



November 10, 2016

To Whom It May Concern,

This letter is in response to your question regarding the latex content of BD Vacutainer® products.

- **The following products contain dry natural rubber (DNR), which is formed from coagulated natural rubber latex material.**
  - BD Vacutainer® Blood Collection Tubes with yellow stoppers and ACD additive (Reference Numbers 364816, 364606, and 364012)
  - BD Vacutainer® Blood Collection Tubes with yellow stoppers and SPS additive (Reference Numbers 366404 and 364960)
- **The following products do not contain dry natural rubber, latex, in the product:**
  - BD Vacutainer® Multiple Sample Needle
  - BD Vacutainer® Eclipse™ Blood Collection Needle
  - BD Vacutainer® Eclipse™ Blood Collection Needle with Pre-Attached Holder
  - BD Vacutainer® Eclipse™ Signal™ Blood Collection Needle with Integrated Holder
  - BD Vacutainer® Passive Shielding Blood Collection Needles
  - BD Vacutainer® Blood Collection Set
  - BD Vacutainer® Safety-Lok™ Blood Collection Set
  - BD Vacutainer® Safety-Lok™ Blood Collection Set with Pre-Attached Holder
  - BD Vacutainer® Push Button Blood Collection Set
  - BD Vacutainer® UltraTouch™ Push Button Blood Collection Set
  - BD Vacutainer® Multiple Sample Luer Adapter
  - BD Vacutainer® Blood Transfer Device
  - BD Vacutainer® Luer-Lok™ Access Device
  - BD Vacutainer® Urine Collection Cup with integrated transfer device
  - BD Vacutainer® Conventional Closures (stoppers) excluding yellow-colored conventional closures
  - BD Vacutainer® Barricor™ LH Plasma Blood Collection Tubes
- **The packaging for the following products contains a "latex free" claim:**
  - BD Vacutainer® Multiple Sample Needle
  - BD Vacutainer® Eclipse™ Blood Collection Needle
  - BD Vacutainer® Eclipse™ Blood Collection Needle with Pre-Attached Holder
  - BD Vacutainer® Eclipse™ Signal™ Blood Collection Needle with Integrated Holder
  - BD Vacutainer® Blood Collection Set
  - BD Vacutainer® Safety-Lok™ Blood Collection Set
  - BD Vacutainer® Safety-Lok™ Blood Collection Set with Pre-Attached Holder



- BD Vacutainer® Push Button Blood Collection Set
- BD Vacutainer® UltraTouch™ Push Button Blood Collection Set
- BD Vacutainer® Urine Collection Tubes (U.S. Products)
- BD Vacutainer® Urine Collection Cup with integrated transfer device (U.S. products)
- BD Vacutainer® Urine Collection Kits (U.S. products)

Since latex allergies have become more prevalent among the patient population as well as among healthcare workers (HCW), healthcare facilities have enacted latex-free policies to protect patients and healthcare workers. BD understands the safety concerns regarding latex allergies and strongly believes that, if handled as described in the package inserts, the BD Vacutainer® products that contain DNR pose a minimal risk to patients and healthcare workers. At the same time, BD recognizes the growing concern and is developing a latex-free product portfolio while maintaining the highest clinical performance and quality.

All naturally derived rubber products contain latex proteins. The term "latex" is non-specific in the sense that it has been used to describe products made using either the natural rubber latex process (NRL) or DNR process. The principal difference between these two substances is the potential for exposure to the proteins found in the natural latex rubber. The DNR process uses coagulated natural latex in the form of dried or milled sheets. Products are formed from dry natural rubber by compression molding, extrusion, or by converting the sheets into a solution for dipping. (This information comes from the FDA's Final Rule on latex labeling issued April 1, 2016 and 21CFR 801.437). The FDA mandates that any product that has DNR in the product carry the label "This Product Contains Dry Natural Rubber."

BD Vacutainer® Brand products have a low risk profile of an adverse medical reaction for the following reasons:

1. Latex allergy is contact reaction, which means physical contact with latex allergens or latex particles is necessary for a reaction to occur. The processing of DNR creates a hard, coagulated material that does not release particulate matter as does NRL (i.e. gloves or balloons). As such, it would be extremely difficult to cause aerosolization of latex particles from a DNR material. Also, in most cases, HCW handle the BD Vacutainer® products containing DNR using gloves, as part of the universal specimen handling protocols. It is very unlikely that DNR can cause allergic reactions under these circumstances.
2. There is an imperceptible risk of exposure to latex through backflow of blood obtained by piercing of the stopper containing DNR. A study that compared the levels of latex allergen contamination of solutions obtained by sampling through DNR – containing stoppers versus when no stoppers were used (latex-free control) showed no



difference in latex allergen concentrations between the two sampling methods. Removal of the dry stopper from vials did not yield solutions with less latex allergen solutions prepared by sampling through the stopper. (Thomas DJ, Burke TG. Am J Health Syst Pharm. 2000;57:44-7). These data indicate that the latex present in DNR in blood collection tubes will most likely not increase the risk of exposure to latex allergens.

Reference sources supporting information regarding DNR and latex reactions:

1. Thomsen DJ and Burke TG. Lack of latex allergen contamination of solution withdrawn from vials with natural rubber stoppers. Am J Health Syst Pharm. 2000;57:44-7
2. Binlkey HM, Schroyer T and Catalano J. Latex Allergies: A review of Recognition, Evaluation, Management, Prevention, Education, and Alternative Product Use, Athl Train. 2003; 38:-133-140

If you have additional questions, please feel free to call the BD Vacutainer® Technical Services Department at 1-800-631-0174.

Sincerely,

A handwritten signature in black ink, appearing to read "Barbara A. Bodden".

---

Barbara Bodden  
EH&S Coordinator  
BD Life Sciences  
PreAnalytical Systems