

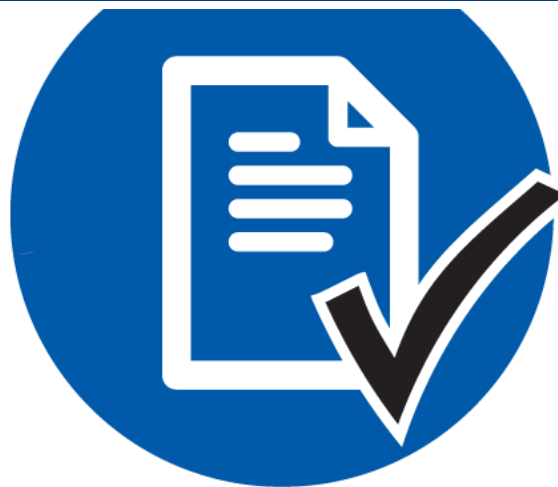


COLLEGE of AMERICAN
PATHOLOGISTS

December 2024 Changes

Transfusion Medicine Checklist

CAP Accreditation Program



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Using the Changes Only Checklist

This document contains new checklist requirements, major and minor requirement revisions, and changes to explanatory text. **Changes appear in a track changes format that compares the previous checklist edition to the December 26, 2024 edition.** Requirements with significant revisions will display a "Revised" flag. These changes may affect your laboratory operations. Requirements with minor revisions will not display a "Revised" flag. They are editorial changes that are not likely to affect your laboratory operations.

Information regarding requirements that are new or have been combined, moved, resequenced or deleted, as applicable, appears in table format below.

2024 CHECKLIST EDITION CHANGES NEW, DELETED, MERGED, AND MOVED REQUIREMENTS *

2023 Requirement	Action Taken	2024 Requirement
	New	TRM 40705

*Deleted – Removed the requirement from the checklist edition

*Merged – Combined the requirement with a similar requirement in the same or different checklist

*Moved – Relocated the requirement to another checklist or resequenced it within the same checklist

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- Master — contains ALL of the requirements and instructions available in PDF, Word/XML or Excel formats
- Custom — customized based on the laboratory's activity (test) menu; available in PDF, Word/XML or Excel formats
- Changes Only — contains only those requirements with significant changes since the previous checklist edition in a track changes format to show the differences; in PDF version only. Requirements that have been moved or merged appear in a table at the end of the file.

INTRODUCTION

This checklist is used in conjunction with the All Common and Laboratory General Checklists to inspect a transfusion medicine laboratory section or department.

NOTE: Many of the requirements in this Checklist reflect United States regulatory requirements, particularly those of the US Food and Drug Administration (FDA). These requirements may not be applicable in other countries for purposes of CAP accreditation. Laboratories not subject to US regulations must follow national, state or provincial, and local laws and regulations at minimum.

The term "transfusion service medical director" is used generically throughout the checklist to refer to the physician who has oversight responsibility for the different services (eg, transfusion service, donor service, apheresis service, cellular therapy service) addressed by the checklist requirements. Some laboratories may have separate directors providing oversight for these services; however, all directors must meet the required qualifications.



Policy/Procedure icon - The placement of this icon next to a checklist requirement indicates that a written policy or procedure is required to demonstrate compliance with the requirement. The icon is not intended to imply that a separate policy or procedure is required to address individual requirements. A single policy or procedure may cover multiple checklist requirements.

Laboratories not subject to US regulations: Checklist requirements apply to all laboratories unless a specific disclaimer of exclusion is stated in the checklist. When the phrase "FDA-cleared/approved test (or assay)" is used within the checklist, it also applies to tests approved by an internationally recognized regulatory authority (eg, CE-marking).

QUALITY MANAGEMENT

****REVISED**** 12/26/2024

TRM.30900 Records of Deviation From SOP

Phase II



The transfusion service medical director or physician designee provides written authorization for deviations from the standard operating procedures.

