

# Beaumont

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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<sub>2</sub>EDTA 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<sub>2</sub> EDTA collection tubes (lavender top, pink tops)
- D. GREINER VACUETTE® K<sub>2</sub>E K<sub>2</sub>EDTA 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](http://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](http://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 MTLLead 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.

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## Attachments

[Specimen Container Evaluation for Analytical Interference \(rev. 05/10/2024\)](#)

## Approval Signatures

Step Description	Approver	Date
	Muhammad Arshad: Chief, Pathology	7/17/2024
	Ann Marie Blenc: System Med Dir, Hematopath	7/17/2024
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## Applicability

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

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