specified in the **DATES** section of this notice.

If you are not presenting during the CLFS Annual Public Meeting, you may view the meeting via webinar or listen-only by teleconference. If you would like to listen to or view the meeting, teleconference dial-in and webinar information will appear on the final CLFS Annual Public Meeting agenda, which will be posted on the CMS website when available at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/index.html?redirect=/ClinicalLabFeeSched/.*

## IV. Special Accommodations

Individuals viewing or listening to the meeting who are hearing or visually impaired and have special requirements, or a condition that requires special assistance, should send an email to the resource box (*CDLT_Annual_Public_Meeting@cms.hhs.gov*). The deadline for submitting this request is listed in the **DATES** section of this notice.

## V. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Lynette Wilson, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: April 13, 2022.

**Lynette Wilson,**

*Federal Register Liaison, Centers for Medicare & Medicaid Services.*

[FR Doc. 2022–08259 Filed 4–15–22; 8:45 am]

**BILLING CODE 4120–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2022–N–0049]**

### Revocation of Five Authorizations of Emergency Use of In Vitro Diagnostic Devices for Detection and/or Diagnosis of COVID–19; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the revocation of the Emergency Use Authorizations (EUAs) (the Authorizations) issued to BillionToOne, Inc. for the qSanger-COVID–19 Assay, RTA Laboratories Biological Products Pharmaceutical and Machinery Industry (RTA) for the Diagnovital SARS–CoV–2 Real-Time PCR Kit, DiaSorin Inc. for the DiaSorin LIAISON SARS–CoV–2 IgM Assay, and CENTOGENE US, LLC for both the CentoFast-SARS–CoV–2 RT–PCR Assay and CentoSure SARS–CoV–2 RT–PCR Assay. FDA revoked these Authorizations under the Federal Food, Drug, and Cosmetic Act (FD&C Act). The revocations, which include an explanation of the reasons for each revocation, are reprinted in this document.

**DATES:** The Authorization for the qSanger-COVID–19 Assay is revoked as of March 10, 2022. The Authorization for the Diagnovital SARS–CoV–2 Real-Time PCR Kit is revoked as of March 14, 2022. The Authorization for the DiaSorin LIAISON SARS–CoV–2 IgM Assay is revoked as of March 15, 2022. The Authorizations for the CentoFast-SARS–CoV–2 RT–PCR Assay and CentoSure SARS–CoV–2 RT–PCR Assay are revoked as of March 17, 2022.

**ADDRESSES:** Submit written requests for a single copy of the revocations to the Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4338, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a Fax number to which the revocations may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the revocations.

**FOR FURTHER INFORMATION CONTACT:** Jennifer J. Ross, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4332, Silver Spring, MD 20993–0002, 240–402–8155 (this is not a toll-free number).

**SUPPLEMENTARY INFORMATION:**

## I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb-3) as amended by the Project BioShield Act of 2004 (Pub. L. 108–276) and the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (Pub. L. 113–5) allows FDA to strengthen the public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. On September 4, 2020, FDA issued an EUA to BillionToOne, Inc. for the qSanger-COVID–19 Assay, subject to the terms of the Authorization. Notice of the issuance of this Authorization was published in the **Federal Register** on November 20, 2020 (85 FR 74346), as required by section 564(h)(1) of the FD&C Act. On June 12, 2020, FDA issued an EUA to RTA for the Diagnovital SARS–CoV–2 Real-Time PCR Kit, subject to the terms of the Authorization. Notice of the issuance of this Authorization was published in the **Federal Register** on November 20, 2020 (85 FR 74346), as required by section 564(h)(1) of the FD&C Act. On September 29, 2020, FDA issued an EUA to DiaSorin Inc. for the DiaSorin LIAISON SARS–CoV–2 IgM Assay, subject to the terms of the Authorization. Notice of the issuance of this Authorization was published in the **Federal Register** on April 23, 2021 (86 FR 21749), as required by section 564(h)(1) of the FD&C Act. On July 1, 2020, FDA issued an EUA to CENTOGENE US, LLC for the CentoFast-SARS–CoV–2 RT–PCR Assay, subject to the terms of the Authorization. Notice of the issuance of this Authorization was published in the **Federal Register** on November 20, 2020 (85 FR 74346), as required by section 564(h)(1) of the FD&C Act. On September 29, 2020, FDA issued an EUA to CENTOGENE US, LLC for the CentoSure SARS–CoV–2 RT–PCR Assay, subject to the terms of the Authorization. Notice of the issuance of this Authorization was published in the **Federal Register** on April 23, 2021 (86 FR 21749), as required by section 564(h)(1) of the FD&C Act. Subsequent changes to the Authorizations were made available on FDA's website. The authorization of a device for emergency use under section 564 of the FD&C Act may, pursuant to section 564(g)(2) of the

