

Beaumont

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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 K₂EDTA 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® K₂ EDTA collection tubes (lavender top, pink tops)
- D. GREINER VACUETTE® K₂E K₂EDTA 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
Policy and Forms Steering Committee (if needed)	Muhammad Arshad: Chief, Pathology	7/17/2024
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Applicability

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

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