



June 20, 2019

Re: Electronic Instruction for Use (eIFU) for BD Vacutainer® Blood Collection Tubes and BD Vacutainer® Urine Collection System Products

Dear Valued Customer:

BD Life Sciences – Preanalytical Systems is committed to providing the highest standard of product experience to our customers.

In the spirit of continuously delivering on our commitment, on June 1, 2019, we began transitioning from hard copies of product inserts to electronically available Instructions for Use (eIFUs) for several BD Vacutainer® Blood Collection Tubes and BD Vacutainer® Urine Collection System products (see attached page for SKU details).

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. Moving our product insert IFU information online will ensure our customers have the most up-to-date product information available at all times.

We are updating both shelf packs and case carton labels of these products with the web address where the electronic IFUs are located, as well as a toll-free number for customer support. To access the electronic product inserts for the BD Vacutainer® Blood Collection Tubes and BD Vacutainer® Urine Collection System products, please go to www.bd.com/vacutainer and select 'Product Inserts' on the right-hand side of the page. Continue by selecting 'Directions for Use' under 'Content Type' on the left-hand side of the page. Finally, select the PDF from the center column to download the document of your choice for use. Additionally, please note that customers without internet access can call our customer service hotline (see below) and request a paper copy of the IFU free of charge.

Additionally, we would be pleased to provide support via our BD Technical Services to help with product related questions. Please call 1.800.631.0174 and select option 4 or email us at San_AntonioComplaintsCEC@bd.com. For all other questions, please contact BD Customer Service at 1.888.237.2762.

We would like to take this opportunity to express our appreciation for your continued patronage and support.

Sincerely,

Julia Wells
Associate Director, Containment Platform - US Region
BD Life Sciences – Preanalytical Systems

Catalogs with eIFU replacing Paper IFU:

Catalog	Description
362753	BD Vacutainer® CPT™ Mononuclear Cell Preparation Tube 8.0 mL, 16x125 mm Glass Tube with Conventional Closure and Sodium Heparin Anticoagulant
362760	BD Vacutainer® CPT™ Mononuclear Cell Preparation Tube 4.0 mL, 13x100 mm Glass Tube with Conventional Closure and Sodium Citrate Anticoagulant
362761	BD Vacutainer® CPT™ Mononuclear Cell Preparation Tube 8.0 mL, 16x125 mm Glass Tube with Conventional Closure and Sodium Citrate Anticoagulant
362788	BD Vacutainer® PPT™ Plasma Preparation Tube 5.0 mL, 13x100 mm Plastic Tube with BD Hemogard™ Closure and K2EDTA Anticoagulant
363706	BD Microtainer® MAP Microtube for automated process 13x75mm with K2EDTA Additive
364943	BD Vacutainer® Urinalysis Transfer Straw Kit: Transfer Straw and 8.0 mL, 16x100 mm Plus Plastic Conical Tube for Urinalysis with Conventional Closure
364951	BD Vacutainer® Plus C&S Preservative Tube 4.0 mL, 13x75 mm Plus Plastic C&S Preservative Tube with Conventional Closure
364953	BD Vacutainer® C&S Transfer Straw Kit: Transfer Straw and 4.0 mL, 13x75 mm Plastic C&S Preservative Tube with Conventional Closure
364956	BD Vacutainer® Complete Urine Kit: Sterile Screw-Cap Collection Cup with integrated transfer device and 8.0 mL, 16x100 mm Plus Plastic Conical Tube for Urinalysis and 4.0 mL, 13x75 mm Plus Plastic C&S Preservative Tube and Castile Soap Towelettes
364957	BD Vacutainer® Complete Urine Kit: Sterile Screw-Cap Collection Cup with integrated transfer device and 8.0 mL, 16x100 mm Plus Plastic Conical Tube with Preservative for Urinalysis and 4.0 mL, 13x75 mm Plus Plastic C&S Preservative Tube and Castile Soap Towelettes
364975	BD Vacutainer® Urine Collection Cup with integrated transfer device
364979	BD Vacutainer® Urinalysis Tube 10.0 mL, 16x100 mm Plus Plastic Round Bottom Tube with Conventional Closure
364980	BD Vacutainer® Urinalysis Tube 8.0 mL, 16x100 mm Plus Plastic Conical Tube with Preservative for urinalysis
364992	BD Vacutainer® Urinalysis Tube 8.0 mL, 16x100 mm Plus Plastic Conical Tube with Preservative for Urinalysis
366703	BD Vacutainer® No Additive Tube 3.0 mL, 13x75 mm with BD Hemogard™ Closure
366704	BD Vacutainer® No Additive Tube 3.0 mL, 13X75 with Conventional Closure
368381	BD Vacutainer® Trace Element Tube 6.0mL, 13X100 with BD Hemogard™ Closure
762165	PAXgene® Blood RNA Tube 2.5mL, 16X100 with BD Hemogard™ Closure

Example of the label change to impacted product (for Catalog# 362753):

