



DEPARTMENT OF VETERANS AFFAIRS
Washington DC 20420

January 25, 2017

The Honorable Carolyn N. Lerner
Special Counsel
U.S. Office of Special Counsel
1730 M Street, NW, Suite 300
Washington, DC 20036

RE: OSC File No. DI-16-3664

Dear Ms. Lerner:

I am responding to your September 26, 2016, letter to the Department of Veterans Affairs (VA) regarding allegations made by a whistleblower at the Miami VA Medical Center, Pathology and Laboratory Medicine Service, Miami, Florida, (the Medical Center). The whistleblower made three allegations regarding screening procedures for the Human Immunodeficiency Virus (HIV) at the Medical Center, and that these may constitute violations of law, rules or regulations, and gross mismanagement, which may lead to a substantial and specific danger to public health. The Secretary has delegated to me the authority to sign the enclosed report and take any actions deemed necessary as referenced in 5 United States Code § 1213(d)(5).

The Under Secretary for Health directed the Office of the Medical Inspector to assemble and lead a VA team to conduct an investigation. The report substantiates none of the three allegations and makes five recommendations to the Medical Center.

Thank you for the opportunity to respond.

Sincerely,

A handwritten signature in black ink that reads "Gina S. Farrisee".

Gina S. Farrisee
Acting Chief of Staff

Enclosure

**DEPARTMENT OF VETERANS AFFAIRS
Washington, DC**

**Report to the
Office of Special Counsel
OSC File Number DI-16-3664**

**Department of Veterans Affairs
Miami VA Medical Center
Miami, Florida**



Report Date: January 3, 2017

TRIM 2016-D-2518

Executive Summary

The Under Secretary for Health for the Department of Veterans Affairs (VA) requested that the Office of the Medical Inspector (OMI) assemble and lead a VA team to investigate allegations lodged with the Office of Special Counsel (OSC) concerning the Miami VA Medical Center (hereafter, the Medical Center), Pathology and Laboratory Medicine Service (PLMS), located in Miami, Florida. Whistleblower (hereafter, the whistleblower) alleged that Medical Center officials failed to follow current guidelines for Human Immunodeficiency Virus (HIV) testing, resulting in inaccurate results which may have constituted a violation of law, rule or regulation, and a substantial and specific danger to public health. The VA team conducted a site visit to the Medical Center on October 11–14, 2016.

Specific Allegations of the Whistleblower

1. The Miami VA Medical Center's procedures for conducting HIV testing are not in compliance with VHA Directive 1113;
2. Patients who were tested for HIV at the Miami VAMC since October 2015 may have received inaccurate diagnoses; and
3. Miami VA Medical Center management officials ignored Whistleblower repeatedly expressed concerns regarding the facility's noncompliance with VHA Directive 1113 and continued use of outdated HIV testing.

VA **substantiated allegations** when the facts and findings supported that the alleged events or actions took place and **did not substantiate allegations** when the facts and findings showed the allegations were unfounded. VA was **not able to substantiate allegations** when the available evidence was not sufficient to support conclusions with reasonable certainty about whether the alleged event or action took place.

After careful review of findings, VA makes the following conclusions and recommendations.

Conclusions for Allegation 1

- VA **does not substantiate** the Miami VA Medical Center's procedures for conducting HIV testing are not in compliance with VHA Directive 1113.
- The Medical Center's Healthcare System Policy Memorandum (HSPM) contained the required sections to comply with the Directive and was published 6 months prior to the deadline.

- The Medical Center was actively pursuing multiple alternatives for confirmatory testing pending acquisition of the new equipment and was compliant with the Centers for Disease Control's (CDC) alternative testing sequence.
- Staffing vacancies delayed processing requests for new equipment purchases.
- PLMS did not have policies for internal coordination for specimen testing involving different sections.

Recommendations to the Medical Center

1. Provide enough staff training to ensure consistent availability of personnel in the procurement process in each section.
2. Provide appropriate administrative and human resource support to PLMS to address vacancies and other staff issues.
3. Develop a policy to provide periodic updates to all PLMS staff regarding new internal and external guidelines/procedures/recommendations/equipment, staying attuned to possible conflicts and/or redundancies between sections.
4. Improve internal coordination and communication with PLMS especially related to specimen testing that crosses sequentially between sections.

Conclusions for Allegation 2

- **VA does not substantiate** that patients tested for HIV at the Medical Center since October 2015 may have received inaccurate diagnoses.
- The Medical Center has a policy that outlines reporting and referral of newly diagnosed HIV patients.
- The Medical Center has a policy on how and whom to notify in case of positive or inconsistent results.

Recommendation to the Medical Center

- None.

Conclusions for Allegation 3

- **VA does not substantiate** that the Medical Center's management ignored **Whistleblower** repeatedly expressed concerns regarding the facility's noncompliance with Directive 1113 and continued use of outdated HIV testing.

- Medical Center leadership immediately responded to concerns of potential noncompliance with CDC-recommended laboratory testing algorithms, when they became aware.
- The Medical Center actively modifies HIV policies and procedures in response to lessons learned.

Recommendations to the Medical Center

5. Review ethical responsibilities of leadership with PLMS supervisors.

Summary Statement

OMI has developed this report in consultation with other Veterans Health Administration (VHA) and VA offices to address OSC's concerns that the Medical Center may have violated law, rule or regulation, or created a substantial and specific danger to public health. In particular, the Office of General Counsel has provided a legal review, VHA Human Resources has examined personnel issues to establish accountability, and the Office of Accountability Review has reviewed the report and has or will address potential senior leadership accountability. VA found no violations of VA and VHA policy, and notes no substantial and specific danger to public health at the Medical Center.

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I. Introduction

The Under Secretary for Health for the Department of Veterans Affairs (VA) requested that the Office of the Medical Inspector (OMI) assemble and lead a VA team to investigate allegations lodged with the Office of Special Counsel (OSC) concerning the Miami VA Medical Center (hereafter, the Medical Center) located in Miami, Florida.

Whistleblower (hereafter, the whistleblower), Supervisor, Chemistry Section, alleged that Medical Center officials failed to follow current guidelines for Human Immunodeficiency Virus (HIV) testing, resulting in inaccurate results which may have constituted a violation of law, rule or regulation, and a substantial and specific danger to public health. The VA team conducted a site visit to the Medical Center on October 11–14, 2016.

