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:

Quidel Sofia II FIA Version 2.X_AI

2. DOD COMPONENT NAME:

Defense Health Agency

3. PIA APPROVAL DATE:

09/27/23

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
- [x] 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.)*

- [x] 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.

Quidel Sofia II FIA Version 2.X_AI (Quidel Sofia II) is a professional use laboratory small bench top analyzer that uses fluorescence detection to identify infectious diseases like Coronavirus Disease (COVID-19). Quidel Sofia II leverages test strips within a cassette to house specimen. Results are reported on a touch screen interface and can also be sent to a Laboratory Information System (LIS)/Emergency Medical Record (EMR) system. The role-based access control allows the supervisor level accounts to configure instrument or manage data were the operator level accounts can run diagnostic tests and calibrate instrument. Optionally, a bar code scanner and label printer can be added to the Radiology's/Cardiology's Picture Archiving Communication System (PACS) along with any other system that communicates with the Composite Health Care System (CHCS).

The source for Personal Identifiable Information (PII) will be collected from an existing accredited hospital information system or health record system within the Department of Defense (DoD). The PII collected includes personal identifiers and medical information including names, DoD ID numbers, medical information, and Protected Health Information (PHI). The following categories of individuals in which PII is collected includes Active Duty Military, Retirees, and their family members. PII is collected from both members of the general public and Federal employees.

The Quidel Sofia II collects PII and feeds the information to the accredited Picture Archiving Communication System (PACS). Information sharing between Defense Health Agency (DHA), the Laboratory Information System (LIS), and Quidel Sofia II FIA Version 2.X_AI.

The PII is collected from Composite Health Care System (CHCS) or Military Health System (MHS) GENESIS through PACS systems. Cyber Logistics (CyberLOG) is responsible for the Risk Management Framework (RMF) process and gaining an approval from DHA's Joint 6 Risk Management Executive Division (DHA's J6 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 approval configurations. Quidel Sofia II FIA Version 2.X_AI is owned by DHA's CyberLOG and operated by various MTF as needed.

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)*

PII is collected to identify the patient test run and results. The intended use of the PII is for enhanced radiology and cardiology health care system.

e. Do individuals have the opportunity to object to the collection of their PII? Yes [x] 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 Quidel Sofia II FIA Version 2.X_AI receives PII from a system-to-system interface and 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 [x] 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 Quidel Sofia II FIA Version 2.X_AI receives PII from a system-to-system interface and 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 | [x] Not Applicable

Quidel Sofia II FIA Version 2.X_AI does not collect PII directly from individuals, so a Privacy Act Statement or 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)*

[x]	Within the DoD Component	Specify.	Military Treatment Facilities (MTFs)
[x]	Other DoD Components *(i.e. Army, Navy, Air Force)*	Specify.	Department of Defense Agencies
[ ]	Other Federal Agencies *(i.e. Veteran's Affairs, Energy, State)*	Specify.	
[ ]	State and Local Agencies	Specify.	
[x]	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 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.
[x]	Other *(e.g., commercial providers, colleges).*	Specify.	Medical Professionals upon referral.

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

[ ]	Individuals	[ ]	Databases
[x]	Existing DoD Information Systems	[ ]	Commercial Systems
[ ]	Other Federal Information Systems		

Picture Archiving Communication System (PACS)
Laboratory Information System (LIS)
Military Health System (MHS) 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
[x]	Information Sharing - System to System	[ ]	Website/E-Form
[ ]	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 [x] 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.

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.

Public Law 104-191, Health Insurance Portability and Accountability Act of 1996; 10 U.S.C., Chapter 55, Medical and Dental Care; 10 U.S.C. 1097a, TRICARE Prime: Automatic Enrollments; Payment Options; 10 U.S.C. 1097b, TRICARE Prime and TRICARE Program: Financial Management; 10 U.S.C. 1079, Contracts for Medical Care for Spouses and Children: Plans; 10 U.S.C. 1079a, TRICARE Program: Treatment of Refunds and Other Amounts Collected Civilian Health and Medical Program of the Uniformed Services (CHAMPUS); 10 U.S.C. 1086, Contracts for Health Benefits for Certain Members, Former Members, and Their Dependents; 10 U.S.C. 1095, Health Care Services Incurred on behalf of Covered Beneficiaries: Collection From Third-party Payers; 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 x 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 does not collect PHI/PII directly from individuals. It is not the initial point of collection for any PHI/PII and is not considered a public information collection IAW DoDM 8910.01, V2, Encl 3, paragraph 8b(5).