NOTE: The standard operating procedures constitute the approved procedures of the laboratory and are to be followed at all times. Any deviations from these procedures must either be authorized by the responsible transfusion medicine medical director or physician designee prior to their performance or, if detected only after the event, must be investigated through the laboratory's quality assurance process. A wide variety of routine procedures may, from time to time, require the transfusion service medical director or physician designee to authorize an alternative approach because of specific clinical situations. Among these, for example, might be the need to give Rh positive red cells to an Rh negative recipient because of inventory shortages, or to provide a unit of platelets that was not HLA-matched (or "crossmatch compatible" or "antigen-negative," depending on the laboratory's routine approach) to an alloimmunized patient in an attempt to control hemorrhage.

REFERENCES

- 1) Lam H-TC, et al. Are retrospective peer-review transfusion monitoring systems effective in reducing red blood cell utilization? *Arch Pathol Lab Med.* 1996;120:810-816
- 2) Shulman G, et al. Creating useful statistics to audit transfusion services. *Lab Med.* 1998;29:371-374

REAGENTS and CRITICAL MATERIALS

****REVISED**** 12/26/2024

TRM.31400 Antisera/Reagent Red Cell QC

Phase II



There are records of acceptable reactivity and specificity of typing sera and reagent red cells on each day of use, including a check against known positive and negative cells or antisera, or manufacturer's instructions for daily quality control are followed.

NOTE: Unless manufacturer's instructions state otherwise, the following apply:

- Typing reagents, including antisera (eg, anti-D, anti-K, anti-Fy(a)) and reagent red cells must be checked for reactivity and specificity on each day of use. Typing antisera must be checked with known positive and negative cells; reagent red cells must be checked with known positive and negative antisera.
- Each cell used for antibody screening must be checked each day of use for reactivity of at least one antigen using antisera of 1+ or greater avidity.

- Anti-IgG reactivity of antiglobulin reagents may be checked during antibody screening and crossmatching.

This checklist requirement can be satisfied by testing one vial of each reagent lot each day of testing.

For red cell antibody panels, manufacturer's instructions ~~and control processes, as outlined in the facility's~~ must be followed. Facilities must have written procedures to assess QC (eg, ~~ruling out antibodies, antigen pattern of reactivity,~~ typing of patient cells for the corresponding antigen, or antibody) ~~must be followed.~~ of known specificity reacting against panel cell(s)).

REFERENCES

- 1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2003(Jan 24):7171 [42CFR493.1271(a)]

PROCEDURES AND TESTS

COMPATIBILITY TESTING

****REVISED**** 12/26/2024

TRM.40300 Historical Record Check

Phase II



ABO, Rh, and antibody screen test results are compared with results of the same tests recorded previously to detect discrepancies and identify patients requiring specially selected units.

NOTE: Comparison of records of previous ABO and Rh typing are an essential step in compatibility testing. Available laboratory records for each patient must be routinely searched whenever compatibility testing is performed. The historical record search can be performed manually by qualified laboratory personnel or by a validated computer system capable of performing historical checks. Acceptable ABO and Rh historical records for transfusion purposes are only those generated or entered by laboratory personnel into the health system's laboratory information system and performed by an accredited laboratory/certified by the relevant government agency in its jurisdiction. If no record of the patient's blood type is available from previous determination(s), the transfusion service should be aware that there is an increased probability of an incorrect blood type assignment and, consequently, of a hemolytic transfusion reaction. If a laboratory collects an additional sample for the purpose of verification of patient identity, a repeat antibody screen need not be performed on this specimen.

Evidence of Compliance:

- ✓ Records of historical checks **OR**
- ✓ Records of LIS historical check validations

Computer Crossmatches

****REVISED**** 12/26/2024

TRM.40670 ABO Group and Rh(D) Type Verification

Phase II



The recipient's ABO group and Rh(D) type has been verified by repeat testing of the same sample, a different sample, or agreement with a historical type in the laboratory's records.

NOTE: Repeat testing of the same sample is inadequate for computer crossmatching for issuing non-type O red cells, unless the sample has been drawn using technology or methods for ensuring positive identification (eg, mechanical barrier system or digital bedside identification system).

Acceptable ABO and Rh historical records for transfusion purposes are only those generated or entered by laboratory personnel into the health system's laboratory information system and performed by an accredited laboratory/certified by the relevant government agency in its jurisdiction.