II. Facility Profile

Part of Veterans Integrated Service Network (VISN) 8, the Miami VA Healthcare System is a Joint Commission accredited, Veterans Health Administration (VHA) complexity level 1a facility serving Veterans in three South Florida counties: Miami-Dade, Broward, and Monroe, with an estimated Veteran population of 154,000.¹ The Medical Center in downtown Miami supports two major satellite outpatient clinics located in Sunrise (Broward County) and Key West (Monroe County); and five community-based outpatient clinics located in Homestead (Miami-Dade); Key Largo (Monroe); Pembroke Pines, Hollywood, and Deerfield Beach (Broward). A Healthcare for Homeless Veterans Clinic is located about a mile from the Medical Center.

III. Specific Allegations of the Whistleblower

1. The Miami VA Medical Center's procedures for conducting HIV testing are not in compliance with VHA Directive 1113;
2. Patients who were tested for HIV at the Miami VAMC since October 2015 may have received inaccurate diagnoses; and
3. Miami VA Medical Center management officials ignored **Whistleblower** repeatedly expressed concerns regarding the facility's noncompliance with VHA Directive 1113 and continued use of outdated HIV testing.

IV. Conduct of Investigation

The VA team conducting the investigation consisted of **OMI Team** M.D., Interim Medical Inspector, **OMI Team** RN, MS, Clinical Program Manager, and **OMI Team** Health Systems Specialist, all of OMI; **OMI Team** M.D., Ph.D., MBI, National Director, VHA HIV, Hepatitis, and Public Health Pathogens Programs; and

¹ Complexity Level 1a facilities have the largest levels of volume, patient risk, teaching and research. They also contain the largest number and breadth of physician specialists. Level 1a facilities contain level 5 ICU units. <http://vaww.bdc.med.va.gov/vapublic/detailcom.htm>.

OMI Team Chief, Employee and Labor Relations, Captain James A. Lovell Federal Health Care Center, Chicago, Illinois. VA reviewed relevant policies, procedures, professional standards, reports, memoranda, and other documents listed in Attachment A. We toured the Medical Center's Pathology and Laboratory Medicine Service (PLMS), and held entrance and exit briefings with its leadership.

The following attended the entrance briefing: **Employee 1** Director; **Employee 2** M.D., Acting Associate Director; **Employee 3** Assistant Director; **Employee 4** Chief of Staff (CoS); **Employee 5** Associate Director, Patient Care Services; **Employee 6** M.D., Chief Medical Service; **Employee 7** M.D., Medical Director, Infection Control; **Employee 8** M.D., Chief, PLMS; **Employee 9** Chief Medical Technologist (CMT); **Employee 10** Accreditation-Quality Management Specialist; **Employee 11** Administrative Officer; **Employee 12** Quality, Safety & Value-Quality Management Intern; **Employee 13** Quality Management Coordinator; and, by teleconference, **Employee 14** Chief, Quality Management Service.

VA interviewed the whistleblower by phone on October 4, 2016, and in person on October 12, 2016. He has worked in the PLMS since 2005. We interviewed the following Medical Center employees:

- **Employee 1** Director
- **Employee 4** M.D., CoS
- **Employee 7** M.D., Medical Director, Infection Control
- **Employee 16** M.D., Chief, Infectious Disease (ID) Section and Facility HIV Lead Clinician (Chief, ID & HIV)
- **Employee 8** M.D., Chief, PLMS
- **Employee 17** M.D., Physician, Patient Aligned Care Team (PACT)
- **Employee 18** M.D., Physician, PACT
- **Employee 13** RN, Coordinator, Quality Management
- **Employee 19** RN, Infectious Disease
- **Employee 9** CMT
- **Whistleblower** Supervisor, Chemistry Section
- **Employee 20** Supervisor, Special Immunology Section (SIS)
- **Employee 21** Technician, SIS
- **Employee 22** Technician, SIS

The following attended the exit briefing: **Employee 1** Director; **Employee 2** Acting Associate Director; **Employee 3** Assistant Director; **Employee 4** MD CoS; **Employee 5** Associate Director, Patient Care Services; **Employee 6** MD, Chief Medical Service; **Employee 7** MD, Medical Director, Infection Control; **Employee 8** MD, Chief, PLMS; **Employee 9** CMT; **Employee 10** Accreditation-Quality Management Specialist; **Employee 11** Administrative Officer; **Employee 12** Quality, Safety & Value-Quality Management Intern; **Employee 13** Quality Management Coordinator; **Employee 14** Chief, Quality Management Service; and **Employee 15** Patient Safety Officer, VISN 8.

VI. Findings, Conclusions, and Recommendations

Background

VHA Directive 1113 defines general policies and programs related to testing for HIV screening that is part of the routine medical care VHA offers to Veterans regardless of whether they have risk factors for HIV infection.² VHA recommends routine screening for all adults age 18 and older, at least once, and annually for HIV-negative adults with defined risk factors.³ The intent of routine screening is to diagnose HIV infection as early as possible and link patients to treatment and care to reduce the possibility of undiagnosed individuals spreading the infection to others. Routine HIV screening is unrelated to a specific exposure or event. HIV screening requires documentation of verbal consent from the Veteran.

