U.S. FOOD & DRUG ADMINISTRATION

July 22, 2021

Matthew Trachtenberg
Becton, Dickinson and Company
Associate Director, Regulatory Affairs
1 Becton Drive
Franklin Lakes, NJ 07417

Device:	BD Vacutainer Plus Citrate Plasma Tubes (UK Manufacturing Site)[1]
EUA Number:	EUA210465
Company:	Becton, Dickinson and Company
Indication:	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.[2] Testing using these blood collection tubes is limited to authorized laboratories.
Authorized Laboratories:	Laboratories 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.

Dear Mr. Trachtenberg:

This letter is in response to your[3] request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of your product,[4] pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3).

---

[1] FDA is using the term "UK Manufacturing Site" to differentiate the authorized version from the FDA-cleared version of these products that are also manufactured by Becton, Dickinson and Company.
[2] In the circumstances of this public health emergency, it would not be feasible to require healthcare providers to seek to limit use of BD Vacutainer Plus Citrate Plasma Tubes (UK Manufacturing Site) to patients with suspected or confirmed COVID-19; therefore, this authorization does not limit use to such patients.
[3] For ease of reference, this letter will use the term "you" and related terms or "BD" to refer to Becton, Dickinson and Company.
[4] For ease of reference, this letter will use the term "your product" to refer to BD Vacutainer Plus Citrate Plasma Tubes (UK Manufacturing Site) used for the indication identified above.

On February 4, 2020, pursuant to section 564(b)(1)(C) of the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19.[5] Pursuant to section 564 of the Act, and on the basis of such determination, the Secretary of HHS declared on March 24, 2020, that circumstances exist justifying the authorization of emergency use of medical devices during the COVID-19 outbreak, subject to the terms of any authorization issued under section 564(a) of the Act.[6]

There has been an increased demand for blood collection tubes during the COVID-19 public health emergency due to an increased hospitalization rate of patients who are being tested for coagulopathy. Patients with COVID-19 have been observed to develop COVID-19 associated coagulopathy, including hypercoagulability, an abnormally increased risk for blood clotting. Laboratory abnormalities commonly observed among hospitalized patients with COVID-19 associated coagulopathy include: increased D-dimer levels, increased fibrinogen levels, thrombocytopenia, and prolonged prothrombin time.[7] Due to the increase in demand of these products, among other issues with these products, there is a shortage of sodium citrate blood specimen collection tubes.[8] Increased availability of these devices will facilitate patient management by healthcare providers during the COVID-19 public health emergency.

FDA considered the totality of scientific information available in authorizing the emergency use of your product for the indication above. A summary of the performance information FDA relied upon is contained in the EUA Summary (identified below).

Having concluded that the criteria for issuance of this authorization under section 564(c) of the Act (21 U.S.C. § 360bbb-3(c)) are met, I am authorizing the emergency use of your product, described in the Scope of Authorization section of this letter (Section II)), subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of your product meets the criteria for issuance of an authorization under section 564(c) of the Act, because I have concluded that:

1. The SARS-CoV-2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected with this virus;

---

[5] U.S. Department of Health and Human Services, Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3. 85 FR 7316 (February 7, 2020).

[6] U.S. Department of Health and Human Services, Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3. 85 FR 17335 (March 27, 2020).

[7] https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-guidance-management-patients.html

[8] Sodium citrate blood collection tubes were added to FDA's device shortage list on June 6, 2021 (see https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/medical-device-shortages-during-covid-19-public-health-emergency#shortage).

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that your product may be effective in aiding in the identification and treatment of coagulopathy in patients, including patients with known or suspected COVID-19, by collecting, transporting, and storing blood specimens for coagulation testing, and that the known and potential benefits of your product when used for such use, outweigh the known and potential risks of your product; and

3. There is no adequate, approved, and available alternative to the emergency use of your product.[9, 10]

II. Scope of Authorization

I have concluded, pursuant to section 564(d)(1) of the Act, that the scope of this authorization is limited to the emergency use of your product 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.[11]

Testing using your product is limited to laboratories that are certified under CLIA, 42 U.S.C. § 263a, and meet requirements to perform moderate and high complexity tests.

Authorized Product Details

The BD Vacutainer Plus Citrate Plasma Tubes (UK Manufacturing Site) are sterile, plastic, evacuated tubes containing 0.109M 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.

The product insert (Manufacturer Instructions for use, entitled -"BD Vacutainer Evacuated Blood Collection System instructions for use", outer box label, shelf label, vial label, and the Fact Sheet for Healthcare Providers and Authorized Laboratories are collectively referred to as "authorized labeling." (Certain authorized labeling is available at http://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.htm.)

The above-described product, when made available with the authorized labeling as set forth in the Conditions of Authorization (Section IV), is authorized to be distributed to and used by authorized laboratories under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

I have concluded, pursuant to section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of your product, when used consist with the Scope of Authorization of this letter (Section II), outweigh the known and potential risks of your product for such use.

[9] No other criteria of issuance have been prescribed by regulation under section 564(c)(4) of the Act.
[10] Refer to footnote 8.
[11] Refer to footnote 2.