When unexplained ABO typing discrepancies exist on the current sample, serologic crossmatch techniques must be employed.

Evidence of Compliance:

- ✓ Work records of test results and/or search of records verifying ABO type

REFERENCES

- 1) Food and Drug Administration. Guidance for Industry. "Computer Crossmatch" (Computerized Analysis of the Compatibility Between the Donor's Cell Type and the Recipient's Serum or Plasma Type). Rockville, MD: Food and Drug Administration, April 2011.

SELECTION OF BLOOD AND COMPONENTS FOR TRANSFUSION

****REVISED**** 12/26/2024

TRM.40700 Selection of Blood Components

Phase II



The ~~written procedure for~~ laboratory has blood component selection of blood components for transfusion requires criteria for the use of following:

- ~~ABO group-specific whole blood, low-titer group O whole blood, or ABO group-specific or compatible red blood cell-containing components, and contains criteria used for selection of plasma or platelet containing components~~
- ABO group-specific whole blood
- Group O whole blood with low anti-A/B titers if given to non-O patients
- Components containing plasma or platelets.

NOTE: To avoid potentially life-threatening ABO incompatibility, the laboratory must have written procedures for the selection of appropriate whole blood, red cells or plasma for recipients. ABO group-compatible plasma and platelet components should be used. If transfusion of ABO incompatible plasma or platelets is permitted due to blood supply and medical necessity, the laboratory has a written policy on ~~the their use of ABO incompatible plasma and platelet components.~~

~~If transfusion of low-titer group O whole blood occurs, the procedure must describe:~~

- ~~Definition of "low-titer" group O whole blood as mutually agreed by the transfusion service and the blood supplier~~
- ~~Indications for the use of these units.~~

****NEW**** 12/26/2024

TRM.40705 Use of Low-titer Group O Whole Blood

Phase II



If low-titer group O whole blood is used, the laboratory follows written policies and procedures for its use.

NOTE: The following must be defined:

- Indications for use
- Product specifications
- Administration instructions
- Indications to switch to component therapy and ABO type selection
- The limit on the number of units to be transfused for each patient during a bleeding event or within a time period.

REFERENCES

- 1) [Association for the Advancement of Blood and Biotherapies, the American Red Cross, America's Blood Centers, and the Armed Services Blood Center. Circular of information for the Use of Human Blood and Blood Components. Bethesda, MD: Association for the Advancement of Blood and Biotherapies; 2021.](#)

****REVISED**** 12/26/2024**TRM.40720 Provisions for Special Components****Phase II**

The laboratory has processes for providing appropriate components for:

- Patients with immunohematologic conditions (clinically significant red cell antibodies, transplantation, etc.)
- Transfusion of special blood components (red cell antigen-negative, irradiated, CMV-reduced risk, hemoglobin S-negative, etc.)
- Aliquoting or volume reduction of blood components for patients identified to be a risk for transfusion associated circulatory overload (TACO)
- Transfusion of low-titer group O whole blood, including the maximum volume/units allowed per event.

NOTE: Exceptions [for deviations](#) to written procedures may be made only with the approval of the physician responsible for the transfusion service, or [physician](#) designee. [\(refer to TRM.47725\).](#)

REFERENCES

- 1) [AABB Association for the Advancement of Blood and Biotherapies, the American Red Cross, America's Blood Centers, and the Armed Services Blood Center. Circular of information for the Use of Human Blood and Blood Components. Bethesda, MD: ~~October 2017~~; Association for the Advancement of Blood and Biotherapies; 2021.](#)
- 2) Alam, A, Lin Y, Lima A, Hansen, M, Callum, JL. The prevention of transfusion-associated circulatory overload. *Trans Med Rev.* 2013; 27(2):105-12.

PERINATAL TESTING

****REVISED**** 12/26/2024**TRM.40820 Historical Record Check****Phase II**

ABO/Rh results are compared with historical result records for each pregnant patient for at least the preceding 12 months.

