ADULT AND PEDIATRIC BLOOD AND MARROW TRANSPLANT PROGRAM

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DOCUMENT TITLE:
Summary of Donor Eligibility and Infectious Disease Testing (ABMT) FRM3

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Control Information

Author: MOORE171
Owner: MOORE171

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DUKE UNIVERSITY
HEALTH SYSTEM

APBMT-COMM-001 FRM3
Summary of Donor Eligibility & Infectious Disease Testing (ABMT)

Product Collection Date: __/__/____ Product: __________________________ Unit ID#: __________________________

Donor Testing Performed by: [ ] LabCorp Viromed  [ ] Other Testing Site __________________________

(Bar Code Label)

<table>
<thead>
<tr>
<th>#</th>
<th>Donor Screening Test</th>
<th>Panel expires on <strong>/</strong>/____</th>
<th>Sample collected: <strong>/</strong>/____</th>
<th>Results (NT= Not Tested)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Hepatitis B Surface Antigen (HBs-Ag) * (Donor Referral Panel)</td>
<td></td>
<td></td>
<td>Reactive  Non-Reactive  Pending</td>
</tr>
<tr>
<td>2</td>
<td>Hepatitis B Core Total Antibody (HBc-Ab) * (Donor Referral Panel)</td>
<td></td>
<td></td>
<td>Reactive  Non-Reactive  Pending</td>
</tr>
<tr>
<td>3</td>
<td>Hepatitis C Virus Antibody (HCV-Ab) * (Donor Referral Panel)</td>
<td></td>
<td></td>
<td>Reactive  Non-Reactive  Pending</td>
</tr>
<tr>
<td>4</td>
<td>Treponema pallidum (syphilis) Antibody Screen (Initial screen) (Donor Referral Panel)</td>
<td></td>
<td></td>
<td>Reactive  Non-Reactive  Pending</td>
</tr>
<tr>
<td>5</td>
<td>Cytomegalovirus CMV Total Antibody * (Donor Referral Panel)</td>
<td></td>
<td></td>
<td>Reactive  Non-Reactive  Pending</td>
</tr>
<tr>
<td>6</td>
<td>HIV 1/0/2 Antibody test (Anti HIV to 1/0/2) * (Donor Referral Panel)</td>
<td></td>
<td></td>
<td>Reactive  Non-Reactive  Pending</td>
</tr>
<tr>
<td>7</td>
<td>HIV/HCV/HBV NAT * (Donor Referral Panel)</td>
<td></td>
<td></td>
<td>Reactive  Non-Reactive  Pending</td>
</tr>
<tr>
<td>8</td>
<td>HTLV I/II Antibodies (HTLV I/II) * (Donor Referral Panel)</td>
<td></td>
<td></td>
<td>Reactive  Non-Reactive  Pending</td>
</tr>
<tr>
<td>9</td>
<td>Zika Virus NAT (Donor Referral Panel)</td>
<td></td>
<td></td>
<td>Reactive  Non-Reactive  Pending</td>
</tr>
<tr>
<td>10</td>
<td>West Nile Virus NAT * (Donor Referral Panel)</td>
<td></td>
<td></td>
<td>Reactive  Non-Reactive  Pending</td>
</tr>
<tr>
<td>11</td>
<td>Trypanosoma cruzi (Chagas) Antibody (Donor Referral Panel)</td>
<td></td>
<td></td>
<td>Reactive  Non-Reactive  Pending</td>
</tr>
</tbody>
</table>

The section below (#12) applies only if Treponema pallidum (syphilis) Antibody Screen (#4 above) is REACTIVE. Otherwise, mark not applicable.

12. Syphilis confirmatory testing (RPR) [ ] Not Applicable [ ] Reactive [ ] Non-Reactive [ ] Pending

If testing is not performed for any sample listed in this section below, (#13-#26), mark Not Tested (NT) and provide rationale in Section B comment line.

13. Toxoplasma gondii IgG Antibody                                    | Reactive  Non-Reactive  Pending  NT |
14. Toxoplasma gondii IgM Antibody                                    | Reactive  Non-Reactive  Pending  NT |
15. EBV IgG                                                         | Reactive  Non-Reactive  Pending  NT |
16. EBV IgM                                                        | Reactive  Non-Reactive  Pending  NT |
17. EBV EBNA                                                        | Reactive  Non-Reactive  Pending  NT |
18. EBV EA IgG                                                     | Reactive  Non-Reactive  Pending  NT |
19. Herpes Simplex IgG Antibody                                     | Reactive  Non-Reactive  Pending  NT |
20. Varicella Zoster IgG Antibody                                    | Reactive  Non-Reactive  Pending  NT |
21. CMV DNA (PCR, quantitative; if CMV +)                            | Reactive  Non-Reactive  Pending  NT |
22. Hepatitis A IgM Antibody                                        | Reactive  Non-Reactive  Pending  NT |
23. Serum Protein Electrophoresis                                  | Reactive  Non-Reactive  Pending  NT |
24. Hemoglobin Electrophoresis Panel (HEP)                          | Reactive  Non-Reactive  Pending  NT |
25. Type and Screen/Blood Type (ABO/Rh)                             | Reactive  Non-Reactive  Pending  NT |
26. Anti-HLA Antibody Screen ∞                                      | Reactive  Non-Reactive  Pending  NT |

List any other relevant Donor Testing Completed in this section below (#27); otherwise mark Not Applicable.

