



IMMUNOHEMATOLOGY DOCUMENT

PENNSYLVANIA DEPARTMENT OF HEALTH
BUREAU OF LABORATORIES
DIVISION OF LABORATORY IMPROVEMENT

| | | | |
|---|-------------|------------------|--|
| CLIA #: | | LABORATORY ID #: | |
| NAME OF LABORATORY: | | | |
| DATE OF SURVEY: | START TIME: | EXAMINER: | |
| PERSON(S) INTERVIEWED: | | | |
| NAME: | | TITLE: | |
| | | | |
| | | | |
| COMMENTS: | | | |
| | | | |
| | | | |
| DEFICIENCIES: | | | |
| | | | |
| | | | |
| DIRECTOR PRESENT AT EXIT INTERVIEW? Y N | | | |

| D-TAGS | REQUIREMENTS | QA | DOC | COMMENTS |
|----------------------|---|----|-----|----------|
| OPERATIONS | | | | |
| | A. Donor suitability and collection (whole blood) <input type="checkbox"/> Homologous <input type="checkbox"/> Autologous <input type="checkbox"/> Directed <input type="checkbox"/> Therapeutic | | | |
| | B. Laboratory (for establishments which collect blood and/or prepare components, includes ABO and Rh and viral testing of blood components) | | | |
| | C. Red blood cells <input type="checkbox"/> Additive solutions <input type="checkbox"/> RBC, frozen <input type="checkbox"/> RBC, deglycerolized <input type="checkbox"/> Rejuvenating solutions <input type="checkbox"/> RBC, leukocytes removed <input type="checkbox"/> Irradiated blood | | | |
| | D. Plasma, liquid plasma, fresh frozen plasma, and recovered plasma | | | |
| | E. Platelets | | | |
| | F. Cryoprecipitate AHF/pooled | | | |
| | G. Labeling | | | |
| | H. Compatibility testing and transfusion reactions | | | |
| | I. Storage, distribution | | | |
| | J. Platelets, pheresis | | | |
| | K. Computerization | | | |
| RESOURCE DATA | | | | |
| | A. Approximately how many units of whole blood are collected each year? 1. Number of autologous collection _____ 2. Number of directed collections _____ | | | |

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| | B. Approximately how many units of whole blood or red blood cells are received from outside sources each year? 1. Number of autologous units received _____ 2. Number of directed units received _____ | | | |
| | C. Approximately how many units of whole blood or red blood cells are transfused each year? | | | |
| SERVICES | | | | |
| | A. Are emergency laboratory services available 24 hours a day? | | | |
| | B. Is a written description of the services provided available to the medical staff? | | | |
| | C. Is a written description of how to handle a suspected transfusion reaction available to medical staff? | | | |
| | D. Is a written description of how to hang a unit of blood available to the appropriate staff? | | | |
| PERSONNEL | | | | |
| | A. Do the following personnel possess a current state license: ___ Director ___ Clinical Consultant ___ Technical Supervisor | | | |
| | B. Are the following personnel qualified by the correct combinations of education and training or experience at the appropriate complexity level: ___ Director ___ Clinical Consultant(s) ___ Technical Supervisor(s) ___ Technical Consultant(s) ___ General Supervisor(s) ___ Testing personnel | | | |
| | C. Are personnel appropriate for the services provided? | | | |

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| | D. Do personnel records contain: <input type="checkbox"/> Job descriptions <input type="checkbox"/> Documentation of education/training/continuing education <input type="checkbox"/> Evaluation/competency records | | | |
| | E. Do the director, technical supervisors and technical consultants remain accessible to provide consultation as needed? | | | |
| | F. Do the director, technical supervisors and technical consultants ensure that: | | | |
| | 1. Delegated duties are properly performed? | | | |
| | 2. Test methodologies are appropriate for the intended use of the test result? | | | |
| | 3. Test procedures are verified and the lab's test performance characteristics, including precision and accuracy (as appropriate), are established for each test? | | | |
| | 4. Test systems maintain acceptable performance levels and provide quality lab services? | | | |
| | 5. Test methodologies, verification procedures and staff performance ensure accurate and reliable results? | | | |
| | G. Does the medical director function in the role of clinical consultant by: | | | |
| | 1. Providing consultation to the facility's clients for proper test ordering? | | | |
| | 2. Ensuring that test result reports contain pertinent information for specific patient interpretation? | | | |
| | 3. Ensuring that consultation is available? | | | |
| | H. Does the general supervisor: | | | |
| | 1. Remain accessible? | | | |
| | 2. Provide day-to-day supervision of personnel? | | | |
| | 3. Monitor testing to ensure that test performance is at an acceptable level? | | | |
| | 4. As delegated by the director or technical supervisor: | | | |
| | a. Ensure that corrective action is taken? | | | |

