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:

Bio-Rad Variant II Hemoglobin Testing System Series v5.x AI

2. DOD COMPONENT NAME:

Defense Health Agency

3. PIA APPROVAL DATE:

10/20/2026

MDE-PMO NCM Cyber

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 Bio-Rad VARIANT II Hemoglobin Testing System is a fully automated, high-volume analyzer that uses ion-exchange high-performance liquid chromatography (HPLC) to measure HbA1c and screen for hemoglobinopathies like β-thalassemia. The Bio-Rad Variant II Series is an FDA 510(k) approved family of medical devices (covering models VARIANT II under K130860, VARIANT II Turbo under K122472, and VARIANT II Turbo Link under K140801) designed for automated sample preparation, separation, and quantitative determination for measuring glycated hemoglobin (HbA1c) in Ethylenediaminetetraacetic acid (EDTA) human whole blood to diagnose and monitor diabetes.

Personal Identifiable Information (PII) includes personal identifiers and medical information (Protected Health Information (PHI)).

The categories of individuals about whom PII and PHI are collected include Military members of the Armed Forces, Military retirees, and their family members; DoD 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 authorized treatment at Military Facilities.

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 an individual with their medical diagnostic reports and to ensure accuracy when these reports are integrated into the medical records for that individual. The intended use of the PII collected is 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.

The Bio-Rad Variant II Series 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.

The Bio-Rad Variant II Series 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

The Bio-Rad Variant II Series does not collect PII directly from individuals.

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 (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.	The MTF may utilize contractor services to support this product. Contractual language that safeguards PII and/or PHI includes: "The Contractor shall comply with DoD Directive 8500.1, "Information Assurance (IA)," DoD Instruction 8500.2, "Information Assurance (IA) Implementation," DoD Directive 5400.11, "DoD Privacy Program," DoD Manual (DoDM) 6025.18, Implementation of the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule in DoD Health Care Programs and DoD 5200.2-R, Personnel Security Program Requirements.
☒ 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

☒ Existing DoD Information Systems ☐ Commercial Systems

☐ Other Federal Information 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)*

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.

The system does not collect and maintain records about an individual where the records is retrieved by the individual's name, number or unique identifier IAW the Privacy Act of 1974, as amended. (Chapter 55 of Title 10 USC, §1071 - 1106.)

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.

Mission Schedules:
- Intermediary Records: 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: Exported patient record information is maintained in the appropriate electronic health record system i.e. MHS Genesis.

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 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 USC 301, Departmental Regulations; 10 USC 136, Under Secretary of Personnel and Readiness; 10 USC Ch. 55, Medical and Dental Care; Public Law 104-191, Health Insurance Portability and Accountability Act of 1996; 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 (MTFS); DoD Manual 6025.18, Implementation of the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule in DoD Health Care Programs.

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.

OMB approval is not required as 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).