NBIMC - Frequently Asked Questions (FAQs):

This document provides various questions NBIMC has received overtime. Highlighted in blue are the topics for which questions are separated under for accessibility, relevance, and organization. If you feel the answers provided do not bring you enough clarity or you have an additional question not listed on this document, please feel free to email NBIMC at https://dha.bethesda.Walter-Reed-Med-Ctr.mbx.nbimc@health.mil.

Specimen Processing: Deficiencies/Rejects, Shipments, Center for Disease Detection (CDD) Protocols, Order Information and more

1. Due to the long weekend, our lab poured off and froze the samples on the shipping list, therefore, they will be sent out today. Is that, ok?

Yes, the specimen(s) will be viable for shipping. (See the <u>HIV Specimen Submission Guidelines</u> <u>CDD</u> -> p. 4-5 -> Procedures – Sample Handling). We will also forward your email with the specimen information to CDD for their awareness.

2. If HIV samples are shipped refrigerated, do they need to be poured off or can they remain in the original SST tubes?

We need to receive samples that are in <u>SST tubes within 7 days from the draw date</u>. If the samples are not going to arrive within 7 days, please pour them off into the aliquot tubes that CDD provides and freeze them.

3. What are the requirements for shipment of specimens?

For specimen shipment requirements, NBIMC and CDD abide by the "Manufacturer Insert for ARCHITECT HIV Ag/Ab Combo: Storage; Serum or plasma specimens should be stored for no longer than 3 days at room temperature or 7 days at 2 to 8°C following specimen collection". If a storage period greater than 7 days is anticipated, the specimens should be removed from the clot, red blood cells, or separator gel, and the serum or plasma should be stored frozen at -20°C or colder. No more than 5 freeze-thaw cycles should be performed on any sample prior to testing. (See the HIV Specimen Submission Guidelines CDD- p. 4-5 -> Procedures – Sample Handling).

4. What is the stability for refrigerated HIV samples?

Refrigerated samples need to arrive within 7 days from the draw date.

5. Is there a Standard Operating Procedure for HIV specimen shipping for sites to reference to ensure they are abiding by all specimen shipping requirements?

The <u>HIV Specimen Submission Guidelines CDD</u> is meant to provide support for sites by detailing the sample submission process, including how to place the barcode, pack, and send samples.

6. Why are my specimens being discarded?

All discarded specimens have a deficiency number or reject code associated with them, indicating the reasoning for why the specimen(s) was discarded. Once the reject code (D1-D9) is determined, utilize the <u>Deficiency Codes list</u> to learn about why your specimen was discarded and the necessary action(s) required to fix this issue. Please email <u>dha.bethesda.walter-reed-med-ctr.mbx.nbimc@health.mil</u> to be added to our distribution list to receive deficiency notifications.

7. How do I find the status of my orders/specimens? (ex. Batch #: DODHML-A1021-3144 (06/21/21) have been transmitted)

To research the status of specific orders and specimens, sites <u>must</u> send the barcode numbers and site Unit Identification Code (UIC) with their request to NBIMC. The testing lab does not receive any batch information, they only receive barcode numbers. Once NBIMC receives a site request, NBIMC will forward the information/request to CDD for their awareness and standby for their update and response.

8. Should sites proceed with requesting new shipping materials that have the new permits attached?

Please contact the CDD If you have any questions, at 877.233.1337 or email: Military@cddmedical.com

9. Would you advise staff to apply the CDC import permit to the package containing specimens? (OCONUS or international locations only)

Yes, the package requires the CDC import permit for international shipping. The testing lab (CDD) sends the most current permits via email. If you are unable to locate the current permit, contact CDD at 877.233.1337 or email: Military@cddmedical.com.

10. Where do I find the CDD's CAP accreditation?

The link for CDD is provided below. Sites can retrieve the CAP accreditation documents directly from CDD's website.

https://www.cddmedical.com/AboutUs/Accreditations

11. How do orders get to CDD?

MRRS barcodes come into HIV Management System (HMS), are formatted into HL7 by HMS, and then forwarded from HMS to CDD.

12. When Personally Identifiable Information (PII) and other identifier information is missing from a blood specimen, what steps need to be taken?