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| | b. Ensure that patient/donor test results are not reported until all corrective actions have been taken and the test system is functioning properly? | | | | |
| | c. Provide orientation to all testing personnel? | | | | |
| | d. Annually evaluate and document the performance of all testing personnel? | | | | |
| PROFICIENCY TESTING | | | | | |
| | A. Is the lab enrolled in an HHS-approved PT program? PT Program _____ | | | | |
| | B. Are there written instructions to staff: | | | | |
| | 1. To test PT samples exactly the same as patient samples (with the regular workload by staff who routinely perform that testing and using the facility's routine test method)? | | | | |
| | 2. Prohibiting discussion of PT results with any other laboratory? | | | | |
| | 3. Prohibiting sending PT samples out for testing? | | | | |
| | C. Do personnel follow these procedures? | | | | |
| | D. Does the lab maintain a copy of the signed attestation statement? | | | | |
| | E. Do records of proficiency surveys indicate overall acceptable performance: ___ ABO/Rh testing 100% ___ Compatibility testing 100% ___ Unexpected Ab detection 80% ___ Ab identification 80% | | | | |
| | F. Are all proficiency testing reports reviewed and signed by the director? | | | | |
| | G. Do records document appropriate corrective actions if performance was unsatisfactory for any testing event? | | | | |

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| PROCEDURE MANUAL | | | | |
| | A. Is there a manual available at all times to the personnel: | | | |
| | 1. Detailing all medical, quality assurance, administrative, safety, technical, and clerical policies and procedures? | | | |
| | 2. That has been reviewed and approved at least annually by the lab director or designee? | | | |
| | B. Does the procedure manual include: | | | |
| | 1. Requirements for sample collection, processing, and rejection? | | | |
| | 2. Criteria for sample storage and preservation? | | | |
| | 3. Step-by-step performance of the procedure? | | | |
| | 4. Preparation of materials used in testing? | | | |
| | 5. Calibration and calibration verification procedures? | | | |
| | 6. Control procedures? | | | |
| | 7. Limitations, including interfering substances? | | | |
| | 8. Reference ranges (normal values)? | | | |
| | 9. Reportable range for test results? | | | |
| | 10. Critical values (results that require immediate action)? | | | |
| | 11. References? | | | |
| | 12. The test result reporting system? | | | |
| | 13. Back-up procedures for use when the test system is inoperable? | | | |
| | 14. Criteria and procedures for sample referrals? | | | |
| SPECIMEN COLLECTION | | | | |
| | DONOR COLLECTION: | | | |
| | A. Does the facility provide adequate space for private examinations of individuals to determine suitability as a blood donor? | | | |
| | B. Does the blood center have a policy on how to screen donors that includes rejection criteria, preparation, proper collection, care of the donor after phlebotomy, and adverse donor reactions? | | | |
| | C. Does the blood center have a policy for processing, labeling, quality control, storage, and shipping of blood and blood components? | | | |

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| | D. How does the center trace a unit of blood back to its source (look-back policy)? | | | | |
| | 1. Is there a retrospective review of records of prior donations for donors found to be HIV positive? | | | | |
| | 2. Does this review determine: | | | | |
| | a. All components prepared? | | | | |
| | b. The disposition of each component? | | | | |
| | 3. Are labs promptly notified of all in-date products? | | | | |
| | 4. Is there a procedure for notifying labs (consignees) of previous products prepared from positive donors within the past six months? | | | | |
| | E. Does the laboratory have a policy or procedure for notifying a donor who has been rejected based on the results of unit screening tests? | | | | |
| | RECIPIENT SAMPLE COLLECTION: | | | | |
| | A. Does the laboratory have a policy for specimen collection and rejection? | | | | |
| | B. Does the staff follow the policy? | | | | |
| | C. How is the patient positively identified? | | | | |
| | D. How is the patient's tube of blood positively identified? | | | | |
| | 1. Does the specimen contain the patient's first and last name, ID#, date of collection, and phlebotomist's initials? | | | | |
| EQUIPMENT MAINTENANCE | | | | | |
| | A. Are equipment maintenance and function checks performed appropriately (according to the methods and intervals specified in the manufacturer's instructions and the facility's written protocols)? | | | | |
| | 1. Is documentation of maintenance complete? | | | | |
| | B. Are all temperatures monitored and recorded according to the laboratory protocol? | | | | |
| | C. Is a temperature recorder used? | | | | |
| | 1. Is it compared daily against the thermometer? | | | | |
| | 2. Are temperature charts changed at proper intervals? | | | | |
| | 3. Are charts retained (dated and initialed)? | | | | |

