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|---|--|-------------------------------------|--|-------------------------------------|--|--------------------------|--|--------------------------|---|
| <p><u>Name of Policy: Supplier Qualification/Reagent Verification</u></p> <p><u>Policy Number: 3364-108-108</u></p> <p><u>Approving Officer: Senior Hospital Administrator<br/>Director, Blood Transfusion Service</u></p> <p><u>Responsible Agent: Blood Transfusion Service<br/>Supervisor<br/>Administrative Director, Lab</u></p> <p><u>Scope: Pathology/Laboratory – Blood Bank</u></p>  | <div style="text-align: center;">  </div> <hr style="border: 0.5px solid red;"/> <p><u>Effective date: 03/01/2025</u></p> <p><u>Original effective date: 03/1999</u></p> |                                     |  |                                     |  |                          |  |                          |   |
| <p><u>Key words: Supplier, Qualification, Reagent, Verification, Agreement</u></p>  |  |                                     |  |                                     |  |                          |  |                          |   |
| <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 10%; text-align: center; vertical-align: top;"><input type="checkbox"/></td> <td style="width: 40%; padding: 2px;"><u>New policy proposal</u></td> <td style="width: 10%; text-align: center; vertical-align: top;"><input checked="" type="checkbox"/></td> <td style="width: 40%; padding: 2px;"><u>Minor/technical revision of existing policy</u></td> </tr> <tr> <td style="text-align: center; vertical-align: top;"><input type="checkbox"/></td> <td style="padding: 2px;"><u>Major revision of existing policy</u></td> <td style="text-align: center; vertical-align: top;"><input type="checkbox"/></td> <td style="padding: 2px;"><u>Reaffirmation of existing policy</u></td> </tr> </table> |  | <input type="checkbox"/>            | <u>New policy proposal</u>                         | <input checked="" type="checkbox"/> | <u>Minor/technical revision of existing policy</u> | <input type="checkbox"/> | <u>Major revision of existing policy</u> | <input type="checkbox"/> | <u>Reaffirmation of existing policy</u> |
| <input type="checkbox"/>  | <u>New policy proposal</u>   | <input checked="" type="checkbox"/> | <u>Minor/technical revision of existing policy</u> |                                     |  |                          |  |                          |   |
| <input type="checkbox"/>  | <u>Major revision of existing policy</u>   | <input type="checkbox"/>            | <u>Reaffirmation of existing policy</u>            |                                     |  |                          |  |                          |   |

(A) ~~(A)~~ — Policy Statement

The Blood Transfusion Service has identified critical reagents, supplies and services and defined specifications for the suppliers of critical reagents, supplies and services.

(B) ~~(B)~~ — Purpose of Policy

To document the specifications, receipt and disposition of critical reagents, supplies and services provided by approved suppliers.

(C) ~~(C)~~ — Procedure

(1) The Blood Transfusion Service has developed a list of critical reagents, supplies and services. Critical reagents, supplies and services are those materials and services that affect quality of service and Patient safety. General specifications for suppliers of critical reagents, supplies and services are as follows:

- (a) Safe, consistent operation or function as intended
- (b) Cost effective
- (c) FDA approved (if applicable)
- (d) Adequate supplies available/ shipping schedule
- (e) Good customer service record
- (f) Quality of product
- (g) Vendor has a defined Quality Plan

(2) Reagents /Reagent Verification

(a) Approved suppliers: Quidel Ortho-~~Diagnosties~~ (QQQ), ~~WerfenImmucor/~~ Gamma (WG), and Alba/Quotient (AQQ). Letter designates most frequent supplier after the reagent type.

| Reagent   | Testing Frequency                                    | Calibration/ Validation Technique  | Acceptable Range        | Corrective Procedure  |
|---|--|--|-------------------------|---|
| ABO antiserum(QO)<br>Rh antiserum(QO)<br>AHG(QO)<br>▪ Albumin(QO)<br>▪ PeG (WG)<br>▪ LISS (WG)<br>A <sub>1</sub> , B cells(QO)<br>Ab scrn cells(QO, AQO, Q)<br>ID-MTS Gel card (QO)<br>ID-MTS ABD cards (QO)<br>ID-MTS Diluent (QO) | Daily for each set to be used; Each lot prior to use | See separate procedure<br>500.050<br>500.055<br>Review package inserts online for revisions. | Defined by manufacturer | Notify supervisor or director; discard unacceptable reagents; notify manufacturer if warranted. |
| Panel cells(QO, WG)<br>rare antiserum (QO, WG)<br>QC kits (QO)<br>Elu-Kit II(WG)  | Each day of use                                      | See manufacturer's instructions.<br>Review package insert online for revisions.<br>500.055   | Defined by manufacturer | Same as above   |