The patients must be redrawn if there is PII and other identifier information missing and specimens missing PII and/or identifier information with be rejected, not tested and no results will be available. Specimens missing PII and other identifier information are not compliant with good laboratory practices and laboratory accreditation organizations' guidelines. The unique accession number, first and last name, date of birth (DOB)or Social Security Number, DoD ID needs be on the blood sample for every patient to get accurate results. We want to protect all service members, beneficiaries, and dependents HIV results.

Additionally, when there is a data mismatch with an order and blood sample accession label, a redraw for the patient is required. ALL submitted specimens must contain:

- 1. Unique accession number
- 2. first name and last name
- 3. DOB, SSN
- 4. DOD ID which matches the patient.

Note: Relabeling cannot be done at the CDD.

13. What does it mean when a specimen submitted is rejected due to the reasoning of "NOT SPUN CORRECTLY"?

The description "NOT SPUN CORRECTLY" is provided for samples that have red blood cells seeping through the gel barrier into the serum. These samples were either not spun fast enough or long enough for the gel barrier to settle/compress properly and maintain the separation. It can also describe samples that were not spun down at all. This deficiency error is deemed a D4 rejection by CDD.

"<u>HIV Specimen Submission Guidelines CDD</u>" is a good guide for site to follow and this document was created by our contracted lab, CDD.

Here is some additional information:

- 1. "Proper centrifuged sample" provide you visual aid of preferred and undesirable specimen.
- 2. "<u>Centrifuge Instructions</u>" provides you with detailed guidance on how to use centrifuge correctly.

Common reasons why specimens are rejected due to not spun correctly:

- 1. The sample was not spun down in a centrifuge at all
- 2. The sample was not spun fast enough
- 3. The sample was not spun for the correct amount of time

Numbers 2 and 3 lead to the red blood cells breaking through the gel barrier into the serum.

Additionally, we would recommend each site check their centrifuge preventive maintenance date, along with ensuring proper maintenance is conducted per the manufacture guideline. Reviewing theses dates and guidelines will increase the probability of properly calibrated centrifuging as well.

14. If there is a data mismatch with an order and blood sample, what needs to occur to resolve this issue?

When there is a data mismatch with an order and blood sample accession label, the patient needs to be redrawn. All submitted specimens must contain the unique accession number, first name and last name, DOB, SSN, and DoD ID which matches the patient. **CDD will not complete any relabeling in these situations.**

Additionally, deficiencies reports are sent daily from NBIMC or CDD to notify sites of deficient submitted specimens, including those with mismatched data. Therefore, please be sure to monitor these emails to ensure specimens are tested timely.

Redraws for patient(s) are required when a data mismatch with an order and blood sample accession label exists. Submitted specimen(s) must contain:

- 1. Unique accession number
- 2. first name and last name
- 3. DOB, SSN
- 4. DOD ID which matches the patient.

Relabeling cannot be done at the CDD.

HIV Testing: MRRS Updates, Testing Location Details, MRRS Result Visibility

15. Who can help me with MRRS updates?

Please send an email with the Service Member(s) full name, and DOD ID to the NBIMC group email: dha.bethesda.Walter-Reed-Med-Ctr.mbx.nbimc@health.mil.

16. How long does it take for HIV test results to become visible on MRRS?

Typically, HIV results are automatically released by CDD and should appear in MRRS within 2 hours. However, if the results transmitted involve barcodes from the Army, Air Force, or a military branch other than the Navy or USCG, then results can take up to 30-60 days to be updated in MRRS. If additional reviews are required, result visibility on MRRS may be delayed. When in doubt that results are not reflected on MRRS appropriately, please email dha.bethesda.walter-reed-med-ctr.mbx.nbimc@health.mil with the Service Member(s) full name, and DOD ID.

17. Can we use a civilian provider or VA result to update the HIV readiness in MRRS?

We cannot use civilian provider or (VA) result to update the HIV readiness in MRRS. HIV results from private/civilian providers are not compliant with the <u>SECNAVINST 5300.30</u> and <u>DODI 6485.01</u>. In these instructions, testing for HIV must be reported to the Defense Medical Surveillance System (DMSS), and the samples must be sent to the DoD Serum Repository. The member will need to go to a Navy MTF or NOSC near the service member location. Additionally, screening tests ordered outside of Force Testing are unacceptable due to this test order will not include the required split specimen sent to the DoD Serum Repository.

