

Immunoematology		
Tag #	Standard	Guidance
	The following specialty sustaining standards of practices shall be incorporated into the laboratory's quality management system, where applicable to the scope of services provided.	
IH1	<p>Immunoematology Standard 1</p> <p>All tests including but not limited to ABO and Rh_o(D) grouping, antibody detection and identification shall employ methods, techniques, or procedures which have been approved or recommended for the particular reagent in use by the FDA or the American Association of Blood Banks, and which are of demonstrated effectiveness in a manner acceptable to the Department.</p>	
IH2	<p>Immunoematology Standard 2</p> <p>All blood grouping sera, reagents, devices, methods, and procedures shall conform to the recommended minimal requirements of the FDA.</p>	Testing should be performed following the manufacturer's package insert.
IH3	<p>Immunoematology Standard 3</p> <p>ABO grouping tests shall include both forward grouping and reverse grouping, except in the case of hospital transfusion services verifying a blood group determination performed elsewhere, in which case forward grouping alone may be performed.</p>	<p>Forward grouping shall include the use of anti-A and anti-B. Anti-A,B is optional.</p> <p>Reverse grouping shall consist of A cells and B cells. Use of A₂ cells is optional.</p> <p>For infants under four months of age, only forward grouping is required.</p>
IH4	<p>Immunoematology Standard 4</p> <p>For anti-human globulin and antibody screening cell testing, if a negative reaction is not seen on a given run, an investigation shall be performed, and controls shall be run.</p>	The routine use of negative controls on each day of use are not required for anti-human globulin and antibody screening cells, provided manufacturer's instructions are followed.

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IH5	<p>Immunoematology Standard 5</p> <p>The reactivity and specificity of each reagent shall be determined whenever a new lot is used.</p>	<p>Exception to standard: New York State does not require that each shipment of antibody identification cell panels be tested with a known antibody.</p>
IH6	<p>Immunoematology Standard 6</p> <p>Quality control records shall be retained for five years.</p>	
IH7	<p>Immunoematology Standard 7</p> <p>To detect the presence of unexpected antibodies, blood samples shall be tested using at least a two cell antibody screen designed for this purpose, tested individually, except that pooled screening cells may be used for testing blood donor specimens.</p>	<p>The use of pooled screening cells is not permitted for recipients.</p>
IH8a IH8b	<p>Immunoematology Standard 8</p> <p>Centrifuges used for testing of red blood cell agglutination:</p> <p>a) shall be calibrated quarterly; and,</p> <p>b) records shall indicate that the optimal centrifugation conditions have been established by the laboratory upon receipt, after any repairs to the centrifuge and on an annual basis.</p>	<p>Quarterly calibration includes RPM and timer checks.</p>

Immunochemistry		
Tag #	Standard	Guidance
IH9	Immunochemistry Standard 9 A microscope shall be available in all immunochemistry laboratories if use of a microscope is specified by the facility's SOPM or by a test kit manufacturer's package insert.	
IH10	Immunochemistry Standard 10 Microscopic examination shall be performed in red blood cell agglutination tests whenever indicated by the procedure in use.	

Blood Services		
Tag #	Standard	Guidance
	<p>The following specialty sustaining standards of practices shall be incorporated into the laboratory's quality management system, where applicable to the scope of services provided.</p>	<p>Laboratories performing non-automated tests to screen for platelet contamination may do so under their Blood Services permit. Laboratories using automated systems must hold, at a minimum, a permit in the category of Bacteriology – Restricted and should refer to Bacteriology Standard 1 for quality control requirements. Autogeneic (autologous) collections that are not crossed over for allogeneic use should not be included, and blood banks that perform only such collection need not file a report. All collections for allogeneic use, including those from community donors, directed donors and crossed-over autogeneic (autologous) donors, should be included.</p>
BS1	<p>Blood Services Standard 1</p> <p>Any blood banks, other than hospitals, collecting blood in New York State, shall file an HIV Antibody Testing Report. This shall be completed by the collecting facility, even if testing is performed elsewhere.</p>	
BS2	<p>Blood Services Standard 2</p> <p>For donor services, the Quality Manual shall include a protocol that defines the qualifications of personnel who respond to donor reactions.</p>	<p>Section 58-2.6(a) of 10NYCRR requires that medical services for emergency care of the donor shall be available. As a minimum, when performing donor collection procedures, a nurse or other qualified person specially trained to recognize and treat donor reactions should be immediately available (within approximately ten seconds or audible calling distance) and a physician should be available by telephone for consultation. Persons drawing blood for transfusion should also be trained to recognize donor reactions.</p>

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BS3	<p>Blood Services Standard 3</p> <p>Blood and blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected.</p> <p>(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period</p> <p>(2) Inspections of the alarm system must be documented.</p>	