BD Microtainer®

Blood Collection Chemistry Tubes

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REF 365964 REF 365966 REF 365968 REF 365979 REF 365986 REF 365988 REF 365993

INTENDED USE

BD Microtainer® Blood Collection Tubes are non-sterile, single use in vitro diagnostic medical devices. They are intended to be used by trained healthcare professionals for the collection, containment and transport of human capillary blood specimens and the subsequent separation of serum or plasma by centrifugation for in vitro diagnostic testing.

BD Microtainer® SST™, BD Microtainer® PST™, BD Microtainer® Serum, and BD Microtainer® Lithium Heparin Blood Collection Tubes are used for testing in chemistry or for other testing where a serum or plasma sample is required as determined by the laboratory.

BD Microtainer® Fluoride Blood Collection Tubes are used for glucose determinations or for other tests where a plasma or whole blood sample is required as determined by the laboratory.

PRODUCT DESCRIPTION

BD Microtainer® Blood Collection Tubes consist of a plastic reservoir and a color-coded BD Microgard™ Closure. The tubes contain various additives depending upon the desired specimen and analytic test method requirements. Refer to Table A for product configurations. Markings on the reservoir show the fill levels. The upper edge of the reservoir serves as a collector.

Serum Tubes

BD Microtainer® Z (No Additive) Blood Collection Tubes and BD Microtainer® SST™ Blood Collection Tubes have a silicone coating on the tube walls to reduce adherence of red cells.

BD Microtainer® SST™ Blood Collection Tubes are coated with micronized silica particles to accelerate clotting. This coating may have a white to slightly cloudy appearance. A separator gel is present at the tube bottom. The density of this material causes it to move upward during centrifugation to the serum-clot interface, where it forms a barrier separating serum from fibrin and cells.

Plasma Tubes

BD Microtainer® Lithium Heparin Blood Collection Tubes and BD Microtainer® PST™ Blood Collection Tubes contain a Lithium Heparin (LH) additive to anticoagulate the specified volume of capillary blood.

BD Microtainer® PST™ Blood Collection Tubes have a separator gel at the tube bottom. The density of this material causes it to move upward during centrifugation to the plasma-cell interface, where it forms a barrier separating plasma from cells.

BD Microtainer® Fluoride Blood Collection Tubes contain Sodium Fluoride/ Disodium EDTA (FE) additive. The Na_2EDTA anticoagulates the specimen while the Sodium Fluoride acts as a glycolytic inhibitor.

Amber Tubes

BD Microtainer® SST™ and PST™ Amber Blood Collection Tubes significantly reduce light transmission and are used when protection is required for light sensitve analytes.

Tube Extender (Optional)

The tube can be used with the optional BD Microtainer® Tube Extender (catalog number 368933). The extender fits into the bottom of the tube and increases the tube length to about 75 millimeters (mm). With this extender, the tube fits in a standard 13 x 75 mm test tube rack. The extender also provides a larger area for specimen labeling.

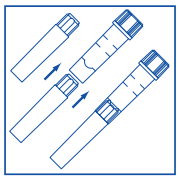


TABLE A

Product	Tube Type	Fill Volume (µL)	Additive	BD Microgard™ Closure Color
Serum Tubes				
Z (No Additive)	Clear Reservoir	250–500	None	Red
BD SST™	Clear Reservoir	400–600	Clot Activator and Gel Barrier	Gold
	Amber Reservoir			
Plasma Tubes				
Lithium Heparin	Clear Reservoir	200–400	Lithium Heparin (LH)	Green
BD PST™	Clear Reservoir	400–600	Lithium Heparin (LH) and Gel Barrier	Light Green
	Amber Reservoir			
Fluoride	Clear Reservoir		Sodium Fluoride/ Disodium EDTA (FE)	Gray

PERFORMANCE CHARACTERISTICS

1. BD Microtainer® Blood Collection Tubes are designed with:
   - an integrated collector to facilitate blood flow into the tube;
   - markings to indicate fill volumes as listed in Table A;
   - a closure that fits snugly over the upper edge of the tube to reduce the potential for sample contact when the cap is removed.
2. BD Microtainer® Fluoride Blood Collection Tubes inhibit glycolysis for up to 24 hours at room temperature.
3. The amber tube reservoir significantly reduces light transmission and is used when protection is required for light sensitive analytes.