I have concluded, pursuant to section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that your product may be effective in aiding in the identification and treatment of coagulopathy in patients, including patients with known or suspected COVID-19, by collecting, transporting, and storing blood specimens for coagulation testing, when used consistently with the Scope of Authorization of this letter (Section II), pursuant to section 564(c)(2)(A) of the Act.

FDA has reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, and concludes that your product (as described in the Scope of Authorization of this letter (Section II)), meets the criteria set forth in section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of your product must be consistent with, and may not exceed, the terms of this letter, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section IV). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination described above and the Secretary of HHS's corresponding declaration under section 564(b)(1), your product is authorized for the indication above.

This EUA will cease to be effective when the HHS declaration that circumstances exist to justify the EUA is terminated under section 564(b)(2) of the Act or when the EUA is revoked under section 564(g) of the Act.

III. Waiver of Certain Requirements

I am waiving the following requirements for your product during the duration of this EUA:

- Current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of your product;
- Labeling requirements under 21 CFR 809.10 for in vitro diagnostic products; and
- Unique device identification (UDI) requirements under Subpart B of 21 CFR Part 801.

IV. Conditions of Authorization

Pursuant to section 564 of the Act, I am establishing the following conditions on this authorization.

BD (You) and Authorized Distributor(s)

A. Your product must be made available with the authorized labeling.

B. You and authorized distributor(s) will inform authorized laboratories of this EUA, including the terms and conditions herein, and any updates made to your product, or the authorized labeling.

C. You and authorized distributors will make available on your website(s) the Fact Sheet for Healthcare Providers and Authorized Laboratories.

D. You and authorized distributor(s) must maintain customer complaint files on record. You will report to FDA any significant complaints, including regarding the usability or deviations from the established performance characteristics of the product, of which you become aware.

E. Through a process of inventory control, you and authorized distributor(s) must maintain records of the number of devices distributed and locations to which your device is distributed.

F. You and authorized distributor(s) are authorized to make available additional information relating to the emergency use of your product that is consistent with, and does not exceed, the terms of this letter of authorization.

BD (You)

G. You must notify FDA of any authorized distributor(s) of your product, including the name, address, and phone number of any authorized distributor(s) along with any alternative names for your product.

H. You must provide authorized distributor(s) with a copy of this EUA and communicate any subsequent amendments that might be made to this EUA and its authorized labeling.

I. You may request changes to this EUA for your product, including to the Scope of Authorization (Section II in this letter) or to the authorized labeling, including requests to make available additional authorized labeling specific to an authorized distributor. Such additional labeling may use another name for the product but otherwise must be consistent with the authorized labeling, and not exceed the terms of authorization of this letter. Any request for changes to this EUA should be submitted to the Division of Immunology and Hematology (DIHD)/Office of Health Technology 7 (OHT7)-Office of In Vitro Diagnostics and Radiological Health (OIR)/Office of Product Evaluation and Quality (OPEQ)/Center for Devices and Radiological Health (CDRH) and require appropriate authorization from FDA prior to implementation.

J. You must have a process in place to track adverse events associated with your product, including occurrences of erroneous coagulation test results that can be attributed to use of the tubes, and report to FDA in compliance with 21 CFR Part 803. Serious adverse events must be immediately reported to DIHD/OHT7/OPEQ/CDRH (via email: CDRH-EUAReporting@fda.hhs.gov).

K. You must submit to FDA a summary report within 30 calendar days of authorization and every 30 days thereafter summarizing any complaints and adverse events associated with your product during that timeframe.

L. If requested by FDA, you must submit a list of lots of your product distributed in the U.S. along with the lot expiration dates. As additional lots of your product are distributed in the U.S., you must update the list of lots (with corresponding expiration dates).

Authorized Laboratories

M. Authorized laboratories must use your product as outlined in the authorized labeling.

N. Authorized laboratories must collect information on the performance of your product and report to DIHD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUAReporting@fda.hhs.gov) and you (e-mail: 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 your product of which they become aware.

BD (You), Authorized Distributor(s), and Authorized Laboratories

O. BD, its authorized distributor(s), and authorized laboratories will ensure that any records associated with this EUA are maintained until notified by FDA. Such records will be made available to FDA for inspection upon request.

Conditions Related to Advertising and Promotion

P. All advertising and promotional descriptive printed matter relating to the use of your product shall be consistent with the authorized labeling, as well as the terms set forth in this EUA and the applicable requirements set forth in section 502(a), (q)(1), and (r) of the Act, as applicable, and FDA implementing regulations.

Q. All descriptive printed matter, advertising, and promotional materials relating to the use of your product shall clearly and conspicuously state that:

- This device has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by laboratories certified under CLIA to perform moderate and high complexity tests;

- This product has been authorized only for 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; and

- This device is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of medical devices under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or the authorization is revoked sooner.

R. No descriptive printed matter, advertising or promotional material relating to the use of your product may represent or suggest that this device is safe or effective 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.

The emergency use of your product as described in this letter of authorization must comply with the conditions and all other terms of this authorization.

V. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of medical devices during the COVID-19 outbreak is terminated under section 564(b)(2) of the Act or the EUA is revoked under section 564(g) of the Act.

Sincerely,

_____

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosures