BD Microtainer® MAP

en

Microtube for Automated Process with K_2EDTA

IVD 4 °C 40 °C NON STERILE eifu.bd.com

REF 363705

INTENDED USE

BD Microtainer® Microtube for Automated Process (MAP) Blood Collection Tubes with K_2EDTA are non-sterile, single use, in vitro diagnostic medical devices. They are intended to be used by trained healthcare professionals for the collection, containment, transport, and storage of human capillary blood specimens for in vitro diagnostic testing.

BD Microtainer® MAP Blood Collection Tubes with K_2EDTA are used for testing in hematology and for lead determinations, or for other testing where an EDTA whole blood specimen is required as determined by the laboratory.

PRODUCT DESCRIPTION

BD Microtainer® MAP Blood Collection Tubes consist of a specially designed 13x75 mm plastic tube with a penetrable color-coded cap for automated processes. The interior surface of the reservoir is spray-coated with K_2EDTA additive. The K_2EDTA additive provides an anticoagulated specimen when used in accordance with the instructions for use. Refer to Table A for product configuration. Markings on the reservoir show the fill levels. The upper edge of the reservoir serves as a collector.

Table A

Size (mm)	Fill Volume (µL)	Additive	Type of Closure	Closure Color
13 x 75	250–500	K_2EDTA (K2E)	MAP Closure (cap is piercable)	Lavender

BD Microtainer® MAP Blood Collection Tubes contain less than 1.0 ng lead per tube when evaluated using Inductively Coupled Plasma Mass Spectroscopy.

PERFORMANCE CHARACTERISTICS

1. BD Microtainer® MAP Blood Collection Tubes are designed with:
   - an integrated collector to facilitate blood flow into the tube;
   - markings to indicate fill volumes of 250 µL, 375 µL and 500 µL;
   - a penetrable closure for compatibility with automated processes which minimizes potential exposure to bloodborne pathogens;
   - standardized dimensions for compatibility with commonly used laboratory instrumentation.
2. Blood collected in the BD Microtainer® MAP Blood Collection Tubes with K_2EDTA is stable at room temperature for up to 12 hours and will provide accurate and clinically useful test results for hematology parameters.

LIMITATIONS OF THE SYSTEM

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. Alcohol contact with transparent tube labels may render label text illegible.
3. Some patients have shown sensitivity to EDTA, resulting in significant and irreversible platelet clumping. This clumping may also artificially elevate white blood cell counts.
4. 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.
5. 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.

WARNING

Dipotassium EDTA Dihydrate, CAS Number: 25102-12-9

H332 Harmful if inhaled.

P261 Avoid breathing dust/fume/gas/mist/vapors/spray. **P271** Use only outdoors or in a well-ventilated area. **P304+P340** IF INHALED: Remove person to fresh air and keep comfortable for breathing. **P312** Call a POISON CENTER/doctor if you feel unwell.

STORAGE

Store tubes at 4–40 °C (39–104 °F). Do not use tubes after their expiration date. If expiration date on the unit label is illegible, refer to shelf pack, 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® Microtube for Automated Process with K_2EDTA.

Document: VDP40476
Valid From: 12-Apr-2022 To: 31-Dec-9999
Print Date: 18-May-2022 15:48:09 GMT Daylight Time
Doc Type: ZMG
Doc Part: EN
Usage: Production Usage
Status: Released EFFECTIVE
Revision: 01
Version: A
Change #: 500000269371
Classification: Confidential

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 (lead-free if lead testing is performed).
4. Soap and water (for lead testing).
5. Gauze and an approved biohazard container.

Optional Materials Not Provided for Specimen Collection

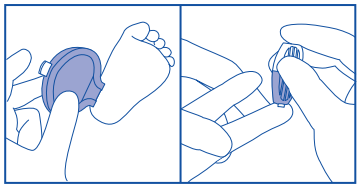
1. Warming device.
2. Adhesive bandage. Avoid use of bandage with patients likely to place fingers or feet in their mouths, as ingestion/aspiration may occur.