The Centers for Disease Control (CDC) recommendation, *Laboratory Testing for the Diagnosis of HIV Infection*, June 27, 2014, provides both a recommended (see Figure 1, Attachment B) and an alternate testing sequence.⁴ Until these new recommendations, the standard since 1987 was a two-step process for HIV screening using enzyme-linked immunosorbent assay (ELISA) as the screening test and the Western blot (WB) as the confirmatory test.⁵

The algorithm recommends that laboratories conduct initial testing for HIV with a Food and Drug Administration (FDA)-approved antigen/antibody combination (4th generation) immunoassay that detects both HIV-1 and HIV-2 antibodies for established infection, and HIV-1 p24 antigen to screen for acute infection with HIV-1.⁶ If the results of this screening test are reactive, CDC recommends additional testing with an FDA-approved antibody immunoassay that differentiates HIV-1 antibodies from HIV-2 antibodies.⁷ Specimens that are initially reactive on the screening test (HIV-1/HIV-2 antibody and p24 HIV antigen) and nonreactive or indeterminate on the confirmatory test (HIV-1/HIV-2 antibody differentiation immunoassay), should be tested with an FDA-approved HIV-1 nucleic acid test (NAT).⁸

The CDC's alternative testing sequence allows for substitution for some of the assays in the recommended algorithm and includes guidance when using other FDA-approved assays. The alternate testing sequence references use of the 3rd generation HIV-1/HIV-2 immunoassay as the screening test followed by additional testing in the recommended algorithm. If a 4th generation test is the initial screening, the alternative testing sequence recommends the use of the HIV-1 WB or HIV-1 immunofluorescent

² VHA Directive 1113, *Testing for Human Immunodeficiency Virus in Veterans Health Administration Facilities*, May 5, 2015.

³ Ibid.

⁴ *Laboratory Testing for the Diagnosis of HIV Infection*, Updated Recommendations <https://stacks.cdc.gov/view/cdc/23447>.

⁵ Centers for Disease Control, Public health service guidelines for counseling and antibody testing to prevent HIV infection and AIDS, MMWR 1987: 36:509-15.

⁶ Ibid.

⁷ Ibid.

⁸ Ibid.

assay (IFA) as the confirmatory test.⁹ If the results from the confirmatory test in this alternative testing sequence are negative or indeterminate, CDC recommends performing an HIV-1 NAT, and if the HIV-1 NAT is negative, performing an HIV-2 antibody immunoassay.¹⁰

There is individual variation between the time of exposure to HIV and the appearance of the various markers in the blood (see Figure 2, Attachment B). HIV ribonucleic acid (RNA) appears in the plasma at approximately day 11 post exposure, but peaks around day 25. This represents the actual virus, and is only detectable by NAT. HIV-1p24 antigen appears around day 15, and drops to zero around day 45. HIV-1 antibodies begin to appear around day 22 and represent an immune response by the patient.¹¹

Allegation 1

The Miami VA Medical Center's procedures for conducting HIV testing are not in compliance with VA Directive 1113.

Findings

In the past, the SIS section had done all the testing for HIV. When the requirements mandated coverage for all Veterans, the responsibility shifted to the Chemistry section because Chemistry had automated machines capable of 3rd generation testing that could complete assays more quickly. The SIS Supervisor reported that because of concerns with the high number of discordant results (positive screening and negative confirmatory tests), they began running NATs for these discordant samples as "test patients" to validate the WB results. If these NATs were positive on the discordant samples, their plan was to contact the ordering provider to request another sample for retesting, but none were ever positive. This process was not formalized in written policy.

As detailed above, VHA Directive 1113 outlines general policies and programs for HIV testing in VHA facilities. It requires each VHA facility to establish a written local HIV testing policy no later than May 5, 2016, that details routine and risk-based HIV screening. It also describes requirements and procedures for obtaining and documenting oral consent for HIV testing and details procedures for performing HIV testing (not HIV screening). The Directive presents procedures for timely patient notification of results and for timely linkage to care for patients newly diagnosed with HIV infection.¹² The Directive does not specifically outline laboratory procedures for HIV screening, but references ensuring availability of HIV testing assays that meet current

⁹ Ibid, p.19.

¹⁰ Ibid.

¹¹ *Laboratory Testing for the Diagnosis of HIV Infection, Updated Recommendations*

<https://stacks.cdc.gov/view/cdc/23447>.

¹² VHA Directive 1113, *Testing for Human Immunodeficiency Virus in Veterans Health Administration Facilities*, May 5, 2015.

CDC recommendations. There was no required date for implementation of the new CDC algorithm.¹³

The Medical Center published Healthcare System Policy Memorandum (HSPM) 111-03-15, *Screening for Human Immunodeficiency Virus Infection*, on October 20, 2015, 6.5 months ahead of the 1-year limit required by the Directive. The HSPM contains a reference to the CDC recommendations, stating specifically: "The testing will be routinely performed by the laboratory in a two-step procedure. The initial testing will be a screening EIA [enzyme immunoassay], and if positive, confirmed by Western Blot. A positive test is reported only if the specimen is positive on both assays." The HSPM names the Director, PLMS, as the person responsible for "Ensuring availability of HIV testing assays that meet current CDC recommendations." The Medical Center provided a copy of a contract with Quest Diagnostics (VA24B-16-C-0041, awarded November 9, 2015, and effective January 1, 2016) indicating that the contract's purpose was to provide reference laboratory testing for VISN 8 medical facilities, which includes HIV testing support.

We reviewed factors that affected the sequence of specific HIV assays used at the Medical Center. In interviews, the whistleblower stated that he began looking for a replacement for the Vitros ECIQ 3rd generation testing equipment contract (V797P-7126A) from Ortho Diagnostics, because the Medical Center's contract expired on September 30, 2015, with no option year to extend further. During this time and with the approval of the previous Laboratory Manager (who left VA employment without notice June 25, 2015), he determined that the Medical Center owned a piece of equipment that could meet the requirement for 4th generation HIV testing (Architect Plus i1000 Multiplex Analyzer). The Chief, PLMS, was not informed of this decision or the subsequent procurement at this time. The whistleblower requested contracting support for the 4th generation HIV testing equipment on June 6, 2015. The Medical Center provided a copy of a modification to the contract V79P-7335A. The modification, dated September 1, 2015, (#P00002) was effective October 1, 2015. The modification allowed the necessary reagents for the Architect Plus i1000 equipment to be ordered. Further, it identified the whistleblower as the program manager and contracting officer's representative (COR).

During her interview, the Chief, PLMS, (who became the Acting Chief in May 2014, a month before the release of the new CDC guidelines) was not aware of the changes in the recommended screening algorithm at that time. She was not involved with the procurement of the 4th generation testing materials and stated it is the CMT's responsibility to coordinate activities between the Chemistry Section (4th generation test) and the SIS (confirmatory WB and NAT). The prior CMT had not coordinated the two sections and left abruptly in June 2015, after the whistleblower ordered the 4th generation equipment.

