# TECHNICAL INFORMATION SHEET

## BD Vacutainer® Citrate Plus Tube with BD Hemogard™ Safety Closure

## Product Catalogue Number: 363047

## Product Description

Single use, evacuated, sterile blood collection tubes containing buffered trisodium citrate intended for the primary containment and preservation of specimens for the purposes of in-vitro diagnostic examination. Used to obtain a citrate plasma sample. These products are intended for use by healthcare professionals.

## Manufacturing Information

| | |
|---|---|
| Manufacturer: | Becton, Dickinson and Company Belliver Industrial Estate Belliver Way Roborough, Plymouth, PL6 7BP, UK. |
| Standards & Certificate Numbers: | ISO 13485:2003 & EN ISO 13485:2012, MD 613320, ISO 14001:2004, EMS 37154 |
| Country of origin: | UK |
| Certification body: | BSI UK (0086) |
| Notified Body: | N/A |
| EU Authorised Representative: | BD Switzerland Sarl, Terre Bonne Park - A4, Route de Crassier 17, 1262 Eysins, Switzerland |

## Sterilisation

| | |
|---|---|
| Method: | Gamma Irradiation, Co-60 |
| SAL: | $10^{-6}$ |
| Standards applied: | EN ISO 11137 |

## Product Standards & Guidelines

| | |
|---|---|
| Standards: | ISO 6710:1995, EN14820 |
| Guidelines: | Clinical and Laboratory Standards Institute (CLSI; Formerly NCCLS): Tubes and Additives for Venous Blood Specimen Collection; Approved Guideline (6th Edition). Document GP39-A6. Wayne, PA, USA, 2010. |

## Compliance

| | |
|---|---|
| Directive: | European In Vitro Diagnostic Medical Devices Directive 98/79/EC |
| Classification: | Non Annex II / General IVD |

## Product Specification

| | |
|---|---|
| Tube material: | Polyethylene Terephthalate (PET) and Polypropylene (PP) |
| Tube size (mm): | 13 x 75 |
| Draw volume (mL): | 1.8 |
| Additives: | 0.2 mL of 0.109M Buffered Trisodium Citrate Solution (9NC) |
| Separator: | None |
| Closure material (cap): | Polymer (low density Polyethylene resin) |
| Closure material (stopper): | Halobutyl Elastomer |
| Closure colour: | Translucent Blue |
| Product Storage: | Do not expose to direct sunlight<br>Store product between 4° and 25°C |
| Label type: | Paper |
| Shelf-life: | 6 months |
| Global medical device nomenclature (GMDN): | 42585 |
| Material Safety Data Sheet (MSDS): | VS8020009 |
| Fill line indicator: | Yes |



**Materials**

| | |
|---|---|
| Latex (NRL): | No |
| Dry Natural Rubber (DNR): | No |
| Phthalates: | No |
| Material of animal origin: | No |

## Packaging Specifications

| | | | |
|---|---|---|---|
| 100 unit pack weight (kg): | 0.88 | 100 unit packaging material: | Expanded Polystyrene (EPS) / Polyolefin film |
| 100 unit pack volume ($m^3$): | 0.002380 | 100 unit packaging weight (kg): | 0.02 |
| 100 unit pack dimensions LxHxW (mm): | 180 x 87 x 152 | 100 unit packaging volume ($m^3$): | 0.000405 |
| 1000 unit pack weight (kg): | 8.83 | 1000 unit packaging material: | Cardboard |
| 1000 unit pack volume ($m^3$): | 0.027374 | 1000 unit packaging weight (kg): | 0.298 |
| 1000 unit pack dimensions LxHxW (mm): | 436 x 327 x 192 | 1000 unit packaging volume ($m^3$): | 0.027374 |

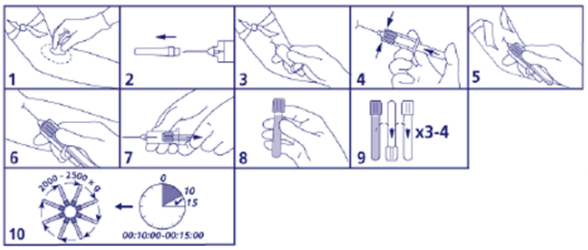
Product Catalogue Number: **363047**

## Labelling Information

All labelling complies with the requirements of the European In Vitro Diagnostic Medical Devices Directive 98/79/EC and includes the CE marking.

