


Name of Policy:	Supplier Qualification/Reagent Verification	 Effective Date: 6/9/2008 Initial Effective Date: 3/1999
Policy Number:	3364-108-108	
Department:	Pathology/Laboratory – Blood Bank	
Approving Officer:	Associate Professor Director, Clinical Pathology/Hematopathology	
Responsible Agent:	Core Lab Coordinator (Michelle Bartkowiak, MT(ASCP)SBB) Manager, Lab (Cynthia O'Connell)	
Scope:	Pathology/Laboratory – Blood Bank	
<input type="checkbox"/> New policy proposal <input type="checkbox"/> Major revision of existing policy		<input type="checkbox"/> Minor/technical revision of existing policy <input checked="" type="checkbox"/> Reaffirmation of existing policy

(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. 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 Quality Plan

Reagents /Reagent Verification

Approved suppliers: Ortho Diagnostics (O), Immucor/ Gamma (G). 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,G) ID-MTS Gel card (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 insert for revisions.	Defined by manufacturer	Notify supervisor or director; discard unacceptable reagents; notify manufacturer if warranted.

Reagent	Testing Frequency	Calibration/ Validation Technique	Acceptable Range	Corrective Procedure
Panel cells(O,G) rare antiserum (O,G) Ficin (G) Chloroquine diphosphate(G) corQC kits (G) Elu-Kit II(G)	Each day of use	See manufacturers instructions. Review package insert for revisions. 500.055	Defined by manufacturer	Same as above

Supplies

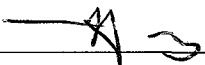
The Materials Management Department (3649) maintains lists of all vendors addresses, phone numbers, fax numbers and account information. Supplies and reagents are ordered through the Lawson system.

Supply	Suppliers	Inside(I)/Outside(O) Order
Rh Immune Globulin (Rhogam)	Ortho Diagnostics	O
ID-MTS pipet tips	Ortho Diagnostics	O
Leukocyte-reduction filters: RC EZ Prime Filter, Purecell Platelet Filter	ARC	O
Component Administration Set (4C2223)	Baxter-Fenwal	I (Central Supply #12531)
Blood Warmer Tubing (4C2480)	Baxter-Fenwal	O
Plastic Bags for Overwrap	Baxter -Fenwal Fisher-CMS	O
Transfer Packs	Terumo	O
Armbands	Burrows Corp.	O
Labels/BB ID forms	Precision Business Solutions/Novation contract	O
Blood Tags/Fasteners	Office Depot	O
Cell Washer Supplies CWI	Sorvall, Inc.	O
12x75 Glass Tubes	Various	I
Polystyrene 12x75 tubes/caps	Fisher-CMS	O
Disposable Plastic Pipettes (uniform drop size)	Fisher-CMS	O
Biohazard Bags	Various	I
Hematype Segment Devices (4R5126)	Baxter-Fenwal	O
Transfusion Forms	Precision Business Solutions	I (General Stores maintains supply)
Blood Bank Saline	Fisher-CMS	O
Gloves	Various	I
Phlebotomy Bags	Baxter/Fenwal	O
Bench Protectors	Fisher-CMS	O
Temperature Recording Charts	Fisher-CMS Graphic Controls Corp.	O O
Misc. Office Supplies	Office Depot General Stores	O I
Misc. Lab Supplies	Fisher-CMS General Stores	O I
Hemotemp II Temperature Indicators	Fisher-CMS	O

Blood and Blood Components/Services

Receipt, storage and handling – see Section #20 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 annual agreement. ARCWLE may, when necessary, supply UMC 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. Testing of blood and blood components is performed by Detroit National Testing Laboratory and ARCWLE using FDA-licensed kits in accordance with manufacturers' instructions. The laboratories are accredited by the American Association of Blood Banks, certified by HCFA and licensed by FDA.

Approved by:  Robert L. Booth, Jr., M.D. Associate Professor Director, Clinical Pathology/Hematopathology Review/Revision Completed By: Michelle Bartkowiak, MT(ASCP)SBB	Review/Revision Date: 3/99 9/02 1/05 1/2008 6/9/2008 Next Review Date: 6/1/2011
Policies Superseded by This Policy:	

It is the responsibility of the reader to verify with the responsible agent that this is the most current version of the 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