TRAINING UPDATE

Lab Location:	SGAH and WAH	**Date Implemented:**	12.22.2014
Department:	Blood Bank	**Due Date:**	01.15.2015

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Cold Agglutinin Screen

Description of change(s):

1. Note this procedure replaces the previous procedure, "Short Cold Panel."

2. We now have a test that will be used to enter this directly into the LIS (CAGS).

    a. The test will be reported as positive, negative, or inconclusive.

    b. The test will automatically generate billing.

3. When we perform this test, we will no longer include A1 and B cells or cord cells. We will simply run screen cells and an auto control. The antibody ID will be reported as "non-specific cold antibody" or "cold autoagglutinin" only.

Quest Diagnostics

Document No.: WAH.BB893[0]
Title: Cold Agglutinin Screen
Owner: LESLIE.X.BARRETT LESLIE BARRETT
Status INWORKS
Effective Date: 18-Jan-2015 **Next Review Date:**

Technical SOP

Title	**Cold Agglutinin Screen**	
Prepared by	Stephanie Codina	Date: 12/18/2014
Owner	Stephanie Codina	Date: 12/18/2014

Laboratory Approval	**Local Effective Date:**	
Print Name and Title	**Signature**	**Date**
Refer to the electronic signature page for approval and approval dates.		

Review		
Print Name	**Signature**	**Date**

TABLE OF CONTENTS

1. TEST INFORMATION

Assay	Method/Instrument	Local Code
Cold Agglutinin Screen	Tube test	N/A

Synonyms/Abbreviations
Short Cold Panel

Department
Blood Bank

2. ANALYTICAL PRINCIPLE

Cold agglutinins are those antibodies that optimally react at temperatures between 4-25°C. Cold agglutinins can be auto or allo in nature; they are differentiated by running an autologous control. These antibodies rarely cause destruction of red blood cells, because body temperature is closer to 37°C. However, the antibodies do interfere with serologic testing in the blood bank and may mask the reactions of other, clinically-significant antibodies. Identifying the specificity of cold antibodies is generally not necessary as this information tends to be more academic than clinically-necessary.

3. SPECIMEN REQUIREMENTS

Refer to procedure 'Sample Specifications for Blood Bank Testing' for labeling requirements.

3.1 Patient Preparation

N/A

3.2 Specimen Type & Handling

Criteria		
Type -Preferred **-Other Acceptable**	Preferred: EDTA Other acceptable: ACD, CPD, CPDA-1, CP2D, oxalate, or clotted blood	
Collection Container	Vacutainer	
Volume - Optimum **- Minimum**	1 ml 1 ml	
Transport Container and Temperature	Transport vacutainer at room temperature	
Stability & Storage Requirements	Room Temperature:	within 8 hours
	Refrigerated:	1 to 10C for 48 hours
	Frozen:	Plasma or serum can be stored frozen indefinitely
Timing Considerations	EDTA samples must be tested within 48 hours of collection	
Unacceptable Specimens & Actions to Take	Heparin, sodium citrate, or vacutainers with gel separators are not acceptable and must be recollected.	
Compromising Physical Characteristics	Specimens must be aseptically collected	
Other Considerations	Not applicable	

4. REAGENTS

Refer to the Material Safety Data Sheet (MSDS) supplied with the reagents for complete safety hazards. Refer to the section in this procedure covering "SAFETY" for additional information.

4.1 Reagent Summary

Reagents / Kits	Supplier & Catalog Number
Screening cells	Immucor, Cat.# 2381 or equivalent

4.2 Reagent Preparation and Storage

NOTES: Date and initial all reagents upon opening. Each container must be labeled with (1) substance name, (2) lot number, (3) date of preparation, (4) expiration date, (5) initials of tech, (6) any special storage instructions; check for visible signs of degradation.
Refer to the Material Safety Data Sheet (MSDS) for a complete description of hazards. If a specific hazard is present, it will be noted in this procedure when the hazard is first encountered in a procedural step.

Screening Cells	
Container	10ml each
Storage/Stability	1-10C / Stable until manufacturer's expiration date.
Preparation	Resuspend red cells before use by gently inverting each vial several times.

5. CALIBRATORS/STANDARDS

N/A

6. QUALITY CONTROL

N/A

7. EQUIPMENT and SUPPLIES

7.1 Assay Platform

N/A

7.2 Equipment

Serological centrifuge
Refrigerator

7.3 Supplies

Test tubes, (10 x 75 mm and/or 12 x 75 mm)
Pipettes

8. PROCEDURE

NOTE: For all procedures involving specimens, buttoned lab coats, gloves, and face protection are required minimum personal protective equipment. Report all accidents to your supervisor.