| | Unit Pack | Shelf Pack | Case Pack |
|---|---|---|---|
| Company name | • | • | • |
| Manufacturer address | • | • | • |
| Product Catalogue Number (PCN) | • | • | • |
| Sterile symbol showing method of sterilisation | • | • | • |
| Colour Coding | • | • | • |
| CE marking | • | • | • |
| Single use symbols | • | • | • |
| Lot number | • | • | • |
| Expiry date | • | • | • |
| Instructions for Use (pictorials) | | • | |
| Draw Volume | • | • | • |
| Storage instructions | | • | • |
| Quantity in package | | • | • |
| Primary barcode (GS1-128) product identification | | • | • |
| Secondary barcode (GS1-128) quantity, expiry, lot number | | | • |
| Product name & short description | • | • | • |

## Instructions For Use




## Sample Storage & Stability

For Platelet Poor Plasma (PPP) after centrifugation and separation from the sedimented cells:[1,2]
< 14 days at –20°C
< 6 months at –70°C
Stability depends on the analyte (see specific analyte).[2,3]

## Further Reading


1. Guder WG, Narayanan S, Wisser H and Zawta B. Samples: From the Patient to the Laboratory: the Impact of Preanalytical Variables on the Quality of Laboratory Results (4th Edition). Darmstadt, Germany: Wiley-VCH; 2009.
2. Kratz A, Stanganelli N and Van Cott EM. "A Comparison of Glass and Plastic Blood Collection Tubes for Routine and Specialized Coagulation Assays: A Comprehensive Study". Arch Pathol Lab Med. 2005; 130(1): 39-44.
3. Tripodi A, Chantarangkul V, Bressi C and Mannucci PM. "How to Evaluate the Influence of Blood Collection Systems on the International Sensitivity Index. Protocol Applied to Two New Evacuated Tubes and Eight Coagulometer/Thromboplastin Combinations". Thromb Res. 2003; 108: 85-95.
4. Smith JM, Bowyer A.E, Cooper PC, Pastorelli D, Makris M and Kitchen SA. "Comparative Study of New Generation Blood Sampling Tubes for Thrombophilia Investigations". Thromb and Haemost Suppl. July 2003.
5. Flanders M, Crist R and Rodgers G. "A Comparison of Blood Collection in Glass Versus Plastic Vacutainers on Results of Esoteric Coagulation Assays". Lab Med. October 2003; 34(10): 732-735.
6. Bowyer A.E, Kitchen S, Pastorelli D and Makris M. "The Effect of Two Novel Plastic Citrate Tubes (BD Vacutainer® Plus): Results in Normal Subjects and Subjects Undergoing Unfractionated Heparin Therapy". J Thromb Haemost Suppl. July 2003.
7. Polack B, Schved J-F and Boneu B. "Preanalytical Recommendations of the 'Groupe d'Etude sur l'Hémostase et la Thrombose' (GEHT) for Venous Blood Testing in Hemostasis Laboratories". Haemostasis. 2001; 31: 61-68.
8. Adcock DM, Kressin DC and Marler RA. "Effects of 3.2% vs. 3.8% Sodium Citrate Concentration on Routine Coagulation Testing". Am J Clin Path. Jan 1997; 107(1): 105-110.
9. Duncan EM, Casey CR, Duncan BM and Lloyd JV. "Effect of Concentration of Trisodium Citrate Anticoagulant of the International Normalized Ratio and the International Sensitivity Index of Thromboplastin". J Thromb Haemost. 1994; 72(1): 84-88.
10. BD White Paper VS7120: "Evaluation of BD Vacutainer® 0.109M 1.8 mL PLUS Plastic Sodium Citrate Tubes Using the Diagnostica Stago STA® Hemostasis Analyzer". 2003.
11. BD White Paper VS7119: "Evaluation of BD Vacutainer® 0.109M 2.7 Ml PLUS Plastic Sodium Citrate Tubes Using the Diagnostica Stago STA® Hemostasis Analyzer". 2003.


## References


1. Clinical and Laboratory Standards Institute (CLSI; formerly NCCLS): Collection, Transport and Processing of Blood Specimens for Testing Plasma based Coagulation Assays and Molecular Hemostasis Assays; Approved Guideline (5th Edition). Document H21-A5. Wayne, PA, USA, 2008.
2. Guder WG, et al. Recommendations of the Working Group on Preanalytical Quality of the German Society for Clinical Chemistry and Laboratory Medicine for Quality of Diagnostic Samples (3rd Edition). Darmstadt, Germany: GIT, 2010.
3. Tietz NW. Clinical Guide to Laboratory Tests (4th Edition). W.B. Saunders, USA: 2006.


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