

FACT SHEET FOR HEALTHCARE PROVIDERS AND AUTHORIZED LABORATORIES

Becton, Dickinson and Company

BD Vacutainer Plus Citrate Plasma Tubes (UK Manufacturing Site)

Sodium Citrate
Blood Collection
Tubes

July 22, 2021

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the BD Vacutainer Plus Citrate Plasma Tubes (UK Manufacturing Site).

What do I need to know about use of the BD Vacutainer Plus Citrate Plasma Tubes (UK Manufacturing Site) ?

The BD Vacutainer Plus Citrate Plasma Tubes (UK Manufacturing Site) is a blood collection tube intended for emergency use in healthcare settings to collect, transport, and store blood specimens for coagulation testing to aid in the identification and treatment of coagulopathy in patients, including patients with known or suspected COVID-19. Patients with COVID-19 have been observed to develop COVID-19 associated coagulopathy, including hypercoagulability, an abnormally increased risk for blood clotting.

Testing using these blood collection tubes is limited to laboratories that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, and meet requirements to perform moderate and high complexity tests.

The BD Vacutainer Plus Citrate Plasma Tubes (UK Manufacturing Site) are sterile, plastic, evacuated tubes containing 0.109M (3.2%) buffered sodium citrate as an anticoagulant intended to prevent whole blood from clotting prior to analysis. The specimen is centrifuged and the plasma portion is analyzed for coagulation parameters to detect clotting time disorders.

When collecting and handling specimens from individuals suspected of being infected with COVID-19, in addition to following universal precautions, appropriate personal protective equipment must be used as outlined in the CDC guidelines (see links provided in “Where can I go for updates and more information?” section).

What factors impact quality or performance of these products?

Incorrect amount of vacuum or sodium citrate will change the final sodium citrate concentrations and lead to erroneous coagulation test results. Other factors that may influence coagulation test results include

magnesium contamination from the rubber stoppers. In patients with COVID-19, false coagulation test results for tests such as the D-dimer, fibrinogen and viscoelastic tests, can impact the diagnosis of COVID-19 associated coagulopathy and the treatment of thromboembolic events. Therefore, the quality and the performance of the citrate blood collection tubes are important for the safety of COVID-19 patients.

What do I need to know about performing testing using these products?

Authorized laboratories must use the product as outlined in the authorized labeling, including the BD Vacutainer Plus Citrate Plasma Tubes (UK Manufacturing Site) Instructions for Use.

Authorized laboratories are required to collect information on the performance of this product and report to FDA (via email: CDRH-EUARreporting@fda.hhs.gov) and the manufacturer (via email: productcomplaints@bd.com or phone: 1-844-8-BD-LIFE (844-823-5433)) any suspected occurrence of erroneous coagulation test results that can be attributed to use of the BD Vacutainer Plus Citrate Plasma Tubes (UK Manufacturing Site) of which they become aware.

What are the approved available alternatives?

There are significant interruptions in the supply of legally marketed sodium citrate blood specimen collection (light blue top) tubes during the COVID-19 public health emergency due to an increased hospitalization rate of COVID-19 patients who are being tested for coagulopathy. While there are several FDA-cleared sodium citrate blood collection tubes, FDA has identified that there are no approved, available, alternative devices.

Is the BD Vacutainer Plus Citrate Plasma Tubes (UK Manufacturing Site) FDA-approved or cleared?

No. The BD Vacutainer Plus Citrate Plasma Tubes (UK Manufacturing Site) is not FDA-approved or FDA-cleared. The FDA has authorized this use of the BD Vacutainer Plus Citrate Plasma Tubes (UK Manufacturing Site) under an Emergency Use Authorization (EUA), described below, for use by laboratories certified under CLIA to perform moderate and high complexity tests.

Report Adverse events, including problems with test performance or results, to MedWatch by submitting the online FDA Form 3500 (<https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home>) or by calling **1-800-FDA-1088**

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How can I distinguish the EUA authorized BD Vacutainer Plus Citrate Plasma Tubes (UK Manufacturing Site) from the FDA-cleared version of this product?

- The vial label (label directly on the collection tube) on the EUA-authorized BD Vacutainer Plus Citrate Plasma Tubes (UK Manufacturing Site) indicates “CE” on the EUA authorized tubes, but not on the labels of the FDA-cleared version of the tubes.
- The manufacturing location on the EUA authorized tubes (UK Manufacturing Site) and carton labels indicates “Belliver Industrial Estate, Plymouth, PL6 7BP, UK,” or “BD-Plymouth, PL6 7BP, UK,” while the FDA-cleared version of the tubes has a manufacturing location of “1 Becton Drive, Franklin Lakes, NJ 07417 USA.”
- The vial label (label directly on the collection tube) on the EUA authorized tubes (UK Manufacturing Site) lacks Unique Device Identification (UDI) System information, while the FDA-cleared version of the tubes provides UDI System information on the tube label.
- The EUA-authorized tubes (UK Manufacturing Site) are under the following product reference numbers, which can be found on the tube and carton labels: REF 363047 for 1.8mL tube and REF 363048 for 2.7mL tube.
- The EUA-authorized tube (UK Manufacturing Site) carton label DOES NOT indicate “Rx only” whereas the FDA-cleared tube carton label does include this symbol.
- In the Instructions For Use (IFU) for the EUA-authorized tubes (UK Manufacturing Site), in the table “Centrifugation RCF and Time,” the “Citrate Plus Tubes” RCF is 2000-2500g for 10-15 minutes. The FDA-cleared “Citrate Tubes” RCF is 1500g for 15 minutes.

How can I report adverse events including suspected occurrences of erroneous coagulation test results that can be attributed to use of the BD Vacutainer Plus Citrate Plasma Tubes (UK Manufacturing Site)?

Report adverse events to MedWatch by submitting the online FDA Form 3500

(<https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home>) or by calling 1-800-FDA-1088.

What is an EUA?

The United States (U.S.) FDA has made this test available under an emergency access mechanism called an EUA. The EUA is supported by the Secretary of Health and Human Services’ (HHS’s) declaration that circumstances exist to justify the emergency use of medical devices for the COVID-19 outbreak. A device made available under an EUA has not undergone the same level of review as an FDA approved or cleared device. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives, and based on the totality of scientific evidence available, it is reasonable to believe that the benefits outweigh the potential risks of this device in the setting of COVID-19. The EUA for this test is in effect for the duration of the COVID-19 declaration justifying emergency use of medical devices, unless the declaration is terminated or the authorization is revoked sooner, after which the device may no longer be used.

An FDA-cleared sodium citrate blood collection tube should be used instead of a sodium citrate blood collection tube under EUA, when available.

EUAs issued by FDA can be found at:

<https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#covid19euas>.

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Where can I go for updates and more information?

CDC Webpages:

General: <https://www.cdc.gov/coronavirus/2019-cov/index.html>

Laboratory Biosafety:

<https://www.cdc.gov/coronavirus/2019-nCoV/lab-biosafety-guidelines.html>

Infection Control:

<https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control.html>

FDA webpages:

General: <https://www.fda.gov/novelcoronavirus>

EUAs: (includes certain authorized labeling)

<https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations>

Citrate Tube Shortage:

<https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/sodium-citrate-blood-specimen-collection-light-blue-top-tubes-frequently-asked-questions>

Becton, Dickinson and Company:

1 Becton Drive
Franklin Lakes, NJ 07417

Phone: 1-844-8-BD-LIFE (844-823-5433)

Website: <https://www.bd.com/en-us/support/alerts-and-notice>

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