INSTRUCTIONS FOR USE

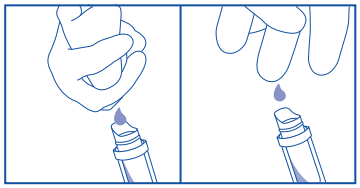
WEAR GLOVES DURING CAPILLARY COLLECTION AND WHEN HANDLING BLOOD COLLECTION TUBES TO MINIMIZE EXPOSURE HAZARD

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 Spot (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. For lead testing, wash area with soap and water and dry thoroughly to minimize surface contamination of skin by environmental lead. Cleanse with lead-free cleansing wipe. Institutional protocols for collection of specimens for blood lead determination should be followed.
5. Twist to remove cap from BD Microtainer® MAP Tube and place on a convenient lead-free surface.

6. Puncture skin with the appropriate lancet, following instructions supplied by the manufacturer.



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

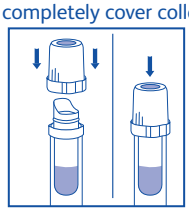


Avoid scraping skin surface to collect blood sample. After collecting two or three drops, blood will freely flow down the interior tube wall. CAUTION: “Milking” of skin puncture site may cause hemolysis and adversely affect test result accuracy.

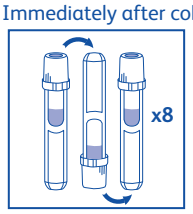
9. Fill BD Microtainer® MAP Tubes between 250 µL and 500 µL to achieve proper blood-to-additive ratio.

    NOTE: A minimum blood volume of 375 µL is required for automated processing on most hematology systems. Refer to your instrument manufacturer’s manual for minimum volume requirements.

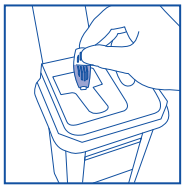
10. Replace cap onto BD Microtainer® MAP Tube. Push cap down to completely cover collar for a secure snap fit.



11. Immediately after collection, gently invert 8 times.



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



13. The specimen should be mixed thoroughly just before analysis in accordance with instrument manufacturers’ instructions.

    NOTE: It is not necessary to remove the penetrable cap from the tube for automated processing.

ANALYTIC EQUIVALENCY

Evaluations of BD Microtainer® MAP Tubes have been performed for an array of parameters 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® MAP 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.
3. CLSI Document C38-A:1997. Control of Preanalytical Variation in Trace Element Determinations; approved guideline, 1st edition. Wayne, PA: Clinical and Laboratory Standards Institute; 1997.

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

Document: VDP40476
Valid From: 12-Apr-2022 To: 31-Dec-9999
Print Date: 18-May-2022 15:48:09 GMT Daylight Time
Doc Type: ZMG
Doc Part: EN
Usage: Production Usage
Status: Released EFFECTIVE
Revision: 01
Version: A
Change #: 500000269371
Classification: Confidential

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

Becton, Dickinson and Company
1 Becton Drive, Franklin Lakes, New Jersey 07417-1885 USA

EC REP Becton Dickinson Ireland Ltd.
Donore Road, Drogheda, Co. Louth, A92 YW26, Ireland

CH REP BD Switzerland Sàrl
Terre Bonne Park – A4, Route de Crassier 17, 1262 Eysins, Switzerland

Australian and New Zealand Sponsors:
Becton Dickinson Pty Ltd., 66 Waterloo Road
Macquarie Park NSW 2113, Australia

Becton Dickinson Limited, 14B George Bourke Drive
Mt. Wellington Auckland 1060, New Zealand

2022-02
VDP40476(01)

Document: VDP40476
Valid From: 12-Apr-2022 To: 31-Dec-9999
Print Date: 18-May-2022 15:48:09 GMT Daylight Time

Doc Type: ZMG
Doc Part: EN
Usage: Production Usage

Status: Released EFFECTIVE
Revision: 01
Version: A

Change #: 500000269371
Classification: Confidential