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|--------------------------------|---|-----------------|-----------------|-----------------|--------------|-------|-----|-------------|-------|-------|----------------|-------|-------|-----------------|-------|-----|--------------------|-------|-----|----------|--------|--------|--|--|--|
| | D. If remote storage areas are used, are storage temperatures monitored? | | | | | | | | | | | | | | | | | | | | | | | | |
| | E. Do all observed temperatures and temperature records meet standards? | | | | | | | | | | | | | | | | | | | | | | | | |
| | 1. Is there an explanation for temperature deviations? | | | | | | | | | | | | | | | | | | | | | | | | |
| | F. Are alarms checked on a regularly scheduled basis? | | | | | | | | | | | | | | | | | | | | | | | | |
| | G. Are blood products distributed to outside facilities? | | | | | | | | | | | | | | | | | | | | | | | | |
| | 1. Are they shipped in such a manner as to assure maintenance of the proper temperature? | | | | | | | | | | | | | | | | | | | | | | | | |
| | 2. Does the lab use shipping containers that have been shown to maintain proper temperature in transit? | | | | | | | | | | | | | | | | | | | | | | | | |
| REAGENT QUALITY CONTROL | | | | | | | | | | | | | | | | | | | | | | | | | |
| | <p>A. Reagent quality control to be performed for each container of sera and RBC in-use:</p> <table border="0" data-bbox="464 667 1188 922"> <thead> <tr> <th></th> <th style="text-align: center;"><u>Positive</u></th> <th style="text-align: center;"><u>Negative</u></th> </tr> </thead> <tbody> <tr> <td>ABO Antisera</td> <td>Daily</td> <td>N/A</td> </tr> <tr> <td>Rh Antisera</td> <td>Daily</td> <td>Daily</td> </tr> <tr> <td>Other Antisera</td> <td>Daily</td> <td>Daily</td> </tr> <tr> <td>ABO Reagent RBC</td> <td>Daily</td> <td>N/A</td> </tr> <tr> <td>Ab Screening Cells</td> <td>Daily</td> <td>N/A</td> </tr> <tr> <td>AHG sera</td> <td>*Daily</td> <td>*Daily</td> </tr> </tbody> </table> | | <u>Positive</u> | <u>Negative</u> | ABO Antisera | Daily | N/A | Rh Antisera | Daily | Daily | Other Antisera | Daily | Daily | ABO Reagent RBC | Daily | N/A | Ab Screening Cells | Daily | N/A | AHG sera | *Daily | *Daily | | | |
| | <u>Positive</u> | <u>Negative</u> | | | | | | | | | | | | | | | | | | | | | | | |
| ABO Antisera | Daily | N/A | | | | | | | | | | | | | | | | | | | | | | | |
| Rh Antisera | Daily | Daily | | | | | | | | | | | | | | | | | | | | | | | |
| Other Antisera | Daily | Daily | | | | | | | | | | | | | | | | | | | | | | | |
| ABO Reagent RBC | Daily | N/A | | | | | | | | | | | | | | | | | | | | | | | |
| Ab Screening Cells | Daily | N/A | | | | | | | | | | | | | | | | | | | | | | | |
| AHG sera | *Daily | *Daily | | | | | | | | | | | | | | | | | | | | | | | |
| | <p>* Requirements satisfied by checking AHG sera (Coombs) in one of the following ways:</p> <ol style="list-style-type: none"> 1. React AHG with a pre-sensitized reagent RBC which is either prepared commercially or by the lab 2. Perform the quality control for Ab detection using a known antibody which is demonstrated by the addition of AHG 3. Add a pre-sensitized reagent RBC to all negative antiglobulin tests (direct antiglobulin, indirect antiglobulin, Ab detection and identification) to indicate that AHG serum present in the test was not inactivated by unbound globulins or diluted by excess residual saline, and that the negative results reflect true absence of reactivity in the test (Using green AHG does not substitute for this control) | | | | | | | | | | | | | | | | | | | | | | | | |

