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Area	Laboratory-Blood Bank
Applicability	All Beaumont Hospitals

Specimen Container Evaluation for Analytic Interference - Blood Bank

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

This document will provide instructions to perform a pre-analytical evaluation of specimen containers (blood collection tubes) to verify they do not contribute to analytic interference with the assays performed and comply with regulatory requirements and standards.

II. DEFINITIONS:

A. Designee: Lead Medical Technologist, Supervisor/Manager, or any Blood Bank Pathologist or Fellow.

III. POLICY:

A. Blood Bank will verify that blood tubes and containers used in testing do not contribute to analytic interference.

B. Evaluations will occur whenever there is a change to container type or when changing to a different vendor.

C. The Medical Director or designee will review these evaluations and approve the containers for use.

IV. SCOPE:

A. Blood Bank currently uses K_2EDTA Tubes supplied by BD® and/or Greiner® for routine immunohematology testing such as ABO grouping, Rh typing, antibody screening, red cell

phenotyping, direct antiglobulin (DAT) and other testing.

V. SUPPLIES/EQUIPMENT:

A. Ortho Vision™ Analyzer
B. Micro Typing System (MTS) gel cards
C. BD VACUTAINER® K_2 EDTA collection tubes (lavender top, pink tops)
D. GREINER VACUETTE® K_2E K_2EDTA collection tubes (pink top)
E. Normal Blood Bank saline
F. Downtime barcode labels

VI. QUALITY CONTROL (QC):

A. QC must be acceptable prior to testing, refer to Transfusion Medicine policy, ORTHO VISION Analyzer QC.

VII. PROCEDURE:

A. Fill a lavender top and a pink top collection tube with 0.9% blood bank saline.
B. Affix a downtime barcode label to each tube and identify with manufacturer,container color and lot number. i.e BDPink(Lot#) and BDLav(Lot#).
C. Perform a Type & Screen on each tube on the Ortho Vision as described in Transfusion Medicine policy, Routine Testing on the Ortho VISION™ Analyzer.
D. Print a Show Order Report for each collection tube from the VISION™.
E. Print a copy of the current Certificate of Conformance for each of the two EDTA tubes and attach these certificates to the VISION™ reports.
    1. The Certificates of Conformance may be accessed at the BD website, www.bd.com , as follows:
        a. Click on the BD web address.
        b. .Quality Certificates Search.
        c. Enter the BD catalog number (reference number from the sticker).
        d. Enter the BD lot number (from the sticker).
        e. Click Search.
        f. Click View Certificate to view the PDF.
        g. Print.
    2. The Certificates of Conformance may be accessed at the Greiner website, www.gbo.com/en-us , as follows:
        a. Click on the Greiner website.
        b. Scroll to Certificates of Quality and click on it.

c. Enter the Lot number from the box and click on the ADD button.

d. Click View Certificate to view the PDF.

e. Print.

F. Document the Specimen Container Evaluation for Analytical Interference Form.

1. The MTLead or technologist performing the assay will document the form with container information, saline lot# and expiration dates, assay results
2. The results of the evaluation will be interpreted as described in the *Expected Values* section below.

a. Documentation as “Satisfactory” indicates that the collection test tubes do not contribute to analytic interference.

b. Documentation as “Unsatisfactory” indicates that the collection test tubes do contribute to analytic interference. Consult the Medical Director if unsatisfactory.

G. Submit the Vision reports , Certificate of Conformance, and the Specimen Container Evaluation for Analytical Interference form to the Lead Technologist or Supervisor for review.

H. Laboratory Director or designee with review Evaluation results and determine acceptability for use.

VIII. EXPECTED VALUES:

A. Satisfactory: Result is negative and non-reactive.

B. Unsatisfactory: Result is positive or shows any reactivity.

C. If any result is positive:

1. Repeat testing
2. If results are still positive repeat using a different lot of collection tube.
3. If testing is still positive, submit an internal variance. Consult the supervisor and Medical Director immediately for further investigation and resolution.

IX. NOTES:

Positive results could be a result of contamination in the collection tube, the saline or gel card or a combination of the three and must be investigated and resolved.

X. REFERENCES:

1. College of American Pathologists, GEN 40942, Specimen Container Analytic Interference, current edition.
2. AABB, Standards for Blood Banks and Transfusion Services, current edition.

Attachments

Specimen Container Evaluation for Analytical Interference (rev. 05/10/2024)

Approval Signatures

Step Description	Approver	Date
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Applicability

Dearborn, Farmington Hills, Grosse Pointe, Royal Oak, Taylor, Trenton, Troy, Wayne