LIMITATIONS OF THE SYSTEM

1. Chemistry analyte concentrations/activities in serum or plasma obtained from capillary specimens may differ from analyte concentrations/activities in serum or plasma obtained from venous specimens.[1] The laboratory should assess whether these differences may be clinically relevant when switching between capillary and venous blood specimens.
2. Blood fill quantity must be within the specified range to ensure proper blood to additive ratio for adequate mixing and accurate test results.
3. For tubes subjected to centrifugation to generate serum or plasma for testing, standard processing conditions do not necessarily completely sediment all cells. Cell-based metabolism, as well as natural degradation ex vivo, can continue to affect plasma analyte concentrations/activities after centrifugation.
4. The stability of analytes should be evaluated for the storage containers and conditions of each laboratory.

PRECAUTIONS

1. Do not use if foreign matter is present or if tube is damaged.
2. Separation of serum or plasma from the cells should take place within 2 hours of collection to prevent erroneous test results, unless conclusive evidence indicates that longer contact times do not contribute to result error.
3. Follow your facility's procedures if clots or other visible obstructions are present in the sample as this could lead to the inability to test the sample.
4. Whenever changing any manufacturer's blood collection tube type, size, handling, processing or storage condition for a particular laboratory assay, the laboratory personnel should review the tube manufacturer's

data and their own data to establish/verify the reference range for a specific instrument/reagent system. Based on such information, the laboratory can then decide if changes are appropriate.

CAUTION

1. Practice Universal Precautions. Use gloves, gowns, eye protection, other personal protective equipment, and engineering controls to protect from blood splatter, blood leakage, and potential exposure to bloodborne pathogens.
2. Handle all biologic samples and blood collection “sharps” (lancets) according to the policies and procedures of your facility. Obtain appropriate medical attention in the event of any exposure to biologic samples (for example, through a puncture injury), since they may transmit viral hepatitis, HIV (AIDS), or other infectious diseases. Utilize any built-in used "sharps" protector, if the blood collection device provides one. The policies and procedures of your facility may differ and must always be followed.
3. Discard all blood collection “sharps” in biohazard containers approved for their disposal.
4. Overfilling or underfilling of tubes will result in an incorrect blood-to-additive ratio and may lead to incorrect analytic results or poor product performance.
5. Endotoxin not controlled. Blood and blood components collected and processed in the tube are not intended for infusion or introduction into the human body.
6. 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.

Note: EU Only: Users shall report any serious incident related to the device to the Manufacturer and National Competent Authority.
Outside EU: Contact your local BD representative for any incident or inquiry related to this device.

DANGER

Sodium fluoride (NaF), CAS Number: 7681-49-4

REF 365993

H301 Toxic if swallowed.
H315 Causes skin irritation.
H319 Causes serious eye irritation.

P264 Wash thoroughly after handling. **P280** Wear protective gloves/ protective clothing/eye protection/face protection. **P301+P310** IF SWALLOWED: Immediately call a POISON CENTER/doctor. **P330** Rinse mouth. **P332+P313** If skin irritation occurs: Get medical advice/attention. **P362+P364** Take off contaminated clothing and wash it before reuse. **P337+P313** If eye irritation persists: Get medical advice/attention. **P501** Dispose of contents/container to an appropriate treatment and disposal facility in accordance with applicable laws and regulations, and product characteristics at time of disposal.

STORAGE

Store tubes below 25 °C (77 °F). Do not use tubes after their expiration date. If expiration date on the tube is illegible, refer to polybag, case label or barcode. If expiration date cannot be determined, do not use the tube.

SPECIMEN COLLECTION AND HANDLING

READ ENTIRE INSTRUCTIONS FOR USE BEFORE PERFORMING SKIN PUNCTURE.

Required Materials Provided for Specimen Collection
BD Microtainer® Blood Collection Tubes.

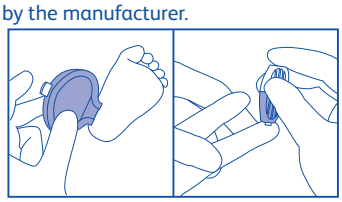
Required Materials Not Provided for Specimen Collection
1. Personal protective equipment as necessary for protection from exposure to bloodborne pathogens.
2. Lancet appropriate for site and volume of blood required.
3. Cleansing wipe.
4. Gauze and an approved biohazard container.

