PRIVACY IMPACT ASSESSMENT (PIA)

PRESCRIBING AUTHORITY: DoD Instruction 5400.16, "DoD Privacy Impact Assessment (PIA) Guidance". Complete this form for Department of Defense (DoD) information systems or electronic collections of information (referred to as an "electronic collection" for the purpose of this form) that collect, maintain, use, and/or disseminate personally identifiable information (PII) about members of the public, Federal employees, contractors, or foreign nationals employed at U.S. military facilities internationally. In the case where no PII is collected, the PIA will serve as a conclusive determination that privacy requirements do not apply to system.

1. DOD INFORMATION SYSTEM/ELECTRONIC COLLECTION NAME:

Sysmex CS Win10 Series Hemostasis Analyzers_AI

2. DOD COMPONENT NAME:

Defense Health Agency

3. PIA APPROVAL DATE:

12/01/23

SECTION 1: PII DESCRIPTION SUMMARY (FOR PUBLIC RELEASE)

a. The PII is: *(Check one. Note: Federal contractors, military family members, and foreign nationals are included in general public.)*

- ☐ From members of the general public
- ☐ From Federal employees
- ☒ from both members of the general public and Federal employees
- ☐ Not Collected *(if checked proceed to Section 4)*

b. The PII is in a: *(Check one.)*

- ☐ New DoD Information System
- ☐ New Electronic Collection
- ☒ Existing DoD Information System
- ☐ Existing Electronic Collection
- ☐ Significantly Modified DoD Information System

c. Describe the purpose of this DoD information system or electronic collection and describe the types of personal information about individuals collected in the system.

The Sysmex CS-Series is a medical device (a hemostasis system). It is made up of two components: an analyzer and an information processing unit (IPU). The CS-Series performs hemostasis related tests on blood samples and is generally found in the testing lab of a medical facility. The device is made by Siemens, but sold by Sysmex. Siemens and Sysmex have a Global Partnership in Hemostasis Testing.

This medical device equipment (MDE) receives PII from an external source (Composite Health Care System (CHCS)) or its replacement MHS Genesis) and returns to that same source: Sample ID, Patient Name, Test Date, Laboratory Name and Device ID, and Protected Health Information (PHI). This medical device directly or indirectly (via middleware or a DII system) also returns to that same external source: test results (generated from blood samples).

Sysmex CS Win10 Series is owned and operated by Military Treatment Facility (MTF)s which purchase the device. CyberLOG is responsible for the risk management framework (RMF) process and gaining approval from DHA J6 Risk Management Executive Division (RMED). Local sites are responsible for day-to-day operations, maintenance, and management of the device. Sites are responsible for ensuring the device is configured to meet CyberLOG and RMED approved configurations.

d. Why is the PII collected and/or what is the intended use of the PII? *(e.g., verification, identification, authentication, data matching, mission-related use, administrative use)*

The PII/PHI received or returned will be used for mission-related purposes to support the delivery of health care services. The received PII/ PHI will be used to ensure the tests results that were generated by the MDE were generated for the correct individual and inserted into the correct medical record. The MDE does not insert the test results into any medical record. It generates test results, then returns those results (directly or indirectly) to the external system.

e. Do individuals have the opportunity to object to the collection of their PII? ☐ Yes ☒ No

(1) If "Yes," describe the method by which individuals can object to the collection of PII.

(2) If "No," state the reason why individuals cannot object to the collection of PII.

This system is not the initial collection point for the PII. The PII is obtained from an existing Department of Defense (DoD) information system or electronic collection. The medical treatment facility (MTF) admission process will include patient admission forms that specifically address PII.

f. Do individuals have the opportunity to consent to the specific uses of their PII? ☐ Yes ☒ No

(1) If "Yes," describe the method by which individuals can give or withhold their consent.

(2) If "No," state the reason why individuals cannot give or withhold their consent.

This system is not the initial collection point for the PII. The PII is obtained from an existing DoD information system or electronic collection.

g. When an individual is asked to provide PII, a Privacy Act Statement (PAS) and/or a Privacy Advisory must be provided. *(Check as appropriate and provide the actual wording.)*

☐ Privacy Act Statement ☐ Privacy Advisory ☒ Not Applicable

This system is not the initial collection point for the PII. The PII is obtained from an existing DoD information system or electronic collection.

h. With whom will the PII be shared through data/system exchange, both within your DoD Component and outside your Component? *(Check all that apply)*

☒ Within the DoD Component	Specify.	Defense Health Agency (DHA) MTFs.
☐ Other DoD Components *(i.e. Army, Navy, Air Force)*	Specify.	
☐ Other Federal Agencies *(i.e. Veteran's Affairs, Energy, State)*	Specify.	
☐ State and Local Agencies	Specify.	
☒ Contractor *(Name of contractor and describe the language in the contract that safeguards PII. Include whether FAR privacy clauses, i.e., 52.224-1, Privacy Act Notification, 52.224-2, Privacy Act, and FAR 39.105 are included in the contract.)*	Specify.	On-site personnel provide routine maintenance for this device. There are some functions that on-site personnel do not provide and the vendor, or a vendor representative, must provide. For example, upgrading the firmware on the analyzer or upgrading the software on the information processing unit (IPU), or the more complicated device failures. During vendor maintenance or repair operations, vendor personnel could gain access to any locally stored PII. The contracting office that supports each specific MTF would have to provide details regarding the contract language that is supposed to safeguard the PII.
☐ Other *(e.g., commercial providers, colleges).*	Specify.	