Step	Action
1	Confirm the specimen acceptability per procedure, "Sample Specifications for Blood Bank Testing."
2	Label 5 tubes with the patient identifiers. A. At a minimum, tubes will contain the first 3 digits of the patient's last name or the patient's last and first initial. B. Additional identifiers will be used if duplicate initials or numbers are present in a testing batch.
3	Prepare a cell suspension from the patient/test cells in one of the tubes per procedure.
4	Label each of the remaining tubes with one of the following: A. Label one tube "I" or "1." B. Label one tube "II" or "2." C. Label one tube "III" or "3." D. Label one tube "AC" or "AUTO."
5	Add 2 drops of patient's plasma/serum to each tube.
6	Add 1 drop of cells to each of the appropriate tubes. A. Add 1 drop of screen cell I to the tube labeled "I" or "1." B. Add 1 drop of screen cell II to the tube labeled "II" or "2." C. Add 1 drop of screen cell III to the tube labeled "III" or "3." D. Add 1 drop of the patient/test cell suspension to the tube labeled "AC" or "AUTO."
7	Mix well and incubate at 4°C for at least 15 minutes.
8	Serofuge immediately after incubation for the time listed on the serofuge.

Step	Action
9	Without delay, resuspend the cells and observe macroscopically for agglutination with the use of an agglutination viewer. Any delay in reading the reactions may cause the agglutination to disperse.
10	Record the reactions on an antigram that corresponds to the correct lot of screen cells used.

9. CALCULATIONS

N/A

10. REPORTING RESULTS AND REPEAT CRITERIA

10.1 Interpretation

Positive: Agglutination or hemolysis is present in any screening cell used for testing.
Negative: No agglutination or hemolysis is presented in any screening cell used for testing.

The autologous control will determine the specificity of the antibody in a positive cold agglutinin screen.
A. Negative autocontrol: Interpret a positive as a "Non-specific cold antibody."
B. Positive autocontrol: Interpret a positive as a "Cold autoantibody.

A positive autocontrol in the presence of a negative cold agglutinin screen must be investigated further. Interpret as "Inconclusive results."

10.2 Rounding

N/A

10.3 Units of Measure

N/A

10.4 Clinically Reportable Range (CRR)

N/A

10.5 Repeat Criteria and Resulting

N/A

11. EXPECTED VALUES

11.1 Reference Ranges

N/A

11.2 Critical Values

N/A

11.3 Priority 3 Limit(s)

N/A

12. CLINICAL SIGNIFICANCE

None

13. PROCEDURE NOTES

- **FDA Status:** LDT without message
- **Validated Test Modifications:** None

Even when a cold agglutinin is identified, it is possible that there is an underlying alloantibody present. If all significant antibodies cannot be ruled out on a panel when a cold reacting autoantibody is present, further antibody work-up is required. A LISS or prewarm screen should be considered.

14. LIMITATIONS OF METHOD

N/A

15. SAFETY

The employee has direct responsibility to avoid injury and illness at work. Nearly all harmful exposures to infectious substances and chemicals, and other injuries, can be avoided with effective training and consistent safe work practices.

Become familiar with the Environmental Health and Safety (EHS) Manual to learn the requirements on working safely and protecting the environment from harm. Although lab work typically focuses on the hazards of working with specimens and chemicals, we must also control other important hazards.

- Slips, trips, and falls cause many serious injuries. Please ensure that spills are cleaned quickly (to avoid slippery floors) and that you can see and avoid obstacles in your path.
- Ergonomic injuries result from performing tasks with too much repetition, force, or awkward position. Ergonomic injuries include strains and back injuries. Learn about ergonomic hazards and how to prevent this type of injury.

- Scratches, lacerations, and needlesticks can result in serious health consequences. Attempt to find ways to eliminate your risk when working with sharp materials.

Report all accidents and injuries immediately to your supervisor or the business unit Environmental Health and Safety Manager or Specialist.

16. RELATED DOCUMENTS

SOP: Sample Specifications for Blood Bank Testing
SOP: Preparing a 2-4% Cell Suspension for Testing
SOP: Prewarmed Antiglobulin Technique
SOP: Antibody Screen, LISS Tube Method

17. REFERENCES

A. Bryant N, An Introduction to Immunohematology, WB Saunders Co., 1976, p 196-199.
B. Johns, G., Gockel-Blessing, E, Zundel, W, and Denesiuk, L. 2015. Pearson Education, Upper Saddle River, NJ.

18. REVISION HISTORY

Version	Date	Section	Reason	Reviser	Approval

19. ADDENDA

Appendix A: LIS entry of the Cold Agglutinin Screen

Appendix A: LIS entry of the Cold Agglutinin Screen

Step	Action
1	Access TS order using Sunquest function, "Blood Order Processing."
2	In the "Add Spec Test" field, type ";CAGS" then press the "Tab" key or click on the ellipses and search for the cold agglutinin screen. This will add the cold agglutinin screen to the TS specimen.
3	Result the CAGS test with one of the following: A. Enter "P" for positive. B. Enter "N" for negative. C. Enter ")" for inconclusive result. Note: Antibody identification should be entered in the ABI field per procedure.
4	Click the "Save" button.
5	Billing for this test will automatically generate when the test is ordered in Sunquest.