1 Becton Drive
Franklin Lakes, NJ 07417
USA
bd.com

March 21, 2022

RE: Indications for Use, Electronic IFU, and Shelf-Life Change Notification for BD Vacutainer® ACD A and B Blood Collection Tubes

Dear Valued Customer:

BD Life Sciences is committed to providing the best possible product experience to our customers. This communication contains important information concerning changes to the Indications for Use, electronic Instructions for Use (IFU), and shelf-life for BD Vacutainer® ACD A and B Blood Collection Tubes. These changes do not impact the design, form, or fit of these products.

Given the time that has passed since our original filing to the U.S. Food and Drug Administration (FDA) for the BD Vacutainer® ACD A and B Blood Collection Tubes, we have submitted, and recently received, a new 510(k) clearance from FDA in order to demonstrate the continued performance of these products. We completed ABO and Rh type testing with representative methods as described in the analytic equivalency section below.

The product codes being updated are listed in the table below.

Product Code	Product Description
364606	16x100 mm 8.5 mL BD Vacutainer® glass whole blood ACD A tube
364816	13x100 mm 6.0 mL BD Vacutainer® glass whole blood ACD B tube

On April 1, 2022, BD Life Sciences will implement the following changes for the BD Vacutainer® ACD A and B Blood Collection tubes:

Changes to Instructions for Use:

Indications for Use Change - The BD Vacutainer® ACD A and B Blood Collection Tubes have not been evaluated for HLA phenotyping and DNA testing. The updated indications for use will read:

> *BD Vacutainer® ACD A and B Blood Collection Tubes are evacuated, sterile, single use, in vitro diagnostic medical devices. They are intended to be used by trained healthcare professionals for the collection, containment, preservation, and transport of human venous blood specimens for the purpose of in vitro diagnostic testing.*
>
> *BD Vacutainer® ACD A and B Blood Collection Tubes may be used for testing in immunohematology, such as ABO grouping and Rh typing.*

BD-53699 (03/22)

1 Becton Drive
Franklin Lakes, NJ 07417
USA
bd.com

The performance characteristics of these tubes have not been established for immunohematology testing in general; therefore, users must validate the use of these tubes for their specific assay- instrument/reagent system combinations and specimen storage conditions.

If you require a product for molecular testing, please use the PAXgene® Blood DNA Tube offering.

Analytic Equivalency - The following information has been added to the IFU:

Clinical Performance has been demonstrated for ABO Grouping and Rh typing using Ortho Clinical Diagnostics column agglutination (gel) and Immunocor Inc. manual tube test methods. A zone of concordance was provided for each parameter with each agglutination reaction score matching exactly (for negative only or mixed field only) or within 0.5 (for weak positive or 1+) or 1 (for ≥ 1+) reaction score. Within tube stability has been demonstrated for ABO Grouping and Rh Typing using BD Vacutainer® ACD Tubes for up to 24 hours with storage at room temperature (15-25 °C) and up to 14 days when stored refrigerated (2-8 °C). Analyte stability can be affected by a wide range of factors and should therefore be evaluated for the storage containers and conditions of each laboratory.

To view the additional tables with data, please go to https://eifu.bd.com/.

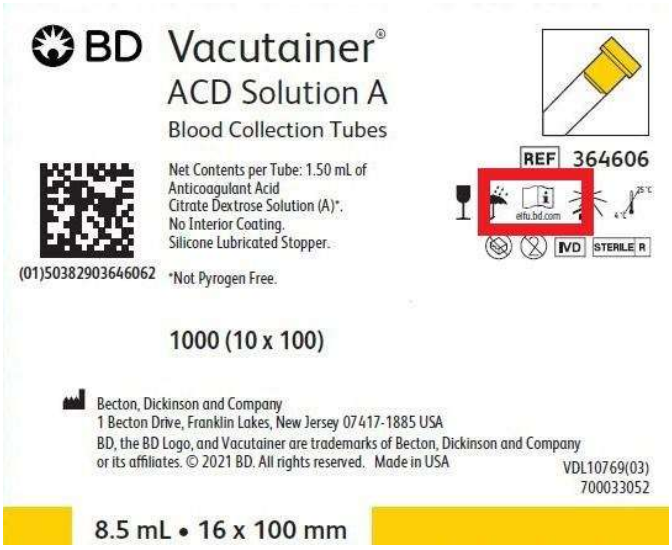
Added Caution Statement - All biological specimens and materials are considered biohazardous and should be handled with caution as the risk of transmitting infection is possible. Dispose of medical waste with proper precautions in accordance with federal, state, and local regulations. Never pipette by mouth. Wear suitable protective clothing, eyewear, and gloves.

Instructions for Use in Electronic Format (eIFU) - BD Life Sciences has transitioned from physical copies of product inserts to electronically available Instructions for Use (eIFUs) for BD Vacutainer® ACD A and B Blood Collection Tubes. Moving our product insert IFU information online will ensure our customers always have the most up-to-date product information available.

To access the eIFU, please go to https://eifu.bd.com/. This website URL will also be available on the case label for the product. An example of the case label is pictured below with the added symbol and URL outlined in red.

BD-53699 (03/22)

1 Becton Drive
Franklin Lakes, NJ 07417
USA
bd.com



Product Shelf-Life Change:

BD Life Sciences is also reducing the shelf-life for BD Vacutainer® ACD A and B Blood Collection Tubes from 24 months to 14 months. This shelf-life change is based on data available at the time of our 510(k) clearance by the FDA and is not the result of a product performance issue. This change does not impact any BD Vacutainer® ACD A and B Blood Collection Tubes manufactured prior to April 1, 2022. Shelf-life testing is ongoing, and the shelf-life may be extended based on the results of this testing.

We understand the important role that our products play in ensuring accurate diagnostic test results for your patients as well as safety and confidence for your clinical staff. We are here to support you throughout the transition and apologize for any inconvenience this may cause.

For more information about these changes, please contact our BD Technical Services Team at 1.800.631.0174 or email us at Technical_Services@bd.com. For all other questions, please contact BD customer service at 1.844.823.5433.

Sincerely,

Brent Ashton
Vice-President / General Manager
BD Life Sciences, Integrated Diagnostic Solutions

Advancing the world of health