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| | B. Is documentation of quality control complete? | | | |
| | C. Are corrective actions taken and documented when problems or errors are identified? | | | |
| TEST METHODS | | | | |
| | A. Are laboratory space, ventilation and utilities adequate? | | | |
| | B. Are safety precautions established, posted, and observed? | | | |
| | ABO AND Rh TESTING: | | | |
| | A. Is the procedure manual complete? | | | |
| | 1. Procedure used? (automated/microplate/slide/tube/gel) | | | |
| | B. Are licensed reagents used for ABO and Rh testing? Reagents used: | | | |
| | C. Are red cells tested with Anti-A and Anti-B, and is serum tested with known A and B cells? | | | |
| | D. Are red cells tested with Anti-D? | | | |
| | E. Are D negatives confirmed by further testing? | | | |
| | F. Do test methods conform to manufacturer's instructions? | | | |
| | G. Are reagents used within the dating period? | | | |
| | H. Are reagents stored properly as prescribed by the manufacturer? | | | |
| | AUTOMATED TESTS FOR ABO AND Rh TESTING: | | | |
| | A. Is an automated system used for ABO and Rh typing? Automated system used: | | | |
| | B. Is the procedure manual complete? | | | |
| | C. Are there procedures for accurate identification of samples? | | | |
| | D. Are all reagents dated when put into use? | | | |
| | E. If the reagents have not been FDA approved or licensed for use with this instrument, have appropriate reagent evaluations been conducted? | | | |
| | F. If reagents are used in a dilution, has an appropriate evaluation been conducted for each lot in use? | | | |

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| | G. If the instrument is unable to determine the blood type, is there a procedure for manual ABO/Rh testing which includes updating test results? | | | |
| | H. Is there a record documenting repairs and preventive maintenance? | | | |
| | COMPATIBILITY TESTING: | | | |
| | A. Is compatibility testing performed? | | | |
| | B. Is the procedure manual complete? | | | |
| | C. Is compatibility testing performed in an area sufficiently removed from other areas to eliminate distractions or other introduction of errors in testing? | | | |
| | D. Does the transfusion request form contain the patient's first and last name, physician name, sex and age of patient, diagnosis, transfusion and pregnancy history, and component ordered? | | | |
| | 1. Are requisitions complete? | | | |
| | 2. How does the lab obtain information missing from the requisition? | | | |
| | E. Does the procedure for compatibility testing include the AHG (Coombs) method or an equivalent method, which includes ABO/Rh, Ab screens, and positive ID of blood samples? | | | |
| | <p>F. Major cross match through the Anti-globulin phase is <u>not</u> required <u>if</u>:</p> <ul style="list-style-type: none"> • There is positive ID of recipient and donor samples • Licensed blood grouping sera for ABO and Rh is used • Ab detection tests will demonstrate allo antibodies at 37°C in serum or plasma of previously transfused or pregnant donors • Recipient serum will demonstrate significant antibodies reactive with the donor's cells at 37°C <p style="text-align: center;">and</p> <ul style="list-style-type: none"> • Procedures are available for emergency transfusions | | | |
| | G. Does the lab review records for results of previous patient testing and perform comparison studies? (Records must be kept for 5 years) | | | |