27. Other [ ] Not Applicable [ ] Reactive [ ] Non-Reactive [ ] Pending

Section A Continued: Table Footnotes: All testing will be performed by a CLIA certified laboratory.
* FDA Required testing. ∞ Anti-HLA Antibody screening is required for all mismatched donor/recipients.
DUKE UNIVERSITY
HEALTH SYSTEM

Summary of Donor Eligibility & Infectious Disease Testing (ABMT)

Product Collection Date: / / Product: ___________________________ Unit ID#: ___________________________
(Bar Code Label)

Section B: Donor Eligibility Requirements: Have the donor eligibility requirements been met based on:

1. Infectious Disease Testing: ☐ Yes ☐ No (see exceptions in Section A and comment below)
2. Donor History Questionnaire: ☐ Yes ☐ No (list exceptions below)

______________________ __________________________
Clinician/Physician Signature Date

If donor eligibility requirements NOT met, record physician notified and date.

______________________ __________________________
Physician notified Date

Section C: Emergency/Exceptional Release:
The physician is responsible for reviewing any exceptions and determining if the product is acceptable as an “Urgent Medical Need.” The physician is responsible for informing the product recipient (or legal guardian) that the donor eligibility requirements have not been met.

☐ This product is determined to be an “Urgent Medical Need” (an urgent medical need means that no comparable HCT/P (Human Cell, Tissue, or Cellular or Tissue-Based Product) is available and the recipient is likely to suffer death or serious morbidity without the HCT/P).

☐ The adult patient (product recipient) has been informed that the donor eligibility requirements have not been met:
  ☐ Product accepted
  ☐ Product not accepted

☐ The Legal guardian of the pediatric patient (product recipient) has been informed that the donor eligibility requirements have not been met:
  ☐ Product accepted
  ☐ Product not accepted

______________________ __________________________
Medical Director/Designee Signature Pager # Date of Notification

______________________ __________________________
Quality Manager/Designee Signature Pager # Date of Notification
## Instructions for Completing the Summary of Donor Eligibility Form

<table>
<thead>
<tr>
<th>Field</th>
<th>Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product collect Date</td>
<td>Enter the date the product is collected.</td>
</tr>
<tr>
<td>Product</td>
<td>Enter the type of product collected: PBSC, Granulocyte, DLI, NK Cell.</td>
</tr>
<tr>
<td>Unit ID #</td>
<td>Place unique product identifier (bar code label) here.</td>
</tr>
</tbody>
</table>

### Section A: Donor Testing:
1. Check where infectious testing was performed. If “Other” is checked, write the name lab performing the tests.
2. Enter the date that blood samples were collected for donor testing.
3. Check each test result as Reactive (positive), Non-Reactive (negative), or Pending (awaiting result).

### Panel Expires On:
Record date the Donor Referral Panel expires.

### Section B: Have donor eligibility requirements been met based on the Infectious Disease Testing and the Donor History Questionnaire?
Review the Donor Testing and Donor History Questionnaire. Check “Yes” if the requirements have been met, check “No” if there are any exceptions. If there are any donor history exceptions, list them on the lines provided. Sign and date. If there are exceptions, notify the physician, and record physician notified.

Apheresis donors: If any testing results are pending, file the original of this form in the “Pending” folder in apheresis. Send a copy to the lab with the product and place a biohazard label on the product bag. The apheresis coordinator or designee will monitor for lab results, update the original form and send to lab. If any of the donor screening test for infectious disease (questions 1 through 12) are reactive (with the exception of CMV), the physician will be notified.

### Section C: Emergency/Exceptional Release
If an emergency/exceptional release is needed, the physician will review the exception(s) noted. If the product is determined to be an “Urgent Medical Need”, check the appropriate box. The physician will inform the product recipient (or legal guardian) that the donor requirements have not been met, and check “Product Accepted” or “Product Not Accepted.” The medical director/designee will sign; provide pager #, and record date of notification. The Quality Manager/designee will sign and date.
# Signature Manifest

**Document Number:** APBMT-COMM-001 FRM3  
**Title:** Summary of Donor Eligibility and Infectious Disease Testing (ABMT) FRM3

All dates and times are in Eastern Time.

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**APBMT-COMM-001 FRM3 Summary of Donor Eligibility and Infectious Disease Testing (ABMT)**

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## Author

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<th>Meaning/Reason</th>
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<tr>
<td>Sally McCollum (MOORE171)</td>
<td></td>
<td>02 Jul 2019, 11:43:12 AM</td>
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## Management

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<td>Nelson Chao (CHAO0002)</td>
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## Medical Director

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<td>Joanne Kurtzberg (KURTZ001)</td>
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## Quality

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<tr>
<td>Bing Shen (BS76)</td>
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<td>03 Jul 2019, 09:52:51 AM</td>
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## Document Release

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<td>Sandy Mulligan (MULLI026)</td>
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