

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

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

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