(1) — Supplies

(3) —

(a) The Materials Management Department (3649) maintains lists of all vendors' addresses, phone numbers, fax numbers and account information. Supplies and reagents are ordered through the Lawson system.

| Supply                      | Suppliers         | Inside(I)/Outside(O) Order |
|-----------------------------|-------------------|----------------------------|
| Rh Immune Globulin (Rhogam) | Kedrion Biopharma | O                          |
| Pipet tips                  | Fisher-SCIENTIFIC | O                          |

| Supply   | Suppliers  | Inside(I)/Outside(O)<br>Order                 |
|--|--|---|
| <u>Component Administration Set (4C2223)</u><br><del>Leukocyte reduction filters:<br/>RC EZ Prime Filter, Purecell Platelet Filter</del> | <u>Baxter-Fenwal</u> <del>ARC</del>  | <u>I (Central Supply #12531)</u> <del>O</del> |
| <u>Plastic Bags for Overwrap</u> <del>Component Administration Set (4C2223)</del>  | <u>Baxter –Fenwal</u><br><u>Fisher-SCIENTIFIC</u> <del>Baxter-Fenwal</del>                           | <u>OI (Central Supply #12531)</u>             |
| <u>Transfer Packs</u> <del>Plastic Bags for Overwrap</del>   | <u>Terumo</u> <del>Baxter –Fenwal</del><br><u>Fisher-SCIENTIFIC</u>                                  | <u>OO</u>                                     |
| <u>Armbands</u> <del>Transfer Packs</del>  | <u>Typenex</u> <del>Terumo</del>   | <u>OO</u>                                     |
| <u>BB forms/ Transfusion Forms</u> <del>Armbands</del>   | <u>UT Storefront</u><br><u>Ordering</u> <del>Typenex</del>   | <u>IO</u>                                     |
| <u>Blood Tags/Fasteners</u> <del>BB forms/ Transfusion Forms</del>   | <u>Amazon</u> <del>UT Storefront</del><br><u>Ordering</u>  | <u>OI</u>                                     |
| <u>Cell Washer Supplies</u> <del>Blood Tags/Fasteners</del>  | <u>Helmer, Inc.</u> <del>Staples</del>   | <u>OO</u>                                     |
| <u>12x75 Glass Tubes</u> <del>Cell Washer Supplies</del>   | <u>Various</u> <del>Helmer, Inc.</del>   | <u>IO</u>                                     |
| <u>Polystyrene 12x75 tubes/caps</u> <del>12x75 Glass Tubes</del>   | <u>Fisher-SCIENTIFIC</u> <del>Various</del>  | <u>OI</u>                                     |
| <u>Disposable Plastic Pipettes (uniform drop size)</u> <del>Polystyrene 12x75 tubes/caps</del>   | <u>Fisher-SCIENTIFIC</u> <del>Fisher-SCIENTIFIC</del>  | <u>OO</u>                                     |
| <u>Biohazard Bags</u> <del>Disposable Plastic Pipettes (uniform drop size)</del>   | <u>Various</u> <del>Fisher-SCIENTIFIC</del>  | <u>IO</u>                                     |
| <u>Hematype Segment Devices (4R5126)</u> <del>Biohazard Bags</del>   | <u>Baxter-Fenwal</u> <del>Various</del>  | <u>OI</u>                                     |
| <u>Printer labels</u> <del>Hematype Segment Devices (4R5126)</del>   | <u>Shamrock Specialty</u> <del>Baxter-Fenwal</del>   | <u>OO</u>                                     |
| <u>Blood Bank Saline</u> <del>Printer labels</del>   | <u>Fisher-SCIENTIFIC</u> <del>Shamrock Specialty</del>   | <u>OO</u>                                     |
| <u>Gloves</u> <del>Blood Bank Saline</del>   | <u>Various</u> <del>Fisher-SCIENTIFIC</del>  | <u>IO</u>                                     |
| <u>Phlebotomy Bags</u> <del>Gloves</del>   | <u>Baxter/Fenwal, ARC</u> <del>Various</del>   | <u>OI</u>                                     |
| <u>Bench Protectors</u> <del>Phlebotomy Bags</del>   | <u>Fisher-SCIENTIFIC</u> <del>Baxter/Fenwal, ARC</del>   | <u>OO</u>                                     |
| <u>Temperature Recording Charts</u> <del>Bench Protectors</del>  | <u>Fisher-SCIENTIFIC</u><br><u>Graphic Controls Corp.</u> <del>Fisher-SCIENTIFIC</del>               | <u>O</u><br><u>OO</u>                         |
| <u>Misc. Office Supplies</u> <del>Temperature Recording Charts</del>   | <u>Amazon</u><br><u>General Stores</u> <del>Fisher-SCIENTIFIC</del><br><u>Graphic Controls Corp.</u> | <u>O</u><br><u>IO</u><br><u>O</u>             |