FD&C Act, be revoked when the criteria under section 564(c) of the FD&C Act for issuance of such authorization are no longer met (section 564(g)(2)(B) of the FD&C Act), or other circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the FD&C Act).

**II. EUA Revocation Requests**

On February 25, 2022, BillionToOne, Inc. requested revocation of, and on March 10, 2022, FDA revoked, the Authorization for the qSanger-COVID–19 Assay. Because BillionToOne, Inc. notified FDA that it has decided to discontinue distribution of the qSanger-COVID–19 Assay and requested FDA revoke the EUA for the qSanger-COVID–19 Assay, FDA has determined that it is appropriate to protect the public health or safety to revoke this Authorization. FDA received a request dated February 15, 2022, from RTA for the revocation of, and on March 14, 2022, FDA revoked, the Authorization for the Diagnovital SARS–CoV–2 Real-Time PCR Kit. Because RTA notified FDA that the EUA for the Diagnovital SARS–CoV–2 Real-Time PCR Kit is no longer required and requested that FDA revoke the EUA for the Diagnovital SARS–CoV–2 Real-Time PCR Kit, FDA has determined that it is appropriate to protect the public health or safety to revoke this Authorization. On March 10, 2022, FDA received a request from DiaSorin Inc. for the revocation of, and on March 15, 2022, FDA revoked, the Authorization for the DiaSorin LIAISON SARS–CoV–2 IgM Assay. Because DiaSorin Inc. notified FDA that DiaSorin Inc. has decided to discontinue commercial distribution and support of the DiaSorin LIAISON SARS–CoV–2 IgM Assay and requested FDA revoke the EUA for the DiaSorin LIAISON SARS–CoV–2 IgM Assay, FDA has determined that it is appropriate to protect the public health or safety to revoke this Authorization. On March 14, 2022, FDA received a request from CENTOGENE US, LLC. for the revocation of, and on March 17, 2022, FDA revoked, the Authorization for the CentoFast-SARS–CoV–2 RT–PCR Assay. Because CENTOGENE US, LLC. notified FDA that it does not offer the CentoFast-SARS–CoV–2 RT–PCR Assay anymore and requested FDA revoke the EUA for the CentoFast-SARS–CoV–2 RT–PCR Assay, FDA has determined that it is appropriate to protect the public health or safety to revoke this Authorization. On March 14, 2022, FDA received a request from CENTOGENE US, LLC. for the revocation of, and on March 17, 2022, FDA revoked, the Authorization for the CentoSure SARS–CoV–2 RT–PCR Assay. Because CENTOGENE US, LLC. notified FDA that it does not offer the CentoSure SARS–CoV–2 RT–PCR Assay anymore and requested FDA revoke the EUA for the CentoSure SARS–CoV–2 RT–PCR Assay, FDA has determined that it is appropriate to protect the public health or safety to revoke this Authorization.