Optional Materials Not Provided for Specimen Collection
1. Warming device.
2. Adhesive bandage. Avoid use of bandage with patients likely to place fingers or feet in their mouths, as ingestion/aspiration may occur.

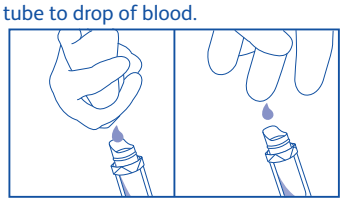
INSTRUCTIONS FOR USE

WEAR GLOVES DURING CAPILLARY COLLECTION AND WHEN HANDLING BLOOD COLLECTION TUBES TO MINIMIZE EXPOSURE HAZARD

1. Order of Draw: The following order of draw is recommended for microcollection tubes when multiple specimens are drawn for medical laboratory testing during a single capillary puncture.
   1. Capillary blood gas
   2. EDTA tubes
   3. Other additive tubes
   4. Non-additive tubes
   5. Filter paper for Dried Blood Spots (DBS) collection
2. Select puncture site, warm as appropriate.
3. Cleanse site and allow to air-dry. Do not dry by wiping, as disinfection occurs during air-drying.
4. Remove closure from the tube and place the closure on a convenient surface.
5. Puncture skin with the appropriate lancet, following instructions supplied by the manufacturer.

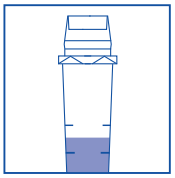


6. Dispose of used lancet in an approved biohazard sharps container.
7. Wipe away first drop of blood with gauze. Hold BD Microtainer® Tube at an angle from surface of puncture site. Touch integrated collector end of tube to drop of blood.

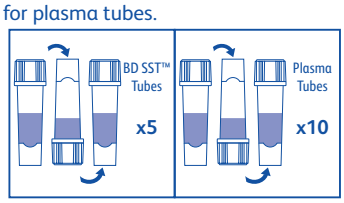


Avoid scraping skin surface to collect the blood sample. After collecting two or three drops, blood will freely flow down the interior tube wall. **CAUTION:** “Milking” of skin puncture site may cause hemolysis and adversely affect test result accuracy.

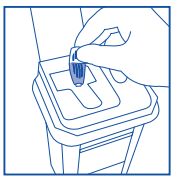
8. Fill the tube to between the fill marks to achieve proper blood to additive ratio.



9. Replace closure by twisting and pushing cap downward until a snap is heard.
10. Immediately after collection mix the sample by inverting filled tubes 5 times for BD Microtainer® SST™ Blood Collection Tubes and 8–10 times for plasma tubes.



11. Reminder: dispose of used lancet into an approved biohazard sharps container. Dispose of any contaminated materials into appropriate container.



PROCEDURE FOR SERUM/PLASMA SEPARATION

1. Serum separation: allow blood to clot for a minimum of 30 minutes.
2. Place sample in centrifuge or centrifuge adapter as necessary, taking care to balance the system.

3. Centrifuge as follows:
   RCF is related to centrifuge speed setting (rpm) using the following equation:

$$rpm = \sqrt{\frac{RCF \times 10^5}{1.12 \times r}}$$

Where "r", expressed in cm, is the radial distance from the center of the centrifuge head to the bottom of the tube.

Recommended Centrifuge RCF and Time		
Product	**RCF**	**Time**
Gel Tubes	6000 – 15000 g	90 seconds
Non-Gel Tubes	Minimum 2000 g	3 minutes

RCF = Relative Centrifuge Force, g's

Note: Use of alternate centrifugation conditions may also provide acceptable performance; this should be evaluated and validated by the laboratory.

4. Remove tube from centrifuge. Serum/Plasma is ready for use and may be pipetted directly into analyzer cup.

CENTRIFUGATION CAUTION

- See centrifuge instruction manual for disinfection instructions.
- Always use appropriate carriers or inserts. Centrifuge carriers and inserts should be of the size specific to the tubes used.
- Use of tubes with cracks or chips or excessive centrifugation speed may cause tube breakage, with release of sample, droplets, and an aerosol into the centrifuge bowl. Release of these potentially hazardous materials can be avoided by using specially designed sealed containers in which tubes are held during centrifugation.
- Ensure that tubes are properly seated in the centrifuge carrier. Incomplete seating could result in extension of the tube above the carrier. Tubes extending above the carrier could catch on centrifuge head, resulting in breakage.
- Match tubes to similar tubes (fill volume, tube type, tube size).
- Always allow centrifuge to come to a complete stop before attempting to remove tubes.
- When centrifuge head has stopped, open the lid and examine for possible broken tubes.
- If breakage is indicated, use mechanical device such as forceps or hemostat to remove tubes.