The Chief, ID & HIV, the subject matter expert, was the Medical Center's responsible lead to develop the new HIV memorandum. He reported collaborating with experts in

¹³ Ibid.

PLMS, Medicine Service, and Quality Management. The Chief, ID & HIV reported to us that prior to writing HSPM 111-03-15, he had not read the CDC's updated recommendations for HIV testing. The Director approved HSPM 111-03-15 on September 14, 2015, with the requirement for EIA and WB testing. This was before the effective date of the contract for the new 4th generation test. The Chief, PLMS stated that she told the whistleblower to stop performing the 4th generation testing the first week of October 2015, because he had not submitted required correlation or validation tests, and had not developed a standard operating procedure (SOP) outlining the process for running the new 4th generation test. After completing the evaluation and validation tests, and SOP documentation, the Chemistry Section began HIV testing with the Architect Plus i1000 HIV (4th generation) on October 8, 2015.

On October 29, 2015, the Chief, ID & HIV replied to an email from the whistleblower, where he indicated the testing protocol needed to be adapted to the new algorithms. The Chief, PLMS, contacted the Chief, ID & HIV, her subject matter expert, who responded, "...do not report out unless the test is confirmed-as has been the method used with older two step approach HIV1 tests-an EIA positive was not reported as positive unless confirmed by western blot...."

An October 30, 2015, email from the whistleblower to the Chief, ID & HIV, Chief of Medicine, Chief, PLMS, Laboratory Manger, and SIS Supervisor states: "I'm also looking for a supplemental test to differentiate within the HIV-1 Ab and HIV-2 Ab to reduce the turnaround time from two days or more for the WB depending on the batching to a 45 minutes test." He raised no concerns in this email regarding 4th generation screening and confirmatory testing.

On November 5, 2015, the whistleblower arranged a vendor demonstration of the Bio-Rad Laboratories Multispot HIV-1/HIV-2 Rapid Test (confirmatory test) that both he and the SIS Supervisor attended. The SIS Supervisor recalled attending the Multispot HIV-1/HIV-2 Rapid Test vendor demonstration with the whistleblower and stated he was under the assumption that the whistleblower was handling the procurement of the new equipment since he had said so in an email when arranging the vendor demonstration. He did not speak to the whistleblower or the CMT about this procurement again after the November 2015 meeting until the issue was raised again in 2016. The whistleblower told us that on that same day in November 2015, a colleague from another facility told him by email that the vendor planned to eliminate the Multispot HIV-1/HIV-2 Rapid Test and thus the only available replacement was the GEENIUS HIV1/2 Supplemental Assay. The whistleblower did not pursue any details on the GEENIUS HIV1/2 Supplemental Assay because he stated that the Chief, PLMS, told him to "stay in his lane." The Chief, PLMS, denies telling the whistleblower to stop looking for replacement confirmatory tests and only recalls telling him to stop running the tests until the test was appropriately validated as noted above.

The Chief, PLMS, stated she had a meeting with the whistleblower, the Chief, ID & HIV, and the Medical Director, Infection Control, on November 5, 2015, to discuss using the alternative testing sequence. As noted above, the Chief, ID & HIV, (the Medical

Center's subject matter expert and the approval level for facility HIV testing policies), advised her that the alternative testing sequence they were utilizing was appropriate.

We interviewed the new CMT, who corroborated the dates and meetings provided by the Chief, PLMS. She recalled the issue with the Multispot HIV-1/HIV-2 Rapid test, and indicated that they had "started to move in that direction," but she then became aware the Multispot HIV-1/HIV-2 Rapid test was no longer going to be available. In addition, she reported that the change to the 4th generation testing had not been coordinated between the Chemistry Section and SIS by her predecessor, and therefore, it had not been budgeted.

The SIS Supervisor became aware of the new CDC guidelines when his section began receiving a large number of 4th generation positive samples that required processing in SIS. He stated that the whistleblower told him that the WB confirmatory test did not align with CDC recommendations. Because SIS concerns with discordant results continued with the 4th generation testing, the SIS staff added the ADVANCE HIV-1/2 ORAQUICK test as an HIV-1/HIV-2 antibody differentiation test (before running the NAT) to capture any HIV-2 infections missed by the WB.

We reviewed logs submitted by SIS showing results of ORAQUICK tests on patients with discordant results from October 2015 to October 11, 2016, and all were negative.

In July 2016, after inquiries from the Office of the Inspector General (OIG) and the White House about the HIV testing sequence, the Medical Center reevaluated its HIV testing. The Medical Center decided to adopt the CDC's recommended primary algorithm and obtain the new necessary equipment. The SIS Supervisor requested a quote for the GEENIUS assay from the vendor; however, the individual responsible for completing and submitting the new equipment procurement request was out on maternity leave. The whistleblower is a COR; however, the CMT reported that she was not aware that he could have completed the request. While awaiting procurement, the Medical Center developed SIS PLMS Policy # SI-002-16, June 20, 2016, putting in writing the alternate testing practice. In addition, the Medical Director, Infection Control Program, developed a flow chart approved on July 28, 2016, outlining the process for discordant results (see Figure 3, Appendix B). On August 15, 2016, recognizing a concern that Veterans did not always return for additional requested blood draws, they modified their collection of HIV screening samples to include a second vial to be held and available for NAT in case of a discordant result. This Veteran-centric approach eliminates the need for Veterans to return to the clinic to give another sample.

In September 2016, the Medical Center identified that the PLMS had not yet requested the GEENIUS assay equipment, and therefore, began sending all confirmatory tests to Quest, its contract laboratory. We reviewed the SIS log and there is no WB confirmatory testing in SIS after September 2016, while there are HIV confirmatory tests sent to Quest. Because of the contract testing, neither of the two July 2016 policies identified above applied at the time of the VA team's site visit.

We found evidence of a Form 2237 signed on October 11, 2016, for the purchase of the GEENIUS assay with a requested delivery date of November 1, 2016. On December 13, 2016, the contractor completed installation of the GEENIUS system at the facility.

Conclusions for Allegation 1

- **VA does not substantiate** that the Miami VA Medical Center's HIV testing procedures are not in compliance with VHA Directive 1113.
- The Medical Center's HSPM contained the required sections that complied with the Directive, and it was published 6 months prior to the deadline.
- The Medical Center was actively pursuing multiple alternatives for confirmatory testing, pending acquisition of the new equipment, and was compliant with the CDC's alternative testing sequence.
- Staffing vacancies delayed processing requests for new equipment purchases.
- PLMS did not have policies for internal coordination for specimen testing involving different sections.

Recommendations to the Medical Center

1. Provide enough staff training to ensure consistent availability of personnel in the procurement process in each section.
2. Provide appropriate administrative and human resource support to PLMS to address vacancies and other staff issues.
3. Develop a policy to provide periodic updates to all PLMS staff regarding new internal and external guidelines/procedures/recommendations/equipment, staying attuned to possible conflicts and/or redundancies between sections.
4. Improve internal coordination and communication with PLMS, especially related to specimen testing that crosses sequentially between sections.

Allegation 2

Patients who were tested for HIV at the Miami VAMC since October 2015 may have received inaccurate diagnoses.

Background

Screening HIV testing is random and not related to a particular exposure except by happenstance. Screening HIV tests detect the presence of disease using a quick and

inexpensive test that has a high *sensitivity* (ability to correctly identify those with disease), but moderate *specificity* (the ability to correctly identify those without the disease). This moderate *specificity* requires following the positive screening test with a more expensive and accurate confirmation test. A negative screening test rules out the presence of the disease and does not require additional testing because the *sensitivity* is high. The 4th generation test used by the Medical Center has 99.77 percent *sensitivity* for individuals at low risk for HIV infection, and 100 percent *sensitivity* for individuals with established HIV-1 and HIV-2 infection.¹⁴ The confirmatory WB testing has 99.9 percent *specificity* for HIV-1 infection.¹⁵ The ORAQUICK test has 99.9 percent *specificity* for HIV-1 and HIV-2.¹⁶ HIV-1 NAT testing has 100 percent *sensitivity* and 99.3 percent *specificity*.¹⁷

The 2014 CDC HIV recommendation increases the *sensitivity* of screening for early disease, which could result in earlier treatment and a decrease in the possibility of transmission of the virus. The new screening test can identify patients earlier in the window period, the most infectious period when the virus is present and before the development of antibodies.¹⁸

In calendar year 2015, the Medical Center had 52,788 unique Veterans with outpatient appointments, 25,849 of them (49 percent) had HIV screening at least once, and 26,939 need HIV screening. In that year, 2,650 Veterans consented to HIV screening, and 22 were confirmed positive, an overall proportion of 0.83 percent positive results.¹⁹ There are no known HIV-2 positive Veterans at the Medical Center. From 1987-2009, the CDC reported 166 HIV-2 cases present in the U.S., concentrated in the Northeast and primarily among individuals born in West Africa.²⁰ At the time of this report, the U.S. had 1.4 million cases of HIV, with HIV-2 cases representing 0.01 percent of this total.²¹

Findings

VA requested all discordant results from October 1, 2015, to October 11, 2016. The Medical Center produced eight discordant specimens from this time period, one of which occurred in a high-risk patient on pre-exposure prophylaxis (PrEP) who was noncompliant with PrEP. Because of the high-risk nature of this patient and in accordance with standard PrEP protocol, his provider simultaneously ordered both screening and NAT. The NAT result indicated an acute infection in the window period (i.e., the period where HIV-1 antibodies are undetectable), and his provider began antiretroviral treatment immediately. Another Veteran with a discordant result identified

¹⁴ FDA product insert for Abbott Architect HIV Ag/AB Combo Assay.

<http://www.fda.gov/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/LicensedProductsBLAs/BloodDisorderScreening/InfectiousDisease/ucm216291.htm>.

¹⁵ Characteristics of HIV tests, New York State Department of Health AIDS Institute <http://www.hivguidelines.org>.

¹⁶ Rapid HIV tests suitable for use in clinical settings (CLIA-moderate complexity).

http://www.cdc.gov/hiv/pdf/testing_listmodcompclinicalsettings.pdf.

¹⁷ Characteristics of HIV tests, New York State Department of Health AIDS Institute <http://www.hivguidelines.org>.

¹⁸ HIV Window Period, Testing, PEP and Acute Infection. NYSDOH AIDS Institute <http://www.hivguidelines.org>.

¹⁹ <https://vaww.vha.vaco.portal.va.gov/sites/PublicHealth/pophealth/hiv-testing/default.aspx>.

²⁰ MMWR July 29, 2011, Vol 60, No. 29 <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6029a3.htm>.

²¹ Ibid.

at the time of the testing was noted to have a possible inhibitor present in the sample and the laboratory requested the provider resubmit a new specimen. As per policy, no result was reported pending repeat testing. The provider acknowledged receiving the notification and initiated attempts to notify the Veteran of the need for additional testing. The Medical Center attempted to contact the Veteran five times between June 2016 and December 2016 (including a certified letter). The Veteran returned to the Medical Center, in December 2016, and submitted a new specimen, which was HIV positive, and treatment was initiated. The remaining six Veterans returned for retesting, and all were negative.

Primary care physicians have the highest likelihood of ordering and reviewing results of HIV screening, and VA interviewed two of them. Neither had received any discordant results. They described the Medical Center's process, which they stated includes clinical reminders to offer HIV screening and assists with documenting verbal consent and with ordering the appropriate tests. These clinical reminders are outlined in HSPM 111-03-15. If there are positive results, the laboratory calls the provider directly. Neither reported any issues with receiving or interpreting HIV results. HSPM 11-03-15 also includes instructions to refer newly diagnosed HIV positive cases immediately to Silver (HIV) Clinic personnel for rapid evaluation and initiation of treatment. The providers voiced an understanding of this practice.

PLMS had standard comments for use by SIS to report results to the ordering provider. In the event of a positive screening result with a negative confirmatory result the standard comment was: "Possible interfering substance in sample causing FALSE positive result in the antibody screening assay." The result is a critical value and requires a call to the provider, including a statement recommending resubmitting a specimen for repeat testing. In the event of a positive screening result and an indeterminate confirmatory result, the standard statement was, "Possible window period. Please resubmit for retesting in a few weeks. For additional information contact Dr ____, Special Immunology Chief at extension ____."

On October 5, 2016, the Medical Center's SOP CH-16-031-040 modified the standard comments for positive screening results. The standard comment for negative confirmatory results was changed to: "Performed by Quest Diagnostics Nichols Institute," and "No laboratory evidence of HIV-1 infection." If the Medical Center screening result is positive followed by a negative Quest screening result, the standard comment reads: "Screening results are inconsistent, please submit redraw for retesting." If the Quest screening results are positive, the provider must order additional HIV-2 testing (described as "QHIV-2 DNA" in the SOP), and the request must be approved by the PLMS Medical Director [Chief, PLMS]. The statement related to communicating the results to the provider is: "Critical value notified to & read back by." When this statement is used it also requires documentation of the provider's name, service, phone number, time/date of notification, and technician who provided the notification. Additionally, the SOP includes a requirement for notifying the Special Immunology Clinic and Lead HIV clinician among others for any positive or inconsistent results.

VA reviewed results of testing for the discordant results and confirmed use of these standard messages by the laboratory in their reports.

Conclusions for Allegation 2

- VA does not substantiate that patients tested for HIV at the Miami VAMC since October 2015 may have received inaccurate diagnoses.
- The Medical Center has a policy that outlines reporting and referral of newly diagnosed HIV patients.
- The Medical Center has a policy on how and whom to notify in case of positive or inconsistent results.

Recommendation to the Medical Center

- None

Allegation 3

Miami VA Medical Center management officials ignored Whistleblower repeatedly expressed concerns regarding the facility's noncompliance with Directive 1113 and continued use of outdated HIV testing.

Background

The physical space housing PLMS is a large open room with cubicles and specific sections divided by temporary walls. The Chemistry Section is approximately 20 feet from the SIS. There are no significant obstructions between these or other areas that would impede conversations. VHA computers with email capability are available at each work station.

Findings

VA asked the Quality Management Coordinator about the process for handling and communicating the changes required by VHA Directive 1113. She provided a series of emails, and a copy of HSPM 00QMPI-07-16, *Procedures for Preparation, Publication, and Maintenance of Healthcare System Policy Memoranda and Bulletins*, June 30, 2016, (replacing the version of November 14, 2012). The HSPM outlines the steps to ensure compliance with applicable VA policies.

On May 22, 2015, the Quality Management and Performance Improvement (QMPI) section sent a notification of the requirement to develop a local policy to comply with VHA Directive 1113 to the CoS and the Chief, PLMS, among others. On July 15, 2015, QMPI sent a follow-up email to the Chief, PLMS, requesting an update on progress and forwarded the email to the CMT, Supervisor, SIS, and Supervisor, Chemistry Section. There is evidence of a meeting attended by the Chief, PLMS, the CMT, and the Chief,

ID & HIV on August 25, 2015. Medical Center Leadership assigned the Medicine Service's Chief, ID & HIV, the task of completing the new policy by September 18, 2015. The Director signed the new HSPM on September 14, 2015.

As reported in response to Allegation 1, the CMT indicated that the whistleblower recommended the Multispot HIV-1/HIV-2 Rapid test, but found out shortly after this discussion that the Multispot HIV-1/HIV-2 Rapid test would not be available after December 2015. Only the GEENIUS assay would be available, and the Medical Center would have to purchase that system. The CMT produced copies of the minutes from the PLMS Chemistry Section monthly meeting. The minutes from the September 3, 2015, meeting mention changing screening for Hepatitis B from an older system to the Architect Plus i1000 but none of the supplied meeting minutes has no mention of any change to HIV screening or concerns with confirmatory testing from September 3, 2015, through June, 2016. There is evidence that the Chief, PLMS, and the whistleblower attended the meeting in October 2015.

VA asked the Chief, PLMS, about when she became aware that the whistleblower was concerned about the HIV testing. There is evidence of a meeting on November 5, 2015, where HIV confirmatory tests were one topic of discussion. She indicated that the end result of this discussion was that the Chief, ID & HIV (the Medical Center's subject matter expert and HIV Lead Clinician) approved the use of the alternative testing sequence which included the use of the 4th generation screening followed by confirmatory WB testing. She also recalled that the whistleblower had recommended that the facility consider the Multispot HIV-1/HIV-2 Rapid Test by Bio-Rad as the confirmatory test. She stated the whistleblower and the SIS Supervisor attended a Bio-Rad representative's demonstration of the Multispot HIV-1/HIV-2 Rapid Test earlier that day.

The Medical Director, Infection Control, recalls the November 5, 2015, discussions, but admitted that he was not an expert in testing or technology and relied on the subject matter expert. He stated his interest as a clinician is to obtain accurate results.

The CoS reported he first became aware of concerns about HIV confirmatory testing when he received OIG and White House inquiries in June 2016. He indicated that there had been "turmoil" in the laboratory for some time including issues with prior leadership in that area. He stated he had full confidence in the current leadership in PLMS.

The CoS, alerted by OIG and White House inquiries, made the Director aware of the HIV testing concerns on or about June 14, 2016. The Director reported this was his first knowledge of any concerns. On or about June 30, 2016, the CoS asked the Medical Director, Infection Control, to respond to the inquiries and investigate confirmatory HIV testing.

The Director reported the whistleblower delivered documents related to these complaints to him on or about June 30, 2016. The Director responded to the whistleblower by email on July 1, 2016, acknowledging receipt of the documents, and

provided the whistleblower a follow-up email on July 13, 2016, informing him that he had assigned staff to investigate the whistleblower's expressed concerns.

The Medical Director, Infection Control, investigated the concerns and provided the response July 2016. At the Director's request, he met with the whistleblower and reviewed the findings.

Conclusions for Allegation 3

- **VA does not substantiate** that the Medical Center's management ignored **Whistlebl** **Whistleblo** repeatedly expressed concerns regarding the facility's noncompliance with Directive 1113 and continued use of outdated HIV testing.
- Medical Center leadership immediately responded to concerns of potential noncompliance with CDC-recommended laboratory testing algorithms, when they became aware.
- The Medical Center actively modifies HIV policies and procedures in response to lessons learned.