| Supply  | Suppliers   | Inside(I)/Outside(O)<br>Order                         |
|---|---|---|
| <u>Misc. Lab Supplies</u> <del>Misc. Office Supplies</del>              | <u>Fisher-SCIENTIFIC</u><br><del>General Stores</del> <del>Staples</del><br><del>General Stores</del> | <u>O</u><br><del>I</del> <del>O</del><br><del>I</del> |
| <u>Hemotemp II Temperature Indicators</u> <del>Misc. Lab Supplies</del> | <u>Fisher-SCIENTIFIC</u> <del>Fisher-SCIENTIFIC</del><br><del>General Stores</del>                    | <u>OO</u><br><del>I</del>                             |
| <u>Hemotemp II Temperature Indicators</u>                               | <u>Fisher-SCIENTIFIC</u>  | <u>O</u>  |

(4) Blood and Blood Components/Services

(a) Receipt, storage and handling – see Section #200 Quality System Manual

(b) Blood, blood components and specialized services are supplied ~~exclusively~~ by American Red Cross Blood Services, Western Lake Erie Region (ARCWLE) and Versiti Blood Center (VBC) in accordance with agreements reviewed by UT Legal and Compliance Office (General Counsel) annually. ARCWLE and VBC may, when necessary, supply UTMC with blood and blood components obtained by import from other regions. ARCWLE provides an annual Quality Assessment Report with results of quality control testing of blood and blood components, proficiency testing, and Regional Disease Marker testing results. Failure to consistently meet specified expectations is reported to UT Legal and Compliance Office (General Counsel). Testing of blood and blood components obtained from ARCWLE is performed by ARC National Testing Laboratory and ARCWLE using FDA-licensed kits in accordance with manufacturers' instructions. Testing of blood and blood components obtained from VBC is performed by VBC. –The laboratories are certified by HCFA, ~~and~~ licensed by FDA, and CLIA and AABB certified.

(D) References

- (1) Food and Drug Administration, Department of Health and Human Services. Title 42, Code of Federal Regulations, Parts 200-299, Parts 493 to end, Washington, DC: U.S. Government Printing Office (revised annually)
- (2) AABB Standards for Blood Banks and Transfusion Services, current edition

|                                  |   |
|----------------------------------|---|
| <u>Approved by:</u><br><br>_____ | <u>Policies Superseded by This Policy:</u><br>• <u>None</u><br><br><u>Initial effective date: 03/1999</u> |
|----------------------------------|---|

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| <p><u>Lauren Stanoszek, M.D.</u><br/> <u>Assistant Professor</u><br/> <u>Director, Blood Transfusion Service</u></p> <hr/> <p><u>Date</u></p> <hr/> <p><u>Russell Smith Pharm D, MBA, BCPS,</u><br/> <u>CPEL, FACHE</u><br/> <u>Senior Hospital Administrator</u></p> <hr/> <p><u>Date</u></p> <hr/> <p><u>Review/Revision Completed by:</u><br/> <u>Danielle Weinau MLS(ASCP)<sup>CM</sup></u></p> | <p><u>All Review/Revision Dates:</u><br/> <u>3/99</u><br/> <u>9/02</u><br/> <u>1/05</u><br/> <u>1/2008</u><br/> <u>6/9/2008</u><br/> <u>03/22/2011</u><br/> <u>3/01/2013</u><br/> <u>3/2/2015</u><br/> <u>3/1/2017</u><br/> <u>3/1/2019</u><br/> <u>3/1/2021</u><br/> <u>3/20/2023</u><br/> <u>3/1/2025</u></p> <p><u>Next review date: 03/01/2027</u></p> |
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| Approved by: | Review/Revision Date: |
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|              | 3/99                  |
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|              | 1/05                  |
|              | 1/2008                |
|              | 6/9/2008              |
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|              | 3/01/2013             |
|              | 3/2/2015              |
|              | 3/1/2017              |
|              | 3/1/2019              |
|              | 3/1/2021              |
|              | 3/20/2023             |

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| Christine Stesney-Ridenour<br>Chief Operating Officer—UTMC<br>Review/Revision Completed<br>By: —Danielle Weinhau, MLS(ASCP) <sup>CM</sup> |  | Date                          |
|   |  |                               |
|   |  | Next Review Date:<br>3/1/2025 |
| Policies Superseded by This Policy:   |  |                               |

References:

~~Food and Drug Administration, Department of Health and Human Services. Title 42, Code of Federal Regulations, Parts 200-299, Parts 493 to end, Washington, DC: U.S. Government Printing Office (revised annually)~~

~~AABB Standards for Blood Banks and Transfusion Services, current edition~~