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| | H. Does the lab have a policy for performing compatibility testing for patients with a history of a prior Antibody? | | | |
| | I. Does the lab have a policy for re-typing, re-screening, re-crossing units not transfused (returned to the lab)? | | | |
| | J. Do all recipients have ABO, Rh, and Ab screen performed? | | | |
| | K. Is the identity of the testing person indicated? | | | |
| | L. Is the selection of blood components appropriate and compatible? | | | |
| | M. Are components labeled with recipient information? | | | |
| | N. Does the lab have a policy for releasing/transporting blood and blood products to various floors? | | | |
| | O. Does the lab have a policy in place stating that each product was visually inspected prior to release? | | | |
| | 1. Is a record of such an inspection maintained? | | | |
| | STORAGE: | | | |
| | A. Is blood segregated to clearly demonstrate contaminated, autologous, crossmatched, units available for crossmatch vs. donors not yet processed into the system? | | | |
| | B. Are blood and blood components stored at their appropriate temperatures? Whole blood and RBC 1-6°C Platelets 20-24°C Cryoprecipitate -18°C or colder Fresh Frozen Plasma -18°C or colder | | | |
| | EMERGENCY TRANSFUSIONS: | | | |
| | A. Are procedures available for life-threatening emergencies (emergency release of blood)? | | | |
| | B. Is the crossmatch completed after the blood is released? | | | |
| | C. Do records include documentation of the need for the emergency procedures, signed by the requesting physician? | | | |
| | TRANSFUSION REACTIONS: | | | |
| | A. Are records kept of reports of suspected adverse transfusion reactions? | | | |

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| | B. Does the blood bank have a procedure for investigating suspected adverse transfusion reactions? | | | | |
| | C. Are results of investigations reviewed by appropriate personnel? | | | | |
| | PLASMA DERIVATIVES: | | | | |
| | A. If plasma derivatives are distributed (Rhogam, factor VIII and IX, albumin, etc.), do the records identify the lot # and recipient? | | | | |
| TEST RECORDS | | | | | |
| | A. Are records maintained as required? | | | | |
| | 1. Do records allow for the tracing of all units from donor bleeding to the final disposition? | | | | |
| | B. Do records include results of compatibility tests, testing of patient samples, antibody screening and identification? | | | | |
| | C. Do records include ABO and Rh testing? | | | | |
| | D. Do records include the date of receipt of recipient samples? | | | | |
| TEST REPORTS | | | | | |
| | A. Does the lab have a system in place to ensure that results are reported in a timely, accurate, and reliable manner? | | | | |
| | B. Does the test report include: | | | | |
| | 1. The name and address of the site where testing was performed? | | | | |
| | 2. The test(s) performed? | | | | |
| | 3. The test result? | | | | |
| | 4. Disposition of any unacceptable specimens? | | | | |
| RECORD RETENTION | | | | | |
| | A. Are records of testing retained for at least 5 years? | | | | |
| | B. If test records are retained as part of the patient's chart/medical record, are they readily available? | | | | |
| | C. Are records of the test requisitions maintained? | | | | |
| | D. Does the record keeping system permit ready identification and timely accessibility of original test reports? | | | | |
| | E. Does the record keeping system maintain records accurately, preventing unauthorized alteration or destruction of results? | | | | |

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| QUALITY ASSURANCE | | | | |
| | A. Does the lab have a complete quality assurance policy? | | | |
| | B. Does the quality assurance policy address all of the following: | | | |
| | 1. Patient test management? | | | |
| | 2. Quality control assessment? | | | |
| | 3. Proficiency testing assessment? | | | |
| | 4. Comparison of test results? | | | |
| | 5. Personnel assessment? | | | |
| | 6. Quality assurance review with staff? | | | |
| | 7. Quality assurance records? | | | |
| | C. Are all policies and procedures properly maintained and executed? | | | |
| LAB TESTS FOR DONOR BLOOD | | | | |
| SEROLOGICAL TEST FOR SYPHILIS: | | | | |
| | A. Is the procedure complete? | | | |
| | B. Are all units tested? | | | |
| | C. Does the test method conform to manufacturer's instructions? | | | |
| | D. Are proper quality control procedures performed each day of testing? | | | |
| HEPATITIS AND HIV TESTING: | | | | |
| | A. Is each unit of blood tested? Tests performed: | | | |
| | B. Are tests done on samples taken at the time of donation? | | | |
| | C. Are only licensed kits used for testing? Kits/Methods used: | | | |
| | 1. Are all procedures complete? | | | |
| | D. Are all tests performed according to manufacturer's instructions? | | | |
| | E. Is automated equipment used during viral testing operated and maintained according to manufacturer's instructions? | | | |

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| | F. Are tests performed in an area segregated from component preparation? | | | |
| | G. Are supplies and reagents used in testing properly disposed? | | | |
| | H. Is test data reviewed before final testing results/interpretations are reported? | | | |
| | I. For invalid runs, are problems documented and resolved? | | | |