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:

Ortho Vitros Series Analyzer Version 3.x AI

2. DOD COMPONENT NAME:

Defense Health Agency

Cyber Logistics

3. PIA APPROVAL DATE:

07/10/23

SECTION 1: PII DESCRIPTION SUMMARY (FOR PUBLIC RELEASE)

a. The PII is: *(Check one. Note: foreign nationals are included in general public.)*

	From members of the general public		From Federal employees and/or Federal contractors
x	From both members of the general public and Federal employees and/or Federal contractors		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	x	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.

Ortho Vitros Series is a collection of automated hematology analyzers (3600, 4600, 5600, XT3400, XT7600) used in clinical laboratories for the treatment and diagnosis of medical disorders that include Covid-19 and various autoimmune diseases. The analyzer can be configured to use PII or it can be configured to use a barcode but the configuration is solely up to the MTF. The analyzers provide for critical process monitoring and complete management of system maintenance and quality control.

Data element types include: Patient ID, Name, Address, Range Attribute, Birth Date, Age, Room, Sex, Collection Date, Collection Time, Physician ID, Physician name and address, and Protected Health Information (PHI). Ortho Vitros contains information on individuals who visit a Medical Treatment Facility - retirees, dependents, and active duty members.

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's tests and results.

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 can be used without connection to a Laboratory Information System in which case PII will not be collected. If the Vitros analyzer is connected to a LIS, then the Vitros Analyzer is not the initial collection point for the PII. The PII is obtained from an existing DoD information 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 is not the initial collection point for the PII. The PII is obtained from an existing DoD information 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

This system is not the initial collection point for the PII. The PII is obtained from an existing DoD information System.

h. With whom will the PII be shared through data exchange, both within your DoD Component and outside your Component? *(Check all that apply)*

x	Within the DoD Component	Specify.	PII will be shared with authorized users at Medical Treatment Facilities.
	Other DoD Components	Specify.	N/A
	Other Federal Agencies	Specify.	N/A
	State and Local Agencies	Specify.	N/A
	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.	N/A
	Other *(e.g., commercial providers, colleges).*	Specify.	N/A

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		

Information sharing between DHA Laboratory Information System (LIS) and Ortho Vitros Analyzers_v3.

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)*
	Face-to-Face Contact		Paper
	Fax		Telephone Interview
x	Information Sharing - System to System		Website/E-Form
x	Other *(If Other, enter the information in the box below)*		

Ortho Vitros Series of Laboratory Analyzers interfaces with the LIS to collect PII.

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-

(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.

10 U.S.C 3013, Secretary of the Army; 10 U.S.C 1071-1085, Medical and Dental Care; 50 U.S.C Supplement IV, Appendix 454, as amended, persons liable for training and service; 42 U.S.C Chapter 117, Sections 11131-1112, Reporting of Information; 10 U.S.C. 1097a and 1097b TRICARE Prime and TRICARE program; 10 U.S.C. 1079, Contracts for Medical Care for Spouses and Children; 10 U.S.C 1079a, CHAMPUS; 10 U.S.C 1086, Contracts for Health Benefits for Certain Members, Former Members, and Their dependents; E.O. 9397 (SSN); DoD Instruction 6015.23, Delivery of Healthcare at Military Treatment Facilities (MTFs); DoD Directive 6040.37, Confidentiality of Medical Quality Assurance (QA) Records; DoD 6010.8-R, Civilian Health and Medical Program of the Uniformed Services (CHAMPUS); Army Regulation 40-66, Medical Record Administration and Health Care Documentation.

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 is not considered a public information collection in accordance with DoDM 8910.01, V2, Encl 3, paragraph 8b(5).