

records are processed and stored in a secure environment.

All records are stored in an area that is physically safe from access by unauthorized persons at all times.

Safeguards conform to the HHS Information Security Program, <http://www.hhs.gov/ocio/securityprivacy/index.html>.

RETENTION AND DISPOSAL:

(1) Records provided from State child support agencies. (a) Electronic records furnished by the State child support agency containing child support case and order information (input files) are retained for 60 days and then deleted. (b) State agency records (as posted to the FCR) remain within the FCR until removed, upon notification by the State agency that the case is closed and notifies OCSE to remove it from the FCR, provided that, upon request, a sample may be retained for research purposes found by OCSE to be likely to contribute to achieving the purposes of child support programs or the TANF program, but without personal identifiers. (c) Records pertaining to closed cases are archived on the fiscal year basis and retained for two years. Family violence indicators are removed from the individual's record, upon request by the State that initiated the indicator. (2) Locate requests and match results. (a) Locate requests submitted by State child support agencies and other authorized persons are retained for 60 days and are then deleted. (b) Audit trail records of locate requests and disclosures of match results pursuant to those requests, which include indications of which Federal agencies were contacted for locate information, whether information was located, and the type(s) of information returned to the requesting entity are archived once a year based on the fiscal year. The records are retained for two completed fiscal years and then destroyed. These records indicate the type of information located for the authorized user, not the information itself. (c) Records containing information from the NDNH or from other agencies obtained pursuant to locate requests are provided to authorized persons through the FCR. Copies of records provided are then retained within the FCR for the purpose of electronically filtering and suppressing redundant information from being provided. NDNH information is retained within the FCR for one year and information from other agencies is retained for up to three years. Thereafter such information is deleted. (3) Match results generated as a result of FCR to FCR comparisons which locate individuals who are

participants in child support cases or orders in more than one State are transmitted to the relevant States. Copies of FCR to FCR match results are retained for 60 days and then deleted. (4) Any record relating or potentially relating to a fraud or abuse investigation or a pending or ongoing legal action including a class action, is retained until conclusion of the investigation or legal action. (5) Copies of the FCR records transmitted annually to the IRS for the purpose of administering the earned income tax credit (routine use 12) are retained for one year and then deleted.

SYSTEM MANAGER(S) AND ADDRESS:

Director, Division of Federal Systems, Office of Automation and Program Operations, Office of Child Support Enforcement, Administration for Children and Families, Department of Health and Human Services, 370 L'Enfant Promenade, SW., 4th Floor East, Washington, DC 20447.

NOTIFICATION PROCEDURES:

Individuals seeking to determine whether this system of records contains information about themselves should address written inquiries to the System Manager. The request should include the name, telephone number and/or email address, SSN, and address of the individual, and the request must be signed by the individual to whom such information pertains. The requester's letter must provide sufficient particulars to enable the System Manager to distinguish between records on subject individuals with the same name. Verification of identity as described in HHS's Privacy Act regulations may be required. 45 CFR 5b.5.

RECORD ACCESS PROCEDURES:

Individuals seeking access to a record about themselves in this system of records should address written inquiries to the System Manager. The request should include the name, telephone number and/or email address, SSN, and address of the individual, and should be signed by the individual to whom such information pertains. The requester's letter must provide sufficient particulars to enable the System Manager to distinguish between records on subject individuals with the same name. Verification of identity as described in HHS's Privacy Act regulations may be required. 45 CFR 5b.5.

CONTESTING RECORD PROCEDURES:

Individuals seeking to amend a record about themselves in this system of records should address the request for amendment to the System Manager. The

request should (1) include the name, telephone number and/or email address, SSN, and address of the individual, and should be signed by the individual to whom such information pertains; (2) identify the system of records that the individual believes includes his or her records or otherwise provide enough information to enable the identification of the individual's record; (3) identify the information that the individual believes is not accurate, relevant, timely, or complete; (4) indicate what corrective action is sought; and (5) include supporting justification or documentation for the requested amendment. Verification of identity as described in HHS's Privacy Act regulations may be required. 45 CFR 5b.5.

