

IMM.40300 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 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.

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]

IMM.40440 Agglutination/Hemolysis Criteria Phase II

Criteria for agglutination and/or hemolysis are defined.

NOTE: Criteria must be defined to provide uniformity of interpretation of positive and negative agglutination and hemolysis results.

IMM.40580 Test Result Recording Phase II

Observations of all test results are recorded properly at the time the test is performed.

NOTE: Test results must be recorded at the time done in order to reduce the risk of transcription errors from delayed recording.

IMM.40720 Anti-D Controls Phase II

Appropriate control(s) are used for anti-D testing.

NOTE: If anti-D reagent contains a potentiating diluent, the appropriate control is the diluent alone. The selection of controls used must be consistent with the manufacturer's instructions.

Evidence of Compliance:

- ✓ Records of anti-D control results

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IMM.40755 Historical Record Check Phase II

ABO/Rh results are compared with historical result records for each 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 patient. The historical record search can be performed manually by qualified laboratory personnel or with 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

IMM.40790 Typing Discrepancies - Investigation/Reconciliation Phase II



There are records of the investigation and reconciliation of all cases in which ABO and Rh typing results were not in accord with the patient's historical record.

NOTE: Available laboratory records for each patient must be routinely searched whenever testing is performed. Quality management records must include an investigation of all cases in which the ABO or Rh typing was not in accordance with the patient's laboratory historical record.

IMM.40795 Forward/Reverse Typing Phase II



For each patient, red blood cells are tested with anti-A, anti-B, and anti-D, and serum/plasma is tested using A1 and B reagent red cells.

NOTE: The ABO/Rh type of the patient's red blood cells must be determined by an appropriate test procedure. Tests on each sample must include forward and reverse grouping.

Evidence of Compliance:

- ✓ Logs or computer records with forward and reverse grouping

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(a)]

IMM.40800 Unexpected Antibody Screen Phase II



The antibody screen to detect unexpected red cell alloantibodies includes the following:

- Incubation at 37°C
- Use of red cells that are not pooled
- Interpretation at the antiglobulin phase

Evidence of Compliance:

- ✓ Logs or computer records indicating the reactions at the different phases of testing

IMM.40825 DAT Algorithm Phase II



When a direct antiglobulin test (DAT) is ordered by a patient's physician, the testing algorithm allows for detection of RBC-bound complement as well as IgG.

NOTE: The testing algorithm is intended to detect patients with complement-mediated hemolysis which may occur in paroxysmal cold hemoglobinuria, autoimmune hemolytic anemia, or drug-induced hemolytic anemia. Detection of complement is not required for the purpose of diagnosing hemolytic disease of the newborn.

The use of anti-IgG alone will fail to detect some cases of complement-mediated hemolysis because not all cases of complement-mediated hemolysis have detectable IgG coating the red blood cell. IMM.40860 and IMM.40980 also apply.