



May 2024

RE: Precaution Statement Update for BD Vacutainer® Urine Products

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 Precaution Statement for BD Vacutainer® Urine Products Instructions for Use (IFU). This change does not impact the design, form, or fit of these products.

The product catalog numbers being updated are listed in the table below.

Product Catalog Number	Product Description
364992	BD Vacutainer® Urinalysis Preservative Tube, 16x100mm, 8.0mL
365017	BD Vacutainer® Urinalysis Preservative Tube, 16x100mm, 8.0mL
364943	BD Vacutainer® Urine Collection Kit, Urinalysis Transfer Straw Kit
364946	BD Vacutainer® Urine Collection Kit, Urinalysis Cup Kit
364957	BD Vacutainer® Urine Collection Kit, Complete Kit

It is recommended to follow your institution's policies and procedures for product validation prior to use.

In June 2024, BD Life Sciences will begin implementing the following update for the BD Vacutainer® Urine Products IFU:

Added additional Precaution Statement item:

BD Vacutainer® Urinalysis Preservative Tubes contain additives which may result in a positive bias for urine pH and specific gravity, compared to unpreserved urine.¹ BD studies have demonstrated average biases of <1% for specific gravity and <0.5 pH units.² Laboratories should assess whether using the same reference range for preserved and unpreserved urine is appropriate for these parameters.

Moving forward, in the US, we will be providing all product updates accessible at <https://go.bd.com/vacutainer-product-updates.html> as these clearances are received by the FDA and will be available for all BD Vacutainer® tube product families. On the website it is recommended that you sign up to receive notifications for future clearances and the most up-to-date product information.

For more information about these changes, please contact our BD Technical Services Team at 1.800.638.8663, option 3, or email us at Technical_Services@bd.com. For all other questions, please contact BD customer service at 1.844.823.5433.

Sincerely,

Attiq Amjad
Associate Director, Marketing
BD Life Sciences

References:

- Salazar-García S, Lares-Villaseñor E, Bárcenas-Morales A, Vargas-Morales Juan M. Impact of chemical preservative in urine samples. EIJFCC. 2020;31(1):56-64.
- BD data on file.