- Hepatitis A Antibody, Total

- Serum Protein Electrophoresis Panel (SPEP)
- HGB Electrophoresis Panel (HEP)
- Toxoplasma gondii IgG Antibody
- Toxoplasma gondii IgM Antibody
- Anti-HLA Antibody Screen

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

10 REFERENCES

10.1 American Association of Blood Banks. Standards for Hematopoietic Progenitor Cell and Cellular Product. Current edition.

10.2 Foundation for the Accreditation of Hematopoietic Cell Therapy (FACT). Standards for Hematopoietic Progenitor Cell Collection, Processing and Transplantation. Current edition

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

11 REVISION HISTORY

Revision No.	Author	Description of Change(s)
01	M. Christen	- Changed document number to reflect its connection with the APBMT-COMM-001 parent SOP. - Updated the lab data with the appropriate tubes and requirements per the APBMT program. - Remove all unnecessary data or duplication - Updated related documents and forms - Update any definitions and/or acronyms

Signature Manifest

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