Laboratory Blood Services	
Former Standard and Guidance	***Proposed Standard and 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 1, 2019 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.	**Deleted**
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. **Guidance –** 10NYCRR subdivision 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	**Laboratory Blood Services Standard of Practice 1 (LBS S1): Donor Reactions** The laboratory must have a protocol for responding to donor reactions and a policy defining the qualifications of personnel who respond. **Guidance –** 10NYCRR subdivision 58-2.4 requires that medical services for emergency care of the donor be available during collection procedures. At a minimum, a nurse or other qualified person specially trained to recognize and treat donor reactions should be immediately available and a physician should be available by

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consultation. Persons drawing blood for transfusion should also be trained to recognize donor reactions.	telephone for consultation. Persons drawing blood for transfusion should also be trained to recognize donor reactions.
	Laboratory Blood Services Standard of Practice 2 (LBS S2): Procedure In addition to the requirements in Test Procedure Content Standard of Practice 1, the laboratory must have standard operating procedures that include: a) obtaining blood or components from other institutions during emergency situations; b) qualifications of personnel who may collect blood specimens for pretransfusion testing; c) specimen and labeling requirements for pretransfusion samples; d) all testing requirements for relevant transfusion transmitted infections as required under 21 CFR 610.40; e) issuance of components, to include: i. the qualifications of personnel issuing components; and ii. visual inspection prior to issuance with the product not being issued if: a. there is any abnormality in color or physical appearance; or b. there is any indication of microbial contamination; and

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	iii. type of infusion sets and filters for all components; iv. use and maintenance of blood warming devices; v. release of blood and blood components to limited transfusion services and ambulance transfusion services, as applicable; and f) emergency release of uncrossmatched blood or blood components to include: i. compatibility testing performed after release; ii. a requirement for the signature of the requesting physician which may be obtained before or after release; and g) criteria for determining whether returned blood is suitable for reissue; and h) procedure(s) for documenting errors or accidents in collection, testing, processing, storage or distribution that may affect the safety or purity of any product, or health of the donor or recipient, with: i. all such errors and accidents not detected prior to product distribution being reported to the Department within seven (7) calendar days of discovery and, if required, to federal authorities.
New Standard **Required under 10NYCRR 58-2.16 (f)**	**Laboratory Blood Services Standard of Practice 3 (LBS S3): Administration of Blood and Blood Components – Bedside Identification not using Automated Technology**

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	Immediately prior to initiating a transfusion, two persons authorized to initiate blood transfusions must positively identify the recipient and the blood component to be transfused at the patient's bedside using the patient's name and a unique numeric or alphanumerical identifier.
Blood Services Standard 2 (BS S2) Facilities utilizing a one-person verification process for matching recipients to the blood or blood component at the time of transfusion must: a) Use an FDA-approved automated identification technology that positively identifies the recipient and matches the blood or blood component to the recipient; b) Follow the manufacturer's instructions for the proper collection and labelling of the pre-transfusion specimen, including the placement and retention of any required secondary bar-coded wristbands; i. All required bar-coded wristbands must be placed on the patient prior to the collection of the pre-transfusion specimen; c) Follow the manufacturer's instructions for the automated matching of the patient to the blood or blood component prior to transfusion; i. If automated scanning mechanisms fail, including the need to perform manual data entry, or if any bar-coded identification band is removed from the patient prior to the transfusion for any reason,	**Laboratory Blood Standard of Practice 4 (LBS S4): Administration of Blood and Blood Components – Bedside Identification using an FDA Approved Automated Identification Technology** Facilities utilizing an automated one-person verification process for matching recipients to blood or blood components at the time of transfusion must: a) use an FDA-approved automated identification technology that positively identifies the recipient and matches the blood or blood component to the recipient; b) follow the manufacturer's instructions for the proper collection and labelling of the pre-transfusion specimen, including the placement and retention of any required secondary bar-coded wristbands: i. all required bar-coded wristbands must be placed on the patient prior to the collection of the pre-transfusion specimen; and c) follow the manufacturer's instructions for the automated matching of the patient to the blood or blood component prior to transfusion: i. if automated scanning mechanisms fail, including the need to perform manual data entry, or if any bar-coded identification band is removed from

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the facility must use a two-person patient identification process. **Guidance –** (c) The 'manufacturer' in this instance includes both the vendor of the electronic ID system and the vendor of the bar-coded wristbands, if not the same.	the patient prior to the transfusion for any reason, the facility must use a two-person patient identification process as described in Laboratory Blood Services Standard of Practice 3. **Guidance –** c) The 'manufacturer' in this instance includes both the vendor of the electronic identification (ID) system and the vendor of the bar-coded wristbands, if not the same.
New Standard **Required under CLIA 493.1271 (e) (1) (2)**	**Laboratory Blood Services Standard of Practice 5 (LBS S5): Transfusion Reaction Investigation** Laboratories performing compatibility testing, or that issue blood or blood products, must have standard operating procedures that ensure prompt investigation and documentation of transfusion reactions, to include: a) review of all transfusion reactions occurring in facilities for which the laboratory has investigational responsibility; b) documentation of root cause analysis of the incident and all necessary preventive and corrective actions taken to prevent recurrences of transfusion reactions; c) a process to provide recommendations to the medical staff regarding improvements in transfusion procedures; d) review of all policies and procedures to assure they are adequate to ensure the safety of individuals being transfused; and e) reporting of serious unexpected reactions and incidents involving blood components that have been issued by

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	the transfusion service to the Department and, if required, to federal authorities.