Recommendation to the Medical Center

5. Review ethical responsibilities of leadership with PLMS supervisors.

VI. Summary Statement

OMI has developed this report in consultation with other VHA and VA offices to address OSC's concerns that the Medical Center may have violated law, rule or regulation, or created a substantial and specific danger to public health. In particular, the Office of General Counsel has provided a legal review, VHA Human Resources has examined personnel issues to establish accountability, and the Office of Accountability Review has reviewed the report to address potential senior leadership accountability. VA found no violations of VA and VHA policy, and notes no substantial and specific danger to public health at the Medical Center.

Attachment A

VHA Directive 1113, Testing for Human Immunodeficiency Virus in Veterans Health Administration Facilities, May 5, 2015.

<https://vaww.vha.vaco.portal.va.gov/sites/PublicHealth/pophealth/hiv-testing/default.aspx>.

Healthcare System Policy Memorandum (HSPM)111-03-15, Screening for Human Immunodeficiency Virus Infection, October 20, 2015.

HSPM 111-03-15, Screening for Human Immunodeficiency Virus Infection, October 20, 2015.

HSPM 00QMPI-07-16 Procedures for Preparation, Publication, and Maintenance of Healthcare System Policy Memoranda and Bulletins dated June 30, 2016.

PLMS Policy # SI-002-16, ORAQUICK Test for negative/indeterminate Western Blot Results, June 20, 2016.

CH-16-031-040, Abbott HIV Ag/Ab Combo, October 5, 2016.

Laboratory Testing for the Diagnosis of HIV Infection, Updated Recommendations <https://stacks.cdc.gov/view/cdc/23447>.

FDA product insert for Abbott Architect HIV Ag/AB Combo Assay <http://www.fda.gov/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/LicensedProductsBLAs/BloodDonorScreening/InfectiousDisease/ucm216291.htm> .

Characteristics of HIV tests, New York State Department of Health AIDS Institute <http://www.hivguidelines.org>.

Rapid HIV tests suitable for use in clinical settings (CLIA-moderate complexity) http://www.cdc.gov/hiv/pdf/testing_listmodcompclinicalsettings.pdf .

HIV Window Period, Testing, PEP and Acute Infection. NYSDOH AIDS Institute <http://www.hivguidelines.org>.

MMWR July 29, 2011, Vol 60, No. 29 <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6029a3.htm> .

Purchase orders related to procurement of equipment related to HIV testing; contract documents and agreements with facilities outside the Medical Center for HIV testing.

Centers for Disease Control, Public health service guidelines for counseling and antibody testing to prevent HIV infection and AIDS, MMWR 1987: 36:509-15.

Attachment B

HIV-1/2 antigen/antibody combination immunoassay

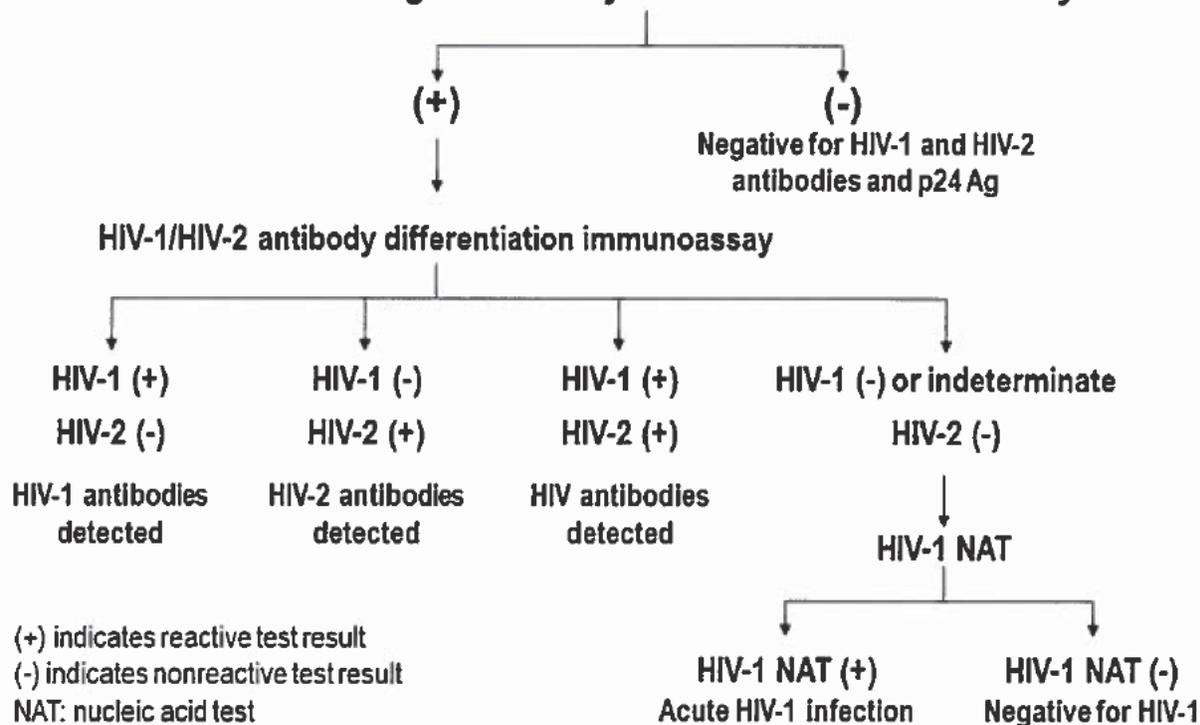


Figure 1: CDC Recommended Laboratory HIV Testing Algorithm for Serum or Plasma Specimens