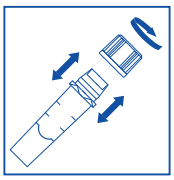
Barrier Information of the Separator Gel

The flow properties of the barrier material are temperature related. Flow may be impeded if chilled before or during centrifugation. To optimize flow and prevent heating during centrifugation, set refrigerated centrifuges to 25 °C (77 °F).

Tubes should not be re-centrifuged once barrier has formed.

Instructions for Removal and Reinsertion of BD Microgard™ Closure

To remove the closure, grasp the ribbed edge and twist while pulling it off. To reinsert, twist the closure and push cap downward onto the reservoir until a snap is heard.



ANALYTIC EQUIVALENCY

Evaluations of BD Microtainer® Blood Collection Tubes have been performed for an array of analytes over a variety of test methods and time periods. BD Life Sciences - Integrated Diagnostic Solutions is available to answer questions regarding these studies. Please contact them to obtain references and technical reports on these evaluations and any other information regarding the use of BD Microtainer® Blood Collection Tubes with your instrument/reagent system.

REFERENCES

1. CLSI Document GP42-ED7:2020. Collection of Capillary Blood Specimens; approved standard, 7th edition. Wayne, PA: Clinical and Laboratory Standards Institute; 2020.
2. CLSI Document GP39-A6:2010. Tubes and Additives for Venous and Capillary Blood Specimen Collection; approved standard, 6th edition. Wayne, PA: Clinical and Laboratory Standards Institute; 2010.

TECHNICAL SERVICES

Technical Service and Support: Contact your local BD representative or bd.com.

Change History

Revision	Date	Change Summary
01	2022-02	Initial IVDR Release

SYMBOLS GLOSSARY [L006715(06) 2021-08]

Some symbols listed below may not apply to this product.

US Customers only: For symbol glossary, refer to **bd.com/symbols-glossary**

Symbol	Meaning
	Manufacturer
EC REP	Authorized representative in the European Community
CH REP	Authorised representative in Switzerland
	Date of manufacture
	Use-by date
LOT	Batch code
REF	Catalogue number
SN	Serial number
STERILE	Sterile
STERILE A	Sterilized using aseptic processing techniques
STERILE EO	Sterilized using ethylene oxide
STERILE R	Sterilized using irradiation
STERILE	Sterilized using steam or dry heat
	Do not resterilize
NON STERILE	Non-sterile
	Do not use if package is damaged and consult *instructions for use*
STERILE	Sterile fluid path
STERILE EO	Sterile fluid path (ethylene oxide)
STERILE R	Sterile fluid path (irradiation)
	Fragile, handle with care
	Keep away from sunlight
	Keep dry
	Lower limit of temperature
	Upper limit of temperature
	Temperature limit
%	Humidity limitation
	Biological risks
	Do not re-use
	Consult *instructions for use* or consult electronic *instructions for use*
	Caution
LATEX	Contains or presence of natural rubber latex
IVD	In vitro diagnostic medical device
CONTROL -	Negative control
CONTROL +	Positive control
Σ	Contains sufficient for <*n*> tests
	For IVD performance evaluation only
	Non-pyrogenic
#	Patient number
	This way up
	Do not stack
	Single sterile barrier system

Symbol	Meaning
PHT DEHP BBP	Contains or presence of phthalate: combination of bis(2-ethylhexyl) phthalate (DEHP) and benzyl butyl phthalate (BBP)
	Collect separately Indicates separate collection for waste of electrical and electronic equipment required.
CE	CE marking; Signifies European technical conformity
	Device for near-patient testing
	Device for self-testing
Rx Only	This only applies to US: "Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner."
CC	Country of manufacture "CC" shall be replaced by either the two letter or the three letter country code.
	Collection time
	Cut
	Peel here
12	Collection date
	Keep away from light
H_2	Hydrogen gas is generated
	Perforation
	Start panel sequence number
	End panel sequence number
	Internal sequence number
MD	Medical device
	Contains hazardous substances
	Ukrainian conformity mark
FC	Meets FCC requirements per 21 CFR Part 15
c UL us	UL product certification for US and Canada
UDI	Unique device identifier

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