

<p>Name of Policy: <u>Supplier Qualification/Reagent Verification</u></p> <p>Policy Number: 3364-108-108</p> <p>Department: Pathology/Laboratory – Blood Bank</p> <p>Approving Officer: Chief Operating Officer - UTMC Director, Blood Transfusion Service</p> <p>Responsible Agent: Blood Transfusion Service Supervisor Administrative Director, Lab</p> <p>Scope: Pathology/Laboratory – Blood Bank</p>	 <p>Effective Date: 3/20/2023 Initial Effective Date: 3/1999</p>
<p> <input type="checkbox"/> New policy proposal <input checked="" type="checkbox"/> Minor/technical revision of existing policy <input type="checkbox"/> Major revision of existing policy <input type="checkbox"/> Reaffirmation of existing policy </p>	

(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) Purpose of Policy

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

(C) Procedure

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:

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

Reagents /Reagent Verification

Approved suppliers: Ortho Diagnostics (O), Immucor/ Gamma (G), and Quotient (Q). Letter designates most frequent supplier after the reagent type.

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

Supplies

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
Leukocyte-reduction filters: RC EZ Prime Filter, Purecell Platelet Filter	ARC	O
Component Administration Set (4C2223)	Baxter-Fenwal	I (Central Supply #12531)
Plastic Bags for Overwrap	Baxter –Fenwal Fisher-SCIENTIFIC	O
Transfer Packs	Terumo	O
Armbands	Typenex	O
BB forms/ Transfusion Forms	UT Storefront Ordering	I
Blood Tags/Fasteners	Staples	O
Cell Washer Supplies	Helmer, Inc.	O
12x75 Glass Tubes	Various	I
Polystyrene 12x75 tubes/caps	Fisher-SCIENTIFIC	O
Disposable Plastic Pipettes (uniform drop size)	Fisher-SCIENTIFIC	O
Biohazard Bags	Various	I
Hematype Segment Devices (4R5126)	Baxter-Fenwal	O
Printer labels	Shamrock Specialty	O
Blood Bank Saline	Fisher-SCIENTIFIC	O
Gloves	Various	I
Phlebotomy Bags	Baxter/Fenwal, ARC	O
Bench Protectors	Fisher-SCIENTIFIC	O

Supply	Suppliers	Inside(I)/Outside(O) Order
Temperature Recording Charts	Fisher-SCIENTIFIC	O
	Graphic Controls Corp.	O
Misc. Office Supplies	Staples	O
	General Stores	I
Misc. Lab Supplies	Fisher-SCIENTIFIC	O
	General Stores	I
Hemotemp II Temperature Indicators	Fisher-SCIENTIFIC	O

Blood and Blood Components/Services

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

Blood, blood components and specialized services are supplied exclusively by American Red Cross Blood Services, Western Lake Erie Region (ARCWLE) in accordance with agreement reviewed by UT Legal and Compliance Office (General Counsel) annually. ARCWLE 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 is performed by ARC National Testing Laboratory and ARCWLE using FDA-licensed kits in accordance with manufacturers’ instructions. The laboratories are certified by HCFA and licensed by FDA.

<p>Approved by:</p> <p><u>/s/</u> _____ <u>03/21/2023</u> Lauren Stanoszek, M.D. Assistant Professor Director, Blood Transfusion Service Date</p> <p><u>/s/</u> _____ <u>03/21/2023</u> Christine Stesney-Ridenour Chief Operating Officer - UTMC Date</p> <p>Review/Revision Completed By: Danielle Weinau, MLS(ASCP)^{CM}</p>	<p>Review/Revision Date:</p> <p>3/99 9/02 1/05 1/2008 6/9/2008 03/22/2011 3/01/2013 3/2/2015 3/1/2017 3/1/2019 3/1/2021 3/20/2023</p> <hr/> <p>Next Review Date: 3/1/2025</p>
<p>Policies Superseded by This Policy:</p>	

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