PROCEDURE
Corewell Health East - Preparation of Quality Controls for Blood Bank - Troy

This Procedure is Applicable to the following Corewell Health sites:
Corewell Health Beaumont Troy Hospital

Applicability Limited to: N/A

Reference #: 33972

Version #: 2

Effective Date: 06/02/2025

Functional Area: Clinical Operations, Laboratory

Lab Department Area: Lab - Blood Bank

1. Principle

A. This document provides directions for the preparation of controls that are used for quality control (QC) testing. The controls that are prepared and tested by the Blood Bank staff are the following:
   1. Positive gel control
   2. Positive tube control

B. QC must be performed in the same manner as patient samples. Since this facility tests patient samples by both the manual gel method and the manual tube method, QC is tested by both the manual gel and manual tube methods. The positive gel control and the positive tube control are prepared as described in this document.

C. A positive control with known IgG antibody activity may be used to establish that antibody screening reagent red cells are reacting appropriately in the test method. When a positive result is obtained with antigen positive test cells in an indirect antiglobulin test (IAT), it indicates that the test system has a desired degree of sensitivity and that the antiglobulin reagent has activity against the IgG class of antibody.

2. Responsibility

Personnel who have completed the competency requirements will perform these tasks.

3. Definitions

A. QC: Quality control
B. IAT: Indirect antiglobulin test
C. Precision: Degree of agreement among repeated measurements of the same characteristic on the same sample
D. Accuracy: Measure of how close results are to what is expected from a test.

4. Reagent/Equipment Needed

A. Pipettes (capable of delivering 5 µL, 10 µL, 25 µL, and 50 µL)
B. 12 x 75 mm plastic test tubes with caps
C. Plastic disposable pipettes
D. Ortho® 0.8% Selectogen Reagent Red Blood Cells.

Entities will reference associated Documentation contained within this document as applicable
Printouts of this document may be out of date and should be considered uncontrolled.

5. Procedure

A. QC samples are expected to be tested identically to patient samples.

1. The purpose of repeated quality control testing is to validate precision and accuracy of the results of patient sample testing.

B. Labeling and Expiration Dates

1. Each of the controls is labeled using the appropriate sticker/label and includes the technologist's initials and the date of preparation.

C. Preparation of the Positive Gel Control

1. Place 200 µL of saline in a 12 x 75 mm labeled test tube.
2. Add 10 µL of the Gamma Clone® Anti-D reagent.
3. Thoroughly mix the contents of the tube.
4. Obtain a new vial of the Gamma Clone® control and transfer 125 µL of the saline/Anti-D mixture from the test tube to the vial of the Gamma Clone® control. Do not discard the test tube.
5. Thoroughly mix the contents of the vial and label the vial with the Positive Gel Control sticker.
6. Perform QC to demonstrate that the positive gel control reacts as expected (weak+, 1+, or 2+) against the 2-cell kit Selectogen® cells.
7. If the positive gel control reacts as expected, proceed to step 8.
    a. If the positive gel control does not react as expected, adjust the reactivity as follows:
        1) If the positive gel control was non-reactive against the screen cells, transfer an additional volume (e.g., 25 additional µL) of saline/Anti-D mixture from the test tube to the vial of the Gamma Clone® control.
        2) Repeat steps 6 and 8.
        3) If the positive gel control was too strong (3+ or 4+) against the screen cells, discard the 12 x 75 mm test tube and the Gamma Clone® control.
        4) Repeat all steps 1-6, but this time add a smaller volume of saline/Anti-D mixture (e.g., add only 100 µL of saline/Anti-D mixture).
        5) If the reactivity of the positive gel control cannot be adjusted to the expected reactivity, consult the supervisor and omit steps 8 and 9.
8. Store the positive gel control in the reagent rack at 2°C – 6°C until its expiration date.
9. The expiration date is the shorter of:
10. 1 year from the preparation date
    a. the original expiration date of the Anti-D
    b. the original expiration date of the Gamma clone® control

B. Preparation of the Positive Tube Control

1. Obtain a new vial of the Gamma Clone® control.
2. Add 50 µL of the Gamma Clone Anti-D reagent to the vial of Gamma Clone Control.
3. Thoroughly mix the contents of the vial.
4. Label the vial with the Positive Tube Control Sticker.
5. Check to confirm that the positive tube control reacts as expected:
    a. WK+, 1+, or 2+ against Surgiscreen® cell #1
    b. WK+, 1+, or 2+ against Surgiscreen® cell #2
    c. Non-reactive with Surgiscreen® cell #3
6. If the positive tube control reacts as expected, proceed to step 7.
    a. If the positive tube control does not react as expected, adjust the reactivity as follows:
        1) If the positive tube control was non-reactive against either of Surgiscreen® cells #1 or #2, transfer an additional volume (e.g., additional 5 µL) of Gamma Clone® Anti-D reagent to the vial of the Gamma Clone® control.
        2) Repeat steps 3 and 5.
        3) If the positive tube control was too strong (3+ or 4+ against cells #1 or #2, or reactive against cell #3) discard the vial.

Entities will reference associated Documentation contained within this document as applicable
Printouts of this document may be out of date and should be considered uncontrolled.

a) Repeat all steps 1–5, but this time in step 2 add a smaller volume of Gamma Clone® Anti-D reagent (e.g., add only10 µL of Gamma Clone® Anti-D reagent).
b) If the reactivity of the positive tube control cannot be adjusted to the expected reactivity, consult the supervisor. Omit steps 7 and 8.

7. Store the positive tube control in the reagent rack at 2°C – 6°C until its expiration date.
8. The expiration date is the shorter of:
   a. 1 year from the preparation date
   b. the original expiration date of the Anti-D
   c. the original expiration date of the Gamma clone® control

6. Results/Interpretation

A. Once prepared, the positive gel control and the positive tube control must be checked to ensure the expected reactivity was obtained.
   1. Unacceptable QC results must be investigated, and corrective action must be implemented, if applicable.

7. Revisions

Corewell Health reserves the right to alter, amend, modify or eliminate this document at any time without prior written notice.

8. References

1. AABB, Technical Manual, current edition.
2. AABB, Standards for Blood Banks and Transfusion Services, current edition.
3. Ortho Clinical Diagnostics. 0.8% Selectogen® Reagent Red Blood Cells, 631991242, March 2019.
4. Ortho Clinical Diagnostics. Surgiscreen® Reagent Red Blood Cells, 631991242, March 2019.

9. Procedure Development and Approval

Document Owner:
Laura Judd (Operations Specialist)

Writer(s):
Alyssa Malone (Medical Technologist Lead)

Reviewer(s):
Hannah Carbary (Medical Technologist), Taylor Stencel (Medical Technologist)

Approver:
Brittnie Berger (Dir Sr, Lab Operations), Elzbieta Wystepek (Dir, Laboratory Services), Kelly Sartor (Mgr, Division Laboratory), Masood Siddiqui (Staff Pathologist), Ryan Johnson (OUWB Clinical Faculty), Sarah Britton (VP, Laboratory Svcs), Teresa Lovins (Supv, Laboratory)

10. Keywords

Not Set

Entities will reference associated Documentation contained within this document as applicable
Printouts of this document may be out of date and should be considered uncontrolled.