

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:

Roche Cobas Infinity Central Lab v3.x_AA

2. DOD COMPONENT NAME:

Defense Health Agency

3. PIA APPROVAL DATE:

05/25/2026

Defense Health Agency (DHA) Medical Device and Equipment (MDE) Program Management Office (PMO)

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.

Cobas Infinity Central Lab (CICL) is a medical software application that provides connectivity between laboratory instruments and information systems. The software automates the three main areas of laboratory operations: pre-analytics, analytics, and post-analytics thereby facilitating the information flow for test orders, results, specimen data, and patient information. The visual displays and seamless data management interface also help laboratory personnel interpret and manage test results. The software receives, sends, stores, and displays PII/PHI. Customer/user access is via a web browser connection.

Personally Identifiable Information (PII) may include numerous types of PII including employee and beneficiary contact information, military information, demographic information, Social Security Number (SSN), and Protected Health Information (PHI). PII is collected from both members of the general public and Federal employees and/or Federal contractors. The following categories of individuals in which PII is collected from includes Department of Defense (DoD) Health Care Beneficiaries such as Military Members of the Armed Forces, Military Retirees, and their family members; DoD Civilian Employees; Foreign Nationals; Members of the United States Coast Guard; Public Health Service; Cadets and Midshipmen of the Military Academies; and other categories of individuals who receive medical treatment at DoD 's Treatment Facilities/Activities.

The Roche Cobas Infinity Central Lab system is owned and operated by Defense Health Agency's MDE PMO

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 is collected for data matching or the intended use of PII is mission-related use.

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.

Cobas Infinity Central Lab receives PII from system-to-system interface; therefore, the opportunity to object is only available at the source system.

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.

Cobas Infinity Central Lab receives PII from system-to-system interface; therefore, the opportunity to object is only available at the source

system.

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, therefore no Privacy Act Statement or Privacy Advisory is required.

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)

- | | | |
|---|----------|---|
| <input checked="" type="checkbox"/> Within the DoD Component | Specify. | Defense Health Agencies' Military Treatment Facilities |
| <input checked="" type="checkbox"/> Other DoD Components (i.e. Army, Navy, Air Force) | Specify. | U.S. Army
U.S. Air Force
U.S. Navy
U.S. Marine Corps |
| <input checked="" type="checkbox"/> Other Federal Agencies (i.e. Veteran's Affairs, Energy, State) | Specify. | U.S. Coast Guard
Veterans Administration
Public Health Service
Center for Disease Control |
| <input type="checkbox"/> State and Local Agencies | Specify. | |
| <input checked="" type="checkbox"/> 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. | The Military Treatment Facilities (MTFs) may utilize contractor services to support this product. DoD Policy requires such contracts include language to safeguard PII including FAR clauses: 52.224-1, Privacy Act Notification; 52.224-2, Privacy Act; and FAR 39.105, Privacy. When the contractor has access to PHI, a HIPAA Business Associate Agreement is also required. |
| <input type="checkbox"/> 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)

- | | |
|--|---|
| <input type="checkbox"/> Individuals | <input type="checkbox"/> Databases |
| <input checked="" type="checkbox"/> Existing DoD Information Systems | <input type="checkbox"/> Commercial Systems |
| <input type="checkbox"/> Other Federal Information Systems | |

Existing DoD Information Systems:
 Picture Archiving and Communication System (PACS)
 Health Level Seven (HL7)
 Digital Imaging and Communications in Medicine (DICOM)_Capable Systems

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

- | | |
|---|--|
| <input type="checkbox"/> E-mail | <input type="checkbox"/> Official Form (Enter Form Number(s) in the box below) |
| <input type="checkbox"/> In-Person Contact | <input type="checkbox"/> Paper |
| <input type="checkbox"/> Fax | <input type="checkbox"/> Telephone Interview |
| <input checked="" type="checkbox"/> Information Sharing - System to System | <input type="checkbox"/> Website/E-Form |
| <input type="checkbox"/> Other (If Other, enter the information in the box below) | |

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://dpcl.d.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.

A system of records notice ("SORN") is not required because the Roche Cobas Infinity Central Lab system is not a system of records as it does not appear to actually retrieve collected and stored information, if any, by an individual's name or other identifying particular assigned to the individual.

I. 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.

Mission Schedules:

- GRS 5.2, item 020 (DAA-GRS-2022-0009-0002)

Other Schedules:

- System Access Records: GRS 3.2, item 030 (DAA-GRS-2013-0006-0003),

- Data Administration and Documentation: GRS 3.1, item 051 (DAA-GRS-2013-0005-0003)

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

(3) Retention Instructions.

Mission Schedules:

FILE NUMBER: 103-14

FILE TITLE: Intermediary Records

DISPOSITION: Temporary. Cut off and destroy upon creation or update of the final record, or when no longer needed for business use, whichever is later.

Other Schedules:

FILE NUMBER: 1601-02

FILE TITLE: System Access Records - Systems not requiring Special Accountability for Access

DISPOSITION: Temporary. Cut off and destroy when business use ceases.

FILE NUMBER: 1601-12

FILE TITLE: Data Administration and Documentation - Temporary Systems

DISPOSITION: Temporary. Cut off after the project/activity/transaction is completed or superseded, or the associated system is terminated, or the associated data is migrated to a successor system. Destroy 5 years after cutoff.

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 statute 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. 136, Under Secretary of Personnel and Readiness; 10 U.S.C. Ch. 55, Medical and Dental Care; Public Law 104-191, Health Insurance Portability and Accountability Act of 1996; 42 U.S.C. 290dd, Substance Abuse Among Government and Other Employees; 42 U.S.C. 290dd-2, Confidentiality Of Records; 42 U.S.C. Ch. 117, Sections 11131-11152, Reporting of Information; 45 CFR 164, Security and Privacy; Department of Defense (DoD) Instruction 6015.23, Foreign Military Personnel Care and

Uniform Business Offices in Military Treatment Facilities (MTFS); DoD Manual 6025.18, Implementation of the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule in DoD Health Care Programs; 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 and is not considered a public information collection in accordance with DoDM 8910.01, V2, Encl 3, paragraph 8b(5).