Mr. Roman Miguel
11317 SW 74th Terr.
Miami, FL 33173

~~March 23, 2017~~
Amended Comments (October 17, 2017)

Ms. Lynn Alexander
U.S. Office of Special Counsel
1730 M Street N.W.
Suite 218
Washington, D.C. 20036-4505

Dear Ms. Alexander:

I am responding to your January 27, 2017 letter and to the report you received from Department of Veterans Affairs (VA) Acting Chief of Staff Gina Farrisee. The VA's report is littered with falsehoods and inaccuracies meant to protect Miami VA management, so I appreciate the opportunity to provide my comments and to address the evidence, findings, and conclusions presented in the agency report.

As background, I submitted a completed copy of OSC Form 12 in May 14, 2016 disclosing (1) that Miami VA's was failing to comply with HIV testing procedures mandated by VA Directive 1113 and recommended by CDC Recommendations, Laboratory Testing for the Diagnosis of HIV Infection (June 27, 2014) at the time of my disclosure; (2) that certain patients may have received inaccurate diagnoses that VA Directive 1113 and the CDC Recommendations were designed to prevent; and (3) that Miami VAMC management ignored my concerns regarding HIV-testing compliance. I have also alleged retaliation for my whistleblowing in a separate complaint with the Office of Special Counsel. While the report does not address the subject, the retaliation has worsened over the past year after this and subsequent disclosures regarding management engaging in prohibited personnel practices, fraud, waste, and abuse.

While the VA and its investigators maintain they do not want to consider the retaliatory behavior of management in their investigation of the allegations contained in the report, they made it relevant by including facts that would appear to have no explanation to the reader. For example, the report mentions meeting minutes from September 3, 2015 to suggest that I never raised concerns regarding confirmatory testing in meetings with my employees. However, the Chemistry section is not responsible for confirmatory testing of HIV; rather, the section is responsible for screening. I chose the Architect i1000 because we already owned the equipment and because it does the required 4th-generation HIV

screening. My concerns about the confirmatory testing since October 2015 are well documented in my communications with PLMS management.

What the report omits is any mention of the retaliatory hostile work environment that I and others endure and the consequences we face when we blow the whistle on management. That section of the VA's report also omits mention of the November 20, 2015 meeting the Chief of PLMS called a "Behavior Evaluation". At that meeting, the Chief of PLMS ordered me to mind my own business and to leave the issue of confirmatory HIV-testing alone and refused to address the fact that the VA Directive mandated that she is responsible for implementing the new recommended algorithm. Implementing the CDC's Recommendations is the Chief's responsibility, not mine. One part of me knew that management would retaliate if I continued to speak up after that meeting and another part hoped that the Chief of PLMS would address the issue. I escalated my concerns outside of the Miami VA because I was concerned that the laboratory was past the deadline and still not following the CDC's recommendations. I had hoped my disclosures would help to address the issue, and they eventually did. In fact, all of the actions taken by management to address the confirmatory-testing issues happened after they learned of my disclosures.

The retaliation I have faced since my outside disclosures also reflect the intransigence of PLMS Management. A couple of examples: When PLMS Management was scrambling to address the issue after being informed that I had disclosed outside of the facility, the SIS Supervisor told me that all this mess was my fault because I spoke up. The Chief of PLMS attempted to dump the all of the responsibilities of HIV-testing onto me and prevent me from delegating any responsibilities to my staff even though I am a supervisor. Around the same time, the Chief of PLMS overrode my selection of a lead technologist. My unit had to function for months afterward without a lead technologist.

There are too many falsehoods and errors to address them all in this letter, but I will do my best to address a few of the major ones below. There are numerous emails that contradict management's asserted reasons for their failure to comply with different parts of the recommendations. There are also numerous emails that contradict management's assertions regarding their knowledge of budgeting, equipment procurement, and changes to testing.

Allegation 1 – The Miami VA's procedures for conducting HIV testing were not in compliance with VHA Directive 1113.

At the outset, the whistleblower disagrees with the VA's interpretation of VHA Directive 1113 about the due date for implementation of the CDC's Recommendations. The Transmittal Sheet is clear:

> "This Directive updates VHA policy on HIV testing and