- 18. <u>Scenario:</u> A service member who knows he/she is positive for HIV and has a confirmed HIV positive test in MRRS is due for their biannual HIV force testing for the Navy Reserves. However, the member wishes not to have the test performed due to the trauma it causes. <u>Question -</u> Is there an exception to a policy to avoid force testing for known positive members?
 - 1. Maintaining the usual biannual HIV force screening protects service members medical privacy by treating the individual equal to all servicemembers. Continuing with the usual HIV screening allows the member to remain anonymous instead of being flagged as "exempt" or "Not Medically Ready" in MRRS. Refusing to follow this policy for Service Members Living with HIV (SMLWH) would risk exposing their HIV status unnecessarily. MRRS only captures the date screening was performed (not the screening results), so there is no way MRRS can share service members HIV statuses. Enclosure (3) paragraph 1.c of <u>SECNAVINST 5300.30</u> states that service members should not be segregated based screening or confirmatory tests. NBIMC's interpretation of this clause is that SMLWH should not be segregated based on their HIV status, and that potential actions causing members to stand out in MRRS should be avoided. These practices truly safeguard the privacy of service members with HIV infection.
 - 2. HIV force testing sustains the DOD Serum Repository's policies. The HIV force screening lab tests are the only way for service members' serum to be sent to the DOD Serum Repository, an important source of DOD medical research. The Repository receives samples from remaining serums from HIV testing programs within the DOD. Excluding SMLWH from the HIV screening would preclude their serum from being sent to the repository and deems any data gained from those samples as unavailable.
- 19. If a service member (SM) cannot visit an approved facility or MTF to complete their HIV testing, is there another option for them to complete testing elsewhere?

Utilizing Leidos QTC Health Services is another option for completing HIV force testing. Please contact the customer service department using the link below prior to visiting their location.

https://www.qtcm.com/government/military-readiness/

Further testing location details for:

- SMs in Reserve Components, active-duty SMs enrolled in TRICARE Prime Remote, and/or United States Coast Guard (USCG)/Reserve SMs:
 - All DOD Reservist, Active Duty enrolled in Tricare Prime Remote (less Air Force and Space Force), and Department of Homeland Security USCG/Reserve Service Members can use Reserve Health Readiness Program (RHRP) for HIV blood draws.
 - Once drawn, samples are shipped to CDD for both Army and Maritime to undergo processing and CDD notifies applicable Service Components of the test results.

- RHRP does not support Reserve or Active-Duty Air Force and Space Force SMs for HIV blood draws.
- SMs should follow normal RHRP procedures to request medical readiness and deployment related services by following their Service Components guidelines and contacting the RHRP supporting contractor (Leidos QTC, link below).

https://www.qtcm.com/government/military-readiness/

Further test order information below:

- HIV blood draws are ordered by calling the RHRP Call Center or placing requests in the RHRP Service Component portal, or RHRP SM portal.
- HIV blood draws can be provided in "Group Events". "Group Events" involve the collection of large numbers (minimum of 30) of SMs typically ordered by Commanders/Unit.
- HIV blood draws can also be provided individually in a RHRP network providers office or clinic in the civilian community.

20. I need assistance with DNA results failing to update in Medical Readiness Reporting System (MRRS), can NBIMC assist me with this?

Unfortunately, NBIMC is unable to update DNA results in MRRS. To inquire about DNA result updates, please directly contact the medical readiness department and submit a MRRS ticket for the DNA update. NBIMC does not have DNA visibility on the MRRS application or information regarding who completes updates on other readiness requirements other than HIV testing requirements.

21. Can I get Force Testing blood draw at Walter Reed without appointment or doctor's order (Walk in)?

Service Members can get their Force Testing blood draw at Walter Reed National Military Medical Center in either Bldg. 9 or 19. Visit the Laboratory (phlebotomy) front desk.