1. **Principle**

To determine the presence of cold autoantibody by performing a screen test at 4°C. Cold agglutinin syndrome (also called cold hemagglutinin disease) is the hemolytic anemia most commonly associated with cold reactive autoantibodies.

This screening method may also be used to indicate if cold agglutinins are present that may interfere where the patient’s body temperature may need to be lowered during surgical procedure.

1. **Scope and Related Policies** 
   1. All tests will be set-up using warm separated (37°C) plasma.
   2. Cold cardiac screen must be performed within one month prior to surgery. For cold cardiac screen see Procedural Notes 8.2 for additional work instructions.
2. **Specimen**

EDTA anticoagulated whole blood

1. **Materials**

**Equipment:** Serological centrifuge

Block for test tubes

4°C refrigerator

For cold cardiac screen – water bath/incubator at   
28°C and 32°C

**Supplies:** Test tubes - 10 x 75 mm

Serological pipettes

**Reagents:** 3% saline suspension reagent screening cells (ensure one cell is P1 Negative)

3% saline suspension of patient’s red cells

1. **Quality Control – N/A**
2. **Procedure**

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| * 1. Check the suitability of the specimen to ensure that the specimen label information matches the request form. See PA.002 - Determining Specimen Suitability. |
| * 1. Warm separate patient specimen by setting in 37°C waterbath/heating block for a minimum of 15 minutes with periodic mixing. Spin approximately 2-5 minutes at 3000 rpm and place in 37°C waterbath immediately after spinning. With a pipette warmed to 37°C remove plasma into a clean, labeled tube avoiding any cells. Re-spin plasma sample to clear. |
| * 1. Perform a patient history check. See PA.003 - Patient History Check. |
| * 1. Label appropriate number of 10 x 75 mm tubes with the first 3 letters of the patient’s family name. Label the screening cells with the appropriate cell number and label one tube ‘auto’. |
| * 1. Dispense 3 drops of patient plasma into each of the labeled tubes. |
| * 1. Dispense 1 drop of the 3% O adult (screening cell) suspensions into the appropriate tubes. |
| * 1. Dispense 1 drop of the 3% patient suspension into the tube labeled auto. |
| * 1. Place tubes in a rack and incubate in a 4°C refrigerator for 1-2 hours. |
| * 1. Centrifuge at 3400 rpm for 10-15 seconds. Resuspend tubes and examine macroscopically for agglutination. Grade and record the results as per established procedure. See RT.001 - Reading and Recording Hemagglutination Reactions. |
| * 1. Interpret the antibody screen results. See 7.0 Reporting. |
| * 1. Initial or sign and record the completion time and date on the request form or verify in the computer. |
| * 1. Perform a clerical check. Check that the patient name and identification number are identical on all specimens and on the request form. Check that the patient name is the same on all test tubes and on request form. Check that the test results have been recorded. Check that the test results have been interpreted correctly. |
| * 1. Report the result of the antibody screen. See 7.0 Reporting. |

1. **Reporting**
   1. No agglutination or hemolysis of red cells indicates that cold autoagglutinins were not present or were undetected. Report the antibody screen as negative.
   2. Agglutination or hemolysis may indicate the presence of cold autoagglutinins. If indicated, refer to NRT.006 Identification of Cold Reactive Antibodies
   3. Interpretation: Report the antibody screen as positive if the autologous cell is agglutinated on its own or in combination with agglutination of the OI (screening) cells.
2. **Procedural Notes**
   1. Cold agglutinin titration and assays to determine thermal range are not routinely performed. These assays are performed only upon physician request.
   2. Cold cardiac screen: the following changes to the above procedure should be made:

* Warm separation of patient specimen is not required
* Commercial screening cells and autologous cells are incubated with 4 drops patient plasma at 28°C for 1 hour
* Centrifuge at 3400 rpm for 10-15 seconds and read microscopically
* If no reaction is seen report as negative
* If a positive reaction is seen, incubate the same tubes at 32°C for 1 hour
* Centrifuge at 3400 rpm for 10-15 seconds and read microscopically
* If no reaction is seen report as positive below 32°C
* If a positive reaction is seen incubate the same tubes at 37°C for 1 hour
* If no reaction is seen report as positive below 37°C
* If reaction is seen at 37°C proceed to NRT.007 Antibody Identification of Warm Reactive Antibodies
* If a positive reaction is seen at 28°C or 32°C the Anesthetist or designate must be notified by phone. The phone call must be documented. If indicated, refer to NRT.006 Identification of Cold Reactive Antibodies.

1. **References**
   1. Roback, JD. ed. AABB Technical Manual, 17th ed. Bethesda, MD: American Association of Blood Banks, 2011: pg 509-510
2. **Revision History**

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| **Revision Date** | **Summary of Revision** |
| September 1, 2014 | * Revised name of manual * Revised wording of section 1.0 to include “This screening method may also be used to indicate if cold agglutinins are present that may interfere where the patient’s body temperature may need to be lowered during surgical procedures.” * Revised and renumbered section 2.0 * Revised section 4.0 to include “For cold cardiac screen- water bath/incubator at 28ºC and 32ºC” and “3% saline suspension reagent screening cells (ensure one cell is P1 Negative).” * Revised wording of section 6.0 * Changed PA.006 to RT.001 in section 6.9 * Revised wording to include “If indicated, refer to NRT.006 Identification of Cold Reactive Antibodies” in sections 7.2 and 8.2 * Updated list of references to include most recent editions |