**III. Electronic Access**

An electronic version of this document and the full text of the revocations are available on the internet at *https://www.regulations.gov/.*

**IV. The Revocations**

Having concluded that the criteria for revocation of the Authorizations under section 564(g)(2)(C) of the FD&C Act are met, FDA has revoked the EUAs for BillionToOne, Inc.'s qSanger–COVID–19 Assay, RTA's Diagnovital SARS–CoV–2 Real-Time PCR Kit, DiaSorin Inc.'s DiaSorin LIAISON SARS–CoV–2 IgM Assay, and CENTOGENE US, LLC's CentoFast–SARS–CoV–2 RT–PCR Assay and CentoSure SARS–CoV–2 RT–PCR Assay. The revocations in their entirety follow and provide an explanation of the reasons for each revocation, as required by section 564(h)(1) of the FD&C Act.

BILLING CODE 4164–01–P


March 10, 2022

Anna Rolda, MS
Sr. Manager, Quality & Regulatory Affairs
BillionToOne, Inc.
1035 O'Brien Drive
Menlo Park, CA 94025
**Re: Revocation of EUA201022**

Dear Ms. Rolda:

This letter is in response to the request from BillionToOne, Inc., received via email on February 25, 2022, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the qSanger-COVID-19 Assay issued on September 4, 2020, and amended on June 23, 2021, and September 23, 2021. BillionToOne, Inc. indicated that it has decided to discontinue distribution of the qSanger-COVID-19 Assay and there is not any viable/non-expired product remaining in distribution.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revoked when circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because BillionToOne, Inc. has notified FDA that it has decided to discontinue distribution of the qSanger-COVID-19 Assay and requested FDA revoke the EUA for the qSanger-COVID-19 Assay, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA201022 for the qSanger-COVID-19 Assay, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the qSanger-COVID-19 Assay is no longer authorized for emergency use by FDA.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

/s/

Jacqueline A. O'Shaughnessy, Ph.D.
Acting Chief Scientist
Food and Drug Administration

U.S. FOOD & DRUG ADMINISTRATION

March 14, 2022

Ilknur Cetin
Quality Assurance Manager
RTA Laboratories Biological Products Pharmaceutical and Machinery Industry (RTA Laboratuvarlari Biyolojik Urunler Ilac ve Makine San)
76 TW Alexander Drive
Research Triangle Park, NC 27709

**Re: Revocation of EUA200486**

Dear Ilknur Cetin,

This letter is in response to RTA Laboratories Biological Products Pharmaceutical and Machinery Industry's (RTA's) request dated February 15, 2022, that the U.S. Food and Drug Administration (FDA) revoke the Emergency Use Authorization (EUA200486) for the Diagnovital SARS-CoV-2 Real-Time PCR Kit issued on June 12, 2020 and revised on September 23, 2021. In its February 15, 2022, letter, RTA requested revocation of the EUA effective February 15, 2022, as the product will no longer be distributed or used by that date. FDA understands that RTA has decided not to continue to commercially support the Diagnovital SARS-CoV-2 Real-Time PCR Kit.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revoked when circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because RTA has notified FDA that the EUA for the Diagnovital SARS-CoV-2 Real-Time PCR Kit is no longer required and requested that FDA revoke the EUA for the Diagnovital SARS-CoV-2 Real-Time PCR Kit, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA200486 for the Diagnovital SARS-CoV-2 Real-Time PCR Kit, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Diagnovital SARS-CoV-2 Real-Time PCR Kit is no longer authorized for emergency use by FDA.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

/s/

Jacqueline A. O'Shaughnessy, Ph.D.
Acting Chief Scientist
Food and Drug Administration

U.S. FOOD & DRUG ADMINISTRATION

March 15, 2022

Mari Meyer
DiaSorin Inc.
1951 Northwestern Avenue
Stillwater, MN 55082-0285

**Re: Revocation of EUA202004**

Dear Mari Meyer:

This letter is in response to a request from DiaSorin Inc., received March 10, 2022, that the U.S. Food and Drug Administration (FDA) revoke the DiaSorin LIAISON SARS-CoV-2 IgM Assay–EUA202004 issued on September 29, 2020, and revised September 23, 2021. DiaSorin Inc. has decided to discontinue commercial distribution and support of the DiaSorin LIAISON SARS-CoV-2 IgM Assay and there is not any viable/non-expired product remaining in distribution.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revoked when circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because DiaSorin Inc. has notified FDA that DiaSorin Inc. has decided to discontinue commercial distribution and support of the DiaSorin LIAISON SARS-CoV-2 IgM Assay and requested FDA revoke the EUA for the DiaSorin LIAISON SARS-CoV-2 IgM Assay, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA202004 for the DiaSorin LIAISON SARS-CoV-2 IgM Assay, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the DiaSorin LIAISON SARS-CoV-2 IgM Assay is no longer authorized for emergency use by FDA.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

/s/

Jacqueline A. O'Shaughnessy, Ph.D.
Acting Chief Scientist
Food and Drug Administration

U.S. FOOD & DRUG ADMINISTRATION

March 17, 2022

Dr. Florian Vogel
Chief Process Officer
CENTOGENE GmbH
Am Strande 7
18055 Rostock
Germany

**Re: Revocation of EUA201018**

Dear Dr. Vogel:

This letter is in response to the request from CENTOGENE US, LLC. ("Centogene"), received on March 14, 2022, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the CentoFast-SARS-CoV-2 RT-PCR Assay issued on July 1, 2020, and amended on August 13, 2021, and September 23, 2021. Centogene indicated that it does not offer this test anymore. FDA understands Centogene has notified all associated laboratories to also stop using this test.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revoked when circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because Centogene has notified FDA that it does not offer the CentoFast-SARS-CoV-2 RT-PCR Assay anymore and requested FDA revoke the EUA for the CentoFast-SARS-CoV-2 RT-PCR Assay, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA201018 for the CentoFast-SARS-CoV-2 RT-PCR Assay, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the CentoFast-SARS-CoV-2 RT-PCR Assay is no longer authorized for emergency use by FDA.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

/s/

Jacqueline A. O'Shaughnessy, Ph.D.
Acting Chief Scientist
Food and Drug Administration

Cc: Justin Bingham, CENTOGENE US, LLC.

U.S. FOOD & DRUG ADMINISTRATION

March 17, 2022

Dr. Florian Vogel
Chief Process Officer
CENTOGENE GmbH
Am Strande 7
18055 Rostock
Germany

**Re: Revocation of EUA202546**

Dear Dr. Vogel:

This letter is in response to the request from CENTOGENE US, LLC. ("Centogene"), received on March 14, 2022, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the CentoSure SARS-CoV-2 RT-PCR Assay issued on September 29, 2020, and amended on August 13, 2021, and September 23, 2021. Centogene indicated that it does not offer this test anymore. FDA understands Centogene and has notified associated laboratories to also stop using this test.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revoked when circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because Centogene has notified FDA that it does not offer the CentoSure SARS-CoV-2 RT-PCR Assay anymore and requested FDA revoke the EUA for the CentoSure SARS-CoV-2 RT-PCR Assay, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA202546 for the CentoSure SARS-CoV-2 RT-PCR Assay, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the CentoSure SARS-CoV-2 RT-PCR Assay is no longer authorized for emergency use by FDA.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

/s/

Jacqueline A. O'Shaughnessy, Ph.D.
Acting Chief Scientist
Food and Drug Administration

Cc: Justin Bingham, CENTOGENE US, LLC.

Dated: April 12, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2022–08230 Filed 4–15–22; 8:45 am]

**BILLING CODE 4164–01–C**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2019–N–0430]**

### Agency Information Collection Activities; Proposed Collection; Comment Request; Generic Clearance for Quick Turnaround Testing of Communication Effectiveness

**AGENCY:** Food and Drug Administration, Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA, we, or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and