	Current	New
Shelf Carton Label	<p>BD Vacutainer® CPT™ Cell Preparation Tube with Sodium Heparin</p> <p>For the separation of mononuclear cells from whole blood. Contains: Minimum of 132 USP Units of Sodium Heparin[®] in 1.0mL Phosphate Buffered Saline Solution, 3.0gm of Polyester Gel and 2.0mL of Polysaccharide Sodium Diatrizoate Solution. Silicone Coated Interior. Silicone Lubricated Stopper.</p> <p>真空密封型採血管 BD バキューテイナ採血管 管理医療機器 単回使用 医療機器認証番号 219AFBZX00109000 製造番号 (ロット番号) : 欄外参照 日本ベクトン・ディッキンソン株式会社 〒960-2152 福島県福島市土船字五反田1</p> <p>REF 362753</p> <p>Becton, Dickinson and Company, 1 Becton Drive, Franklin Lakes, NJ 07417-1885 USA www.bd.com/vacutainer/reference material Call 1.800.631.0174 (USA Only) 700006289 © 2016 BD, BD, the BD Logo and all other trademarks are property of Becton, Dickinson and Company.</p> <p>(01)30382903627531</p> <p>YYYY-MM-DD 2345678</p> <p>Made in USA Rx Only (USA)</p> <p>IVD (STERILE)</p> <p>(17)160530(10)5149711(30)60</p> <p>8 mL • 16 x 125 mm</p>	<p>BD Vacutainer® CPT™ Cell Preparation Tube with Sodium Heparin</p> <p>For the separation of mononuclear cells from whole blood. Contains: Minimum of 132 USP Units of Sodium Heparin[®] in 1.0mL Phosphate Buffered Saline Solution, 3.0gm of Polyester Gel and 2.0mL of Polysaccharide Sodium Diatrizoate Solution. Silicone Coated Interior. Silicone Lubricated Stopper.</p> <p>真空密封型採血管 BD バキューテイナ採血管 管理医療機器 単回使用 医療機器認証番号 219AFBZX00109000 製造番号 (ロット番号) : 欄外参照 日本ベクトン・ディッキンソン株式会社 〒960-2152 福島県福島市土船字五反田1</p> <p>REF 362753</p> <p>Becton, Dickinson and Company, 1 Becton Drive, Franklin Lakes, NJ 07417-1885 USA www.bd.com/bd (U) US: +1 855 236 0910; BR: 0200 591 1055; CA: +1 855 805 8539; EU, AR, CO, AU, NZ: +800 135 79 135; Intel: +31 20 794 7071 www.bd.com/vacutainer/reference material BD and the BD Logo are trademarks of Becton, Dickinson and Company. © 2019 BD and its subsidiaries. All rights reserved. 700019352</p> <p>(01)30382903627531</p> <p>YYYY-MM-DD 2345678</p> <p>Made in USA Rx Only (USA)</p> <p>IVD (STERILE)</p> <p>(17)160530(10)5149711(30)60</p> <p>8 mL • 16 x 125 mm</p>
Case Carton Label	<p>BD Vacutainer® CPT™ Cell Preparation Tube with Sodium Heparin</p> <p>For the separation of mononuclear cells from whole blood. Contains: Minimum of 132 USP Units of Sodium Heparin[®] in 1.0mL Phosphate Buffered Saline Solution, 3.0gm of Polyester Gel and 2.0mL of Polysaccharide Sodium Diatrizoate Solution. Silicone Coated Interior. Silicone Lubricated Stopper.</p> <p>真空密封型採血管 BD バキューテイナ採血管 管理医療機器 単回使用 医療機器認証番号 219AFBZX00109000 製造番号 (ロット番号) : 欄外参照 日本ベクトン・ディッキンソン株式会社 〒960-2152 福島県福島市土船字五反田1</p> <p>REF 362753</p> <p>Becton, Dickinson and Company, 1 Becton Drive, Franklin Lakes, NJ 07417-1885 USA www.bd.com/vacutainer/reference material Call 1.800.631.0174 (USA Only) 700008420 © 2016 BD, BD, the BD Logo and all other trademarks are property of Becton, Dickinson and Company.</p> <p>YYYY-MM-DD 2345678</p> <p>STERILE IVD</p> <p>8 mL • 16 x 125 mm</p>	<p>BD Vacutainer® CPT™ Cell Preparation Tube with Sodium Heparin</p> <p>For the separation of mononuclear cells from whole blood. Contains: Minimum of 132 USP Units of Sodium Heparin[®] in 1.0mL Phosphate Buffered Saline Solution, 3.0gm of Polyester Gel and 2.0mL of Polysaccharide Sodium Diatrizoate Solution. Silicone Coated Interior. Silicone Lubricated Stopper.</p> <p>真空密封型採血管 BD バキューテイナ採血管 管理医療機器 単回使用 医療機器認証番号 219AFBZX00109000 製造番号 (ロット番号) : 欄外参照 日本ベクトン・ディッキンソン株式会社 〒960-2152 福島県福島市土船字五反田1</p> <p>REF 362753</p> <p>Becton, Dickinson and Company, 1 Becton Drive, Franklin Lakes, NJ 07417-1885 USA www.bd.com/bd (U) US: +1 855 236 0910; BR: 0800 591 1055; CA: +1 855 805 8539; EU, AR, CO, AU, NZ: +800 135 79 135; Intel: +31 20 794 7071 www.bd.com/vacutainer/reference material BD and the BD Logo are trademarks of Becton, Dickinson and Company. © 2019 BD and its subsidiaries. All rights reserved. 700019444</p> <p>YYYY-MM-DD 2345678</p> <p>STERILE IVD</p> <p>8 mL • 16 x 125 mm</p>