NOTE: The purpose of this comparison is to detect sample/patient identification errors or other errors that might lead to the attribution of an incorrect blood type or antibody screen result to a pregnant patient; this might result in a missed opportunity to provide prophylaxis against or appropriate treatment for perinatal alloimmunization. The historical record search can be performed manually by qualified laboratory personnel or by a validated computer system capable of performing historical checks. [Acceptable ABO and Rh historical records for transfusion purposes are only those generated or entered by laboratory personnel into the health system's laboratory information system and performed by an accredited laboratory/certified by the relevant government agency in its jurisdiction.](#) If the laboratory performing the testing does not maintain records that would allow this check to be performed, the testing shall be reported with a disclaimer alerting the ordering physician that the check has not been performed and that verifications of the sample's identity and the test results are strongly recommended.

Evidence of Compliance:

- ✓ Records of historical checks **OR**
- ✓ Records of LIS historical check validations

TRANSFUSION PROCEDURES

ADVERSE REACTION PROCEDURES

****REVISED**** 12/26/2024

TRM.42050 Transfusion Reaction Interpretation

Phase II



The transfusion service medical director or physician designee interprets and reports the findings of an adverse reaction investigation in a timely and effective manner.

NOTE: The patient's physician must be immediately notified of suspected cases of hemolytic transfusion reactions, bacterial contamination, or other serious reactions. A prompt and complete adverse reaction investigation report, including interpretation and evaluation by the transfusion medicine medical director or physician designee, must be placed in the patient's chart.

Evidence of Compliance:

- ✓ Adverse reaction investigation reports in patient charts

REFERENCES

- 1) AuBuchon JP. The role of transfusion medicine physicians. A vanishing breed? *Arch Pathol Lab Med.* 1999;123:663-667
- 2) Food and Drug Administration. Current good manufacturing practice for blood and blood components. Records and reports. Adverse reaction file. Washington, DC: US Government Printing Office, 2020(Apr 1):[21CFR606.170(b)].

****REVISED**** 12/26/2024

TRM.42170 Notifications for Potentially Infectious Blood and Blood Component Units

Phase II



The transfusion service notifies and counsels recipients, or notifies their caregivers physician of record, or other authorized individual, about potentially infectious blood components, such as specified in regulations for HIV and HCV.

NOTE: ~~When the recipient of potentially infectious blood components is deceased,~~ attempts ~~Attempts are required~~ to notify the recipient, recipient's physician of record, next of kin, or legal representative, consistent with national, federal, state (or provincial), and local regulations, ~~is required~~.

Evidence of Compliance:

- ✓ Records of ~~provider or attempts to notify the~~ recipient ~~or next~~, recipient's physician of ~~kin or legal representative notifications~~ record, or other authorized individual consistent with national, federal, state (or provincial), and counseling, as applicable local regulations

REFERENCES

- 1) CMS. Condition of participation: laboratory services Washington, DC: US Government Printing Office, 2011(42CFR482.27(b))
- 2) Food and Drug Administration. General biological products standards. "Lookback" requirements. Washington, DC: US Government Printing Office, 2020(Apr 1):[21CFR610.46].
- 3) Food and Drug Administration. General biological products standards. "Lookback" requirements. Washington, DC: US Government Printing Office, 2020(Apr 1):[21CFR610.47].
- 4) Guidance for industry: Nucleic acid testing (NAT) for human immunodeficiency virus type 1 (HIV-1) and hepatitis C virus (HCV): testing, product disposition, and donor deferral and reentry. Rockville, MD, Food and Drug Administration, May 2010
- 5) Guidance for Industry: "Lookback" for hepatitis C virus (HCV); product quarantine, consignee notification, further testing, product disposition, and notification of transfusion recipients based on donor test results indication infection with HCV. Rockville, MD, Food and Drug Administration, December 2010
- 6) Guidance and rules may be found at <http://www.fda.gov/BiologicsBloodVaccines/default.htm>

COMPONENT PREPARATION, STORAGE AND MODIFICATION

****REVISED**** 12/26/2024**TRM.42750 Storage Unit Alarms****Phase II**

All component storage units are equipped with an alarm system that is monitored 24 hours/day (in laboratory or remote), with alarm checks (for both low and high settings) performed according to the manufacturer's recommended interval, or at least quarterly if not specified by the manufacturer, with results recorded.