i. Source of the PII collected is: *(Check all that apply and list all information systems if applicable)*

☐ Individuals ☐ Databases

☒ Existing DoD Information Systems ☐ Commercial Systems

☐ Other Federal Information Systems

The information is primarily sourced from primary hospital information systems such as the Composite Health Care System (CHCS), or its replacement Genesis.

j. How will the information be collected? *(Check all that apply and list all Official Form Numbers if applicable)*

☐ E-mail ☐ Official Form (*Enter Form Number(s) in the box below)*

☐ In-Person Contact ☐ Paper

☐ Fax ☐ Telephone Interview

☒ Information Sharing - System to System ☐ Website/E-Form

☐ Other *(If Other, enter the information in the box below)*

The information is primarily sourced from primary hospital information systems such as the Composite Health Care System (CHCS), or its replacement Genesis.

k. Does this DoD Information system or electronic collection require a Privacy Act System of Records Notice (SORN)?

A Privacy Act SORN is required if the information system or electronic collection contains information about U.S. citizens or lawful permanent U.S. residents that is retrieved by name or other unique identifier. PIA and Privacy Act SORN information must be consistent.

☐ Yes ☒ No

If "Yes," enter SORN System Identifier

SORN Identifier, not the Federal Register (FR) Citation. Consult the DoD Component Privacy Office for additional information or http://dpcld.defense.gov/Privacy/SORNs/

or

If a SORN has not yet been published in the Federal Register, enter date of submission for approval to Defense Privacy, Civil Liberties, and Transparency Division (DPCLTD). Consult the DoD Component Privacy Office for this date

If "No," explain why the SORN is not required in accordance with DoD Regulation 5400.11-R: Department of Defense Privacy Program.

N/A

l. What is the National Archives and Records Administration (NARA) approved, pending or general records schedule (GRS) disposition authority for the system or for the records maintained in the system?

(1) NARA Job Number or General Records Schedule Authority. GRS 5.2, item 020 (DAA-GRS-2017-0003-0002)

(2) If pending, provide the date the SF-115 was submitted to NARA.

(3) Retention Instructions.

FILE NUMBER: 103-14
DISPOSITION: Temporary. Delete no more than 7 years from the date last modified. (See DoD DTM 22-001 on default disposition policies and OSD Records Manager guidance which file number to associate).

m. What is the authority to collect information? A Federal law or Executive Order must authorize the collection and maintenance of a system of records. For PII not collected or maintained in a system of records, the collection or maintenance of the PII must be necessary to discharge the requirements of a statue or Executive Order.

(1) If this system has a Privacy Act SORN, the authorities in this PIA and the existing Privacy Act SORN should be similar.
(2) If a SORN does not apply, cite the authority for this DoD information system or electronic collection to collect, use, maintain and/or disseminate PII. (If multiple authorities are cited, provide all that apply).

(a) Cite the specific provisions of the statute and/or EO that authorizes the operation of the system and the collection of PII.

(b) If direct statutory authority or an Executive Order does not exist, indirect statutory authority may be cited if the authority requires the operation or administration of a program, the execution of which will require the collection and maintenance of a system of records.

(c) If direct or indirect authority does not exist, DoD Components can use their general statutory grants of authority ("internal housekeeping") as the primary authority. The requirement, directive, or instruction implementing the statute within the DoD Component must be identified.

5 U.S.C. 301, Departmental Regulations; 10 U.S.C. Chapter 55, Sections 1071-1097b, Medical and Dental Care; 42 U.S.C. Chapter 117, Sections 11131-11152, Reporting of Information; DoDM 6025.18, Implementation Of The HIPAA Privacy Rule In DoD Health Care Programs; DoD 6010.8-R, CHAMPUS; DoD Instruction 6015.23, Delivery of Healthcare at Military Treatment Facilities: Foreign Service Care; Third-Party Collection; Beneficiary Counseling and Assistance Coordinators (BCACs); Pub.L. 104-91, Health Insurance Portability and Accountability Act of 1996; and E.O. 9397 (SSN), as amended.

n. Does this DoD information system or electronic collection have an active and approved Office of Management and Budget (OMB) Control Number?

Contact the Component Information Management Control Officer or DoD Clearance Officer for this information. This number indicates OMB approval to collect data from 10 or more members of the public in a 12-month period regardless of form or format.

☐ Yes ☒ No ☐ Pending

(1) If "Yes," list all applicable OMB Control Numbers, collection titles, and expiration dates.
(2) If "No," explain why OMB approval is not required in accordance with DoD Manual 8910.01, Volume 2, " DoD Information Collections Manual: Procedures for DoD Public Information Collections."
(3) If "Pending," provide the date for the 60 and/or 30 day notice and the Federal Register citation.

The information collected in this system is for the diagnosis and treatment of medical disorders and not considered a public information collection in accordance with DoDM 8910.01, Volume 2, Enclosure 3, paragraph 8b(5).