

## 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:**

Abbott Alinity CI v3x

**2. DOD COMPONENT NAME:**

Defense Health Agency

Cyber Logistics

**3. PIA APPROVAL DATE:**

01/01/24

### 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 Abbott Alinity CI-series (Alinity CI) is intended for In Vitro diagnostic use only. Alinity CI has a scalable design to provide full integration of clinical chemistry and immunoassay analysis. The Alinity CI processing module is a fully automated chemistry analyzer allowing random and continuous access, as well as priority and automated retest processing using photometric and potentiometric detection technology. The Alinity CI processing module uses photometric detection technology to measure sample absorbency for the quantification of analyte concentration and uses potentiometric detection technology to measure the electrical potential in a sample. In addition, Alinity processing module uses an integrated chip technology (ICT) module to measure potentiometric assays (electrolytes). The Alinity CI processing module is a fully automated immunoassay analyzer allowing random and continuous access, as well as priority and automated retest processing using chemiluminescent micro-particle immunoassay (CMIA) technology. CMIA technology is used to determine the presence of antigens, antibodies, and analytes in samples.

Personally Identifiable Information (PII) collected include Dates of Birth, Device Identifiers or Serial Numbers, and Test Results and Protected Health Information (PHI). 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.

Abbott Alinity CI system is owned and operated by Military Treatment Facility (MTF)s which purchase the device.

**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 PHI & PII collected is used for mission-related purposes to support the delivery of health care services, to match an individual with their medical diagnostic reports and ensure accuracy when these reports are integrated in the individual medical records.

**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.

Abbott Alinity CI receives PII from system-to-system interface; 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.

Abbott Alinity CI receives PII from system-to-system interface; the opportunity to consent 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

Abbott Alinity CI does not collect PII from individuals; Privacy Act Statement or Privacy Advisory is not 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)

- Within the DoD Component                      Specify.    DHA Military Treatment Facilities (MTF).
- Other DoD Components (i.e. Army, Navy, Air Force)                      Specify.    Army, Navy and Air Force MTFs
- Other Federal Agencies (i.e. Veteran's Affairs, Energy, State)                      Specify.    U.S. Coast Guard, Veterans Administration, Public Health Service, Center for Disease Control.
- State and Local Agencies                      Specify.    The MTF 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.
- 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.    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.
- 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

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

**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)

Abbott Alinity CI obtains the individual's PII through an interface with the DoD EHR.

**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://dpcltd.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.

Records are not retrieved by unique personal identifier.

**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. 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 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.

Public Law 104-191, Health Insurance Portability and Accountability Act of 1996; 10 USC Chapter 55, Medical and Dental Care; 10 USC 1097a, TRICARE Prime: Automatic Enrollments; Payment Options; 10 USC 1097b, TRICARE Prime and TRICARE Program: Financial Management; 10 USC 1079, Contracts for Medical Care for Spouses and Children: Plans; 10 USC 1079a, TRICARE Program: Treatment of Refunds and Other Amounts Collected Civilian Health and Medical Program of the Uniformed Services (CHAMPUS); 10 USC 1086, Contracts for Health Benefits for Certain Members, Former Members, and Their Dependents; 10 USC 1095, Health Care Services Incurred on behalf of Covered Beneficiaries: Collection From Third-party Payers; 42 USC 290dd, Substance Abuse Among Government and Other Employees; 42 USC 290dd-2, Confidentiality Of Records; 42 USC 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 (MTF); DoDI 6025.18; and EO 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 conditions and is not considered a public information collection per DoDM 8910.01, V2, Encl 3, paragraph 8b(5).