NOTE: The laboratory must demonstrate that all components of the alarm system (including chart/graph recordings) work as expected and that there is a process to ensure a timely response to alarms, including remote alarms. When facilities perform alarm checks, the temperature at which the alarm sounds must be recorded.

~~*When facilities perform alarm checks, the temperature at which the alarm sounds must be compared to the temperature on the recording chart/log.*~~ Examples of recording systems include:

- Paper chart records
- Paper graphs
- Electronic records
- Event logs

Evidence of Compliance:

- ✓ Records of alarm checks at defined frequency

REFERENCES

- 1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2003(Jan 24): [42CFR493.1271(c)]

PLATELETS****REVISED**** 12/26/2024**TRM.44850 Platelet Preparation****Phase II**

Platelets are prepared within eight hours of the collection of whole blood that has not been cooled below 20°C; or, if prepared by apheresis methods, platelets are prepared according to the instrument manufacturer's instructions.

NOTE: ~~Platelets~~ For cold-stored platelets (CSP), the unit must be placed in storage at 1-6°C no later than four hours from the end of collection if an FDA-approved pathogen reduction device is not used. If a pathogen reduction device is used, CSPs must be placed at 1-6°C no later than four hours after completion of pathogen reduction.

NOTE: Conventional (room-temperature) platelets must be separated within eight hours from whole blood that has not been cooled to below 20°C to allow appropriate refrigerated storage of Red Blood Cells and storage of platelets at room temperature (20 to 24°C) with agitation. However, whole blood may be held for a longer period at room temperature prior to separation of components, not to exceed 24 hours, provided that safety and efficacy of the components are recorded. Storage at lower temperatures may result in reduced platelet survival. Apheresis platelets must be prepared according to the instructions of the manufacturer.

REFERENCES

- 1) Moroff G, Holme S. Concepts about current conditions for the preparation and storage of platelets. *Transf Med Rev*. 1991;5:48-59
- 2) Food and Drug Administration. Additional standards for human blood and blood products. Platelets. Collection of source material. Washington, DC: US Government Printing Office, 2020(Apr 1):[21CFR640.22(c)]
- 3) Food and Drug Administration. Additional standards for human blood and blood products. Processing. Washington, DC: US Government Printing Office, 2020(Apr 1):[21CFR640.24]
- 4) Silberman S. Platelets. Preparations, transfusion, modifications, and substitutes. *Arch Pathol Lab Med*. 1999;123:889-894

PERSONNEL

****REVISED**** 12/26/2024

TRM.50050 Transfusion Service Medical Director (Technical Supervisor) Qualifications

Phase II

The transfusion service medical director (technical supervisor) is qualified.

NOTE: The transfusion service medical director (technical supervisor) must be an MD or DO, licensed to practice medicine or osteopathy in the jurisdiction in which the laboratory is located, and either 1) ~~possess qualifications required for~~ be board ~~certification~~certified in blood banking/transfusion medicine or clinical pathology, or 2) have at least one year training or experience in immunohematology.

In Department of Defense laboratories, technical supervisors for the subspecialty of immunohematology must meet the qualifications defined in the Clinical Laboratory Improvement Program (CLIP) Procedures. A qualified medical director must perform duties requiring medical expertise.

The transfusion service medical director has oversight responsibility for the different services addressed by the checklist (eg, transfusion, donor, apheresis, cellular therapy). Some laboratories may have separate directors providing oversight for these services; however, all directors must meet these qualifications.

Specific technical supervisor functions (listed in GEN.53400) may be delegated to an individual qualifying under 42CFR493.1449(d) with a minimum of a bachelor's degree in a chemical, biological, clinical or laboratory science, or medical technology from an accredited institution and at least four years of laboratory training or experience, or both, in immunohematology.

Evidence of Compliance:

- ✓ Records of transfusion service medical director (technical supervisor) qualifications including diploma, transcript(s), equivalency evaluation, current license (if required) **AND**
- ✓ Records of work history in related field

REFERENCES

- 1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2002(~~Oct 1~~):~~4054~~2023(Dec 28); [42CFR493.1449(~~q~~)(1-2)]~~d~~].