

## 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:**

BioFire Defense FilmArray 2.0 System v2.x AI

**2. DOD COMPONENT NAME:**

Defense Health Agency

**3. PIA APPROVAL DATE:**

07/07/2026

Cybersecurity Logistics (CyberLOG)

### 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.)

- |   |  |
|---|--|
| <input type="checkbox"/> From members of the general public                                       | <input type="checkbox"/> From Federal employees                          |
| <input checked="" type="checkbox"/> from both members of the general public and Federal employees | <input type="checkbox"/> Not Collected (if checked proceed to Section 4) |

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

- |  |   |
|--|---|
| <input type="checkbox"/> New DoD Information System                    | <input type="checkbox"/> New Electronic Collection      |
| <input checked="" type="checkbox"/> Existing DoD Information System    | <input type="checkbox"/> Existing Electronic Collection |
| <input type="checkbox"/> 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 BioFire Defense FilmArray 2.0 System is an automated in vitro diagnostic (IVD) device intended for use with FDA cleared or approved IVD BioFire FilmArray Panels. The BioFire FilmArray 2.0 System is intended for use in combination with assay specific reagent pouches to detect nucleic acid targets contained in clinical specimens. The BioFire FilmArray 2.0 Instrument interacts with the reagent pouch to both purify nucleic acids and amplify targeted nucleic acid sequences using nested multiplex PCR in a closed system. The resulting PCR products are evaluated using DNA melting analysis. The BioFire FilmArray 2.0 software automatically determines the results and provides a test report.

Personally Identifiable Information (PII) collected includes personal identifiers and medical information including Protected Health Information (PHI). 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 War (DoW).

The categories of individuals with records in this system are DoW health care beneficiaries to include Military members of the Armed Forces, Military retirees, and their family members; DoW Civilian employees; Foreign Nationals; members of the U.S. Coast Guard and Public Health Service; cadets and midshipmen of the military academies; and other categories of individuals who receive medical treatment at DoD treatment facilities/activities.

Medical Devices and Equipment (MDE) PMO is responsible for the Risk Management Framework (RMF) process and gaining an approval from DHA's Joint 6 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 Medical Devices and Equipment (MDE) PMO and RMED approval configurations. BioFire Defense FilmArray 2.0 System is owned by DHA's MDE PMO and operated by various MTFs 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)

The PII is collected for identification purposes to match an individual with his/her medical diagnostic reports and to ensure accuracy when these reports are integrated in the medical record for that individual. The PII is used for mission-related purposes to support the delivery of health care services.

**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.

Individuals do not have the opportunity to object to the collection of their PII /PHI because this system is not the initial point of collection;

however, the source system may provide the individual the opportunity to object to the collection.

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.

Individuals do not have the opportunity to object to the collection of their PII /PHI because this system is not the initial point of collection; however, the source system may provide the individual the opportunity to object to the collection.

BioFire Defense FilmArray 2.0 System receives PII from system-to-system interface; therefore, 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

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)

- Within the DoD Component Specify.
- 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.
- 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

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
- Information Sharing - System to System  Website/E-Form
- Other (If Other, enter the information in the box below)

Sharing between systems upstream from the LIS.

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.

**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.

RM Note: This is a medical device. The output is the official record and maintained in the individual's medical record.

**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).