Blood Services

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. Effective July 14, 2014	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 – Other and should refer to Bacteriology Standard of Practice 1 (BT S1): Reagent QC 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.
Blood Services Standard 1 (BS S1) For donor services, the Quality Manual shall include a protocol that defines the qualifications of personnel who respond to donor reactions.	10NYCRR Subpart 58-2.6(a) 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.

Immunohematology

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. Effective January 2008; IH S8 revised effective July 14, 2014.	
Immunohematology Standard 1 (IH S1) 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.	
Immunohematology Standard 2 (IH S2) All blood grouping sera, reagents, devices, methods, and procedures shall conform to the recommended minimal requirements of the FDA.	Testing should be performed following the manufacturer's package insert.
Immunohematology Standard 3 (IH S3) 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.	Forward grouping shall include the use of anti-A and anti-B. Anti-A,B is optional. Reverse grouping shall consist of A cells and B cells. Use of A_2 cells is optional. For infants under four months of age, only forward grouping is required.

Immunohematology

Standard	Guidance
Immunohematology Standard 4 (IH S4) 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.	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.
Immunohematology Standard 5 (IH S5) The reactivity and specificity of each reagent shall be determined whenever a new lot is used.	Exception to standard: New York State does not require that each shipment of antibody identification cell panels be tested with a known antibody.
Immunohematology Standard 6 (IH S6) Quality control records shall be retained for five years.	
Immunohematology Standard 7 (IH S7) 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.	The use of pooled screening cells is not permitted for recipients.

Immunohematology

Standard	Guidance
Immunohematology Standard 8 (IH S8) Centrifuges used for testing of red blood cell agglutination: a) shall undergo RPM and timer checks quarterly; and, b) shall undergo a functional calibration to determine optimal centrifugation conditions prior to testing, after any repairs to the centrifuge, and on an annual basis. Documentation of such checks and functional calibrations, which include records of actual results, shall be maintained.	Repairs that require a functional calibration prior to resumption of use include those that may affect the speed or timer function of the centrifuge.
Immunohematology Standard 9 (IH S9) A microscope shall be available in all immunohematology laboratories if use of a microscope is specified by the facility's SOPM or by a test kit manufacturer's package insert.	
Immunohematology Standard 10 (IH S10) Microscopic examination shall be performed in red blood cell agglutination tests whenever indicated by the procedure in use.	