Immunohematology	
Former Standard and Guidance	***Proposed Standard and 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. (IH S8 revised and effective July 14, 2014)	**Deleted**
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 of Practice 1 (IH S1): Antibody Detection and Identification** The laboratory must follow manufacturer instructions for FDA approved, cleared or exempt tests, including for: a) ABO grouping and Rh_o(D) typing; b) unexpected antibody detection and identification; and c) compatibility testing, as applicable, according to 21 CFR 606.151. In the absence of manufacturer instructions, the laboratory must receive approval from the Department for a laboratory developed test (LDT). **Guidance –** Information on Departmental approval of a laboratory developed test (LDT) is available at: https://www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit/test-approval. The laboratory must employ methods, techniques, or procedures that have been approved by the FDA and/or recommended by AABB when available.

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Immunohematology Standard 2 (IH S2) All blood grouping sera, reagents, devices, methods, and procedures shall conform to the recommended minimal requirements of the FDA. **Guidance –** Testing should be performed following the manufacturer's package insert.	**Standard deleted** **Required under Reagents and Media Standard of Practice 2 (RGM S2): Verification of Reagents and Media – Control Procedures**
I**mmunohematology 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. **Guidance –** 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.	I**mmunohematology Standard of Practice 2 (IH S2): Grouping Tests** The laboratory must perform: a) ABO grouping tests by concurrently testing unknown red cells with anti-A and anti-B grouping reagents; and b) ABO group confirmation with the unknown serum must be tested with known with A_1 and B red cells. **Guidance –** 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 (4) months of age, only forward grouping is required. Hospital transfusion services verifying a blood group determination performed elsewhere may perform forward grouping alone.

Immunohematology	
Former Standard and Guidance	***Proposed Standard and Guidance***
New Standard **Required under CLIA 493.1271 (a) (3)**	**Immunohematology Standard of Practice 3 (IH S3): Rh Factor Tests** The laboratory must determine the D(Rho) type by testing unknown red cells with anti-D (anti-Rho) blood typing reagent.
New Standard **Required under 10NYCRR 58-2.8 and CLIA 493.1271 (b)**	**Immunohematology Standard of Practice 4 (IH S4): Standard Operating Procedure** The laboratory must have standard operating procedures that meet the requirements of Test Procedure Content Standard of Practice 1, and includes: a) requirements for establishing performance specifications; b) all testing requirements including ABO blood grouping and D(Rho) typing; and c) all transfusion-related testing, prenatal testing, and neonatal testing.
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. **Guidance –** 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.	**Standard deleted** **Result Review Standard of Practice 3 (RR S3): Nonconformance Identification**

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Immunohematology Standard 5 (IH S5) The reactivity and specificity of each reagent shall be determined whenever a new lot is used. **Guidance –** Exception to standard: New York State does not require that each shipment of antibody identification cell panels be tested with a known antibody.	**Standard deleted** **Reagents and Media Standard of Practice 2 (RGM S2): Verification of Reagents and Media – Control Procedures**
Immunohematology Standard 6 (IH S6) Quality control records shall be retained for five years.	**Standard deleted** **Required under Document and Specimen Retention Standard of Practice 8 (DSR S8): Analytic System Records Retention**
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. **Guidance –** The use of pooled screening cells is not permitted for recipients.	**Immunohematology Standard of Practice 5 (IH S5): Unexpected Antibody Testing** To detect the presence of unexpected antibodies, blood samples must be tested using at least a two (2) cell antibody screen designed for this purpose, tested individually. Pooled screening cells: a) must not be used to detect unexpected antibodies in patients' specimens; but b) may be used for testing blood donor specimens.
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	**Immunohematology Standard of Practice 6 (IH S6): Serologic Centrifuge Verification** In addition to the requirements in Laboratory Equipment and Instruments Standard of Practice 3, centrifuges used for testing of red blood cell agglutination, the laboratory must

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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. **Guidance –** Repairs that require a functional calibration prior to resumption of use include those that may affect the speed or timer function of the centrifuge.	perform and document: a) verification of revolutions per minute (RPM) and timer checks quarterly; and b) functional calibration to determine optimal centrifugation conditions prior to testing, after any repairs to the centrifuge, and on an annual basis.
New Standard **Required under CLIA 493.1271 (c)**	**Immunohematology Standard of Practice 7 (IH S7): Environmental Temperature Monitoring** The laboratory must store blood and blood products under appropriate conditions that include a temperature alarm system that: a) has an audible alarm system to monitor proper blood and blood product storage temperature over a twenty-four (24) hour period; and b) is regularly inspected and the inspections of the alarm system documented.
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.	**Standard deleted** **Required under Document Control Standard of Practice 2 (DC S2): Compliance**
Immunohematology Standard 10 (IH S10) Microscopic examination shall be performed in red blood cell agglutination tests whenever indicated by the procedure in use.	**Immunohematology Standard of Practice 8 (IH S8): Microscopic Examination** Microscopic examination must be performed in red blood cell agglutination tests whenever indicated by the test procedure in use, according to Document Control Standard of Practice 2.

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New Standard **Required under CLIA 493.1271 (d)**	**Immunohematology Standard of Practice 9 (IH S9):** Blood that has not been retained for further testing according to Document and Specimen Retention Standard of Practice 10, and that has passed its expiration date, must be promptly disposed of by the laboratory.