RECORD SOURCE CATEGORIES:

Records maintained within the FCR are furnished by State child support agencies. Records disseminated from the FCR for the purpose of providing locate information from the NDNH and other Federal agencies are furnished by departments, agencies, or instrumentalities of the United States or any State, employers, financial institutions, and insurers or their agents. Records maintained for the purpose of filtering redundant data are also furnished by these sources.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

The portions of this system consisting of investigatory material compiled for law enforcement purposes have been exempted pursuant to 5 U.S.C. 552a(k)(2) from the following provisions of the Privacy Act, subject to the limitations set forth in that subsection and to the limitation in 42 U.S.C. 653(b)(2); 5 U.S.C. 552a(c)(3) and (d).

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-D-0634]

Draft Guidance for Industry and Food and Drug Administration Staff; Establishing the Performance Characteristics of Nucleic Acid-Based In Vitro Diagnostic Devices for the Detection and Differentiation of Methicillin-Resistant *Staphylococcus aureus* and *Staphylococcus aureus*; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Establishing the Performance Characteristics of Nucleic Acid-Based *In vitro* Diagnostic Devices for the Detection and Differentiation of Methicillin-Resistant *Staphylococcus aureus* (MRSA) and *Staphylococcus aureus* (SA)." The draft guidance document provides industry and Agency staff with updated recommendations for studies to establish the analytical and clinical performance of nucleic acid-based *in vitro* diagnostic devices (IVDs) intended for the detection and differentiation of methicillin-resistant *Staphylococcus aureus* (MRSA) and *Staphylococcus aureus* (SA). This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment of this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by *April 5, 2011*.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled "Establishing the Performance Characteristics of Nucleic Acid-Based *In vitro* Diagnostic Devices for the Detection and Differentiation of Methicillin-Resistant *Staphylococcus aureus* (MRSA) and *Staphylococcus aureus* (SA)" to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-847-8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Li Li, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5558, Silver Spring, MD 20993-0002, 301-796-6200.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is issuing the draft guidance to provide industry and Agency staff with recommendations for studies to establish the analytical and clinical performance of nucleic acid-based IVDs intended for the detection and differentiation of MRSA and SA. These devices are used to aid in the prevention and control of MRSA/SA infections in healthcare settings. This document is limited to studies intended to establish the performance characteristics of devices that detect the MRSA/SA genome (nucleic acid). It does not address detection of MRSA/SA antigens or serological response from the host to the MRSA/SA antigens, nor does it address establishing performance of non-MRSA/SA components of multi-analyte or multiplex devices.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on establishing the performance characteristics of nucleic acid-based IVDs for the detection and differentiation of MRSA and SA. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.regulations.gov>. To receive "Establishing the Performance Characteristics of Nucleic Acid-Based *In vitro* Diagnostic Devices for the Detection and Differentiation of Methicillin-Resistant *Staphylococcus aureus* (MRSA) and *Staphylococcus aureus* (SA)," you may either send an email request to dsmica@fda.hhs.gov to receive an electronic copy of the document or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number 1722 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

The draft guidance refers to previously approved collections of information found in FDA regulations and guidance documents. These

collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 807, subpart E have been approved under OMB control number 0910-0120; the collections of information in 21 CFR part 812 have been approved under OMB control number 0910-0078; the collections of information in 21 CFR 50.23 have been approved under OMB control number 0910-0586; and the collections of information in 21 CFR 56.115 have been approved under OMB control number 0910-0130.

V. Comments

Interested persons may submit to the Division of Dockets Management (*see ADDRESSES*), either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 30, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-D-0636]

Draft Guidance for Industry and Food and Drug Administration Staff; Establishing the Performance Characteristics of *In Vitro* Diagnostic Devices for the Detection of Antibodies to *Borrelia burgdorferi*; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Draft Guidance for Industry and Food and Drug Administration Staff; Establishing the Performance Characteristics of *In Vitro* Diagnostic Devices for the Detection of Antibodies to *Borrelia burgdorferi*." FDA is issuing this draft guidance to provide industry and agency staff with recommendations for studies to establish the analytical and clinical performance of *in vitro*