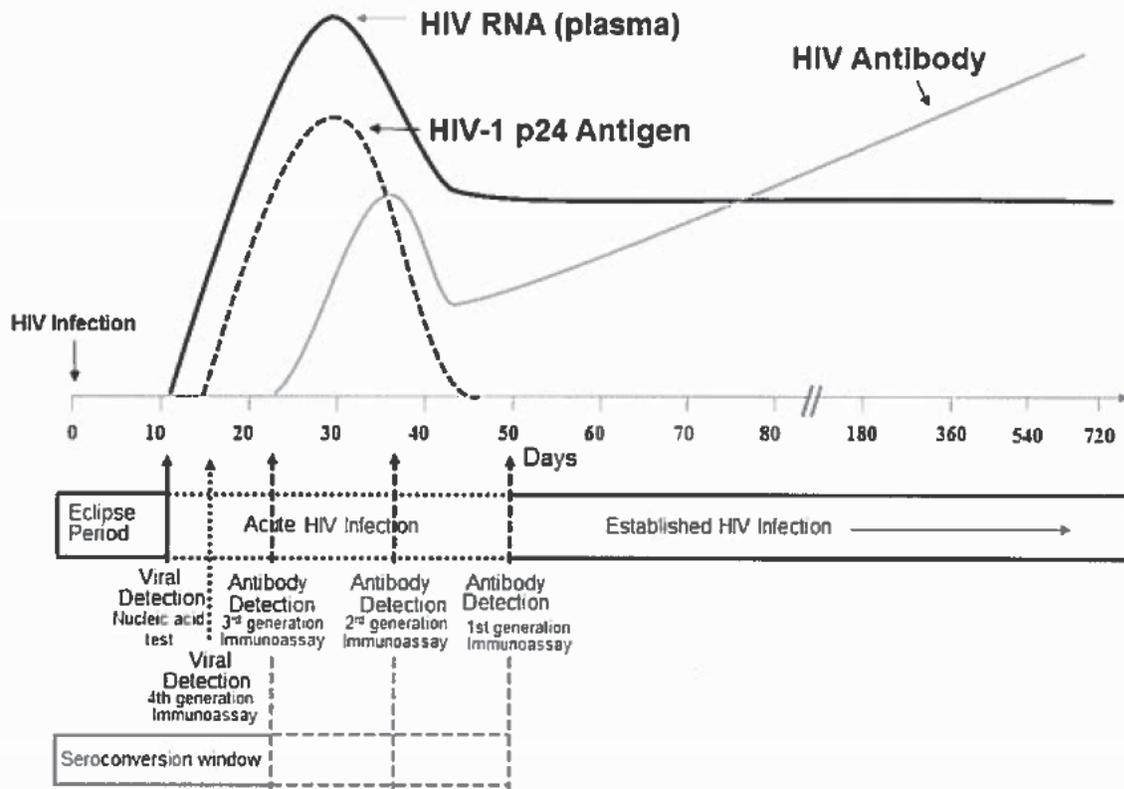


Figure 2: Sequence of appearance of laboratory markers for HIV-1 infection

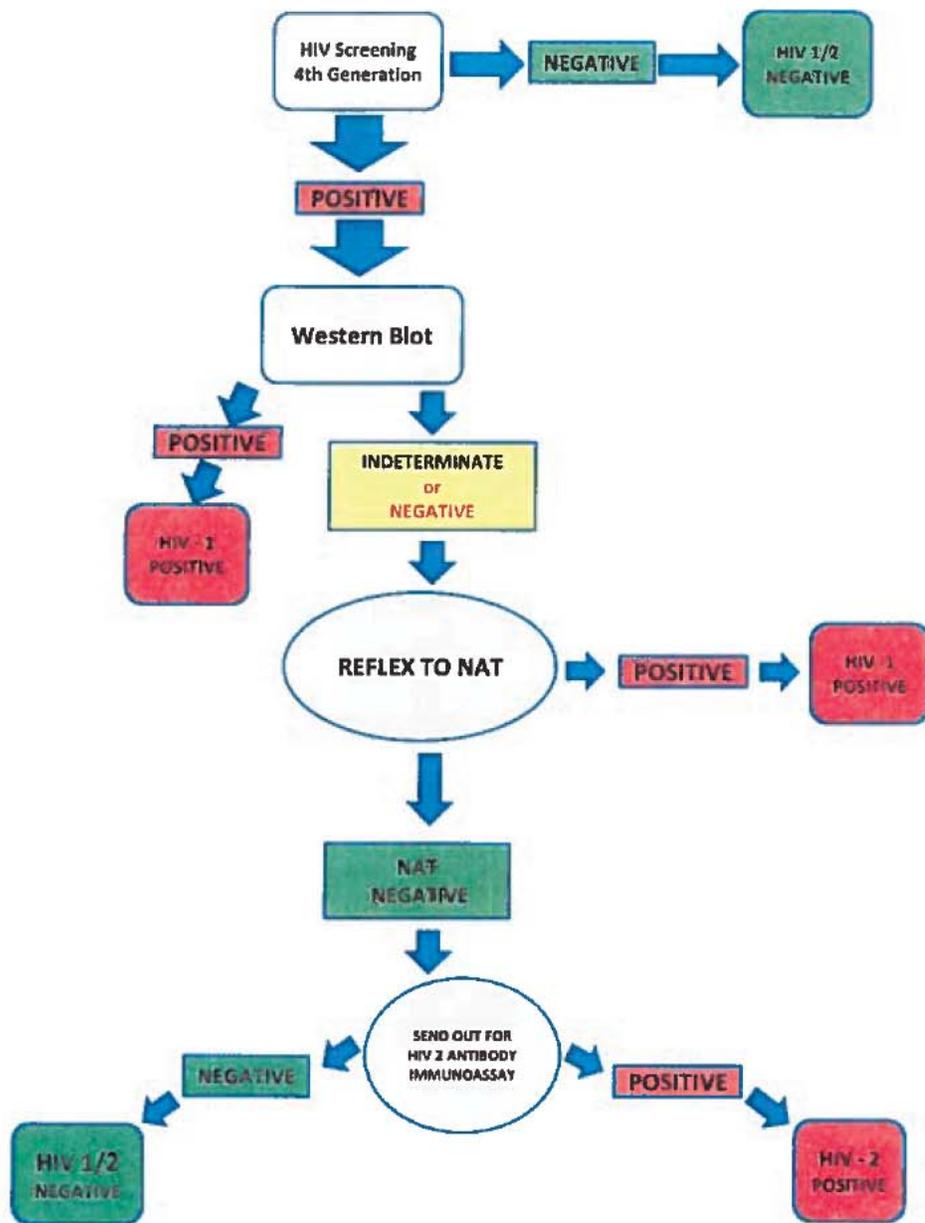


Figure 3: Miami VA Medical Center HIV screening process (approved July 28, 2016)