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.

Evidence of Compliance:

✓ Records for DAT consistent with procedure

REFERENCES

1) Sokol RJ, *et al.* Autoimmune haemolysis: an 18-year study of 865 cases referred to a regional transfusion centre. *Brit Med J.* 1981;282:2023-2027
2) Packman CH, Leddy JP, Cryopathic hemolytic syndromes. In: Beutler E, *et al*, eds. William's Hematology, 5th ed. New York: McGraw-Hill, 1995:685-691
3) Vengelen-Tyler V, ed. American Association of Blood Banks Technical Manual, 13th ed. Bethesda, MD: AABB Press, 1999:259-262

IMM.40860 Antiglobulin Test Controls - Anti-IgG or Polyspecific Reagents Phase II

When performing an antiglobulin test with anti-IgG or polyspecific antiglobulin reagents, IgG-coated red blood cells are used as a control in all negative antiglobulin tests.

NOTE: IgG-coated red blood cells must be used to confirm all negative antiglobulin tests when the antiglobulin reagent used for testing has anti-IgG reactivity. Tests found negative by tube methodology must be verified by obtaining a positive test result after adding IgG-coated (control) red blood cells. If a licensed system is used that does not require verification of negative test results using IgG-coated cells, an appropriate quality control procedure must be followed, as recommended by the manufacturer.

Evidence of Compliance:

✓ Records of testing that include control results confirming negative antiglobulin tests

IMM.40980 Antiglobulin Test Controls - Anti-C3 Reagents Phase II

When performing an antiglobulin test with anti-C3 antiglobulin reagents, C3-coated red blood cells are used as a control in all negative antiglobulin tests.

NOTE: Complement-coated red blood cells must be used to confirm all negative antiglobulin tests when the antiglobulin reagent used for testing has anti-C3 reactivity. Tests found negative by tube methodology must be verified by obtaining a positive test result after adding C3-coated (control) red blood cells. If a licensed system is used that does not require verification of negative test results using C3-coated cells, an appropriate quality control procedure must be followed, as recommended by the manufacturer. If a polyspecific antiglobulin reagent is used, refer to checklist item IMM.40860.

Evidence of Compliance:

✓ Records of testing that include control results confirming negative antiglobulin tests

SYPHILIS SEROLOGY

Inspector Instructions:

READ	• Sampling of syphilis serology policies and procedures • Sampling of QC records • Needle delivery volume logs
ASK	• What is your laboratory's course of action prior to performing RPR, VDRL, TPPA, and/or USR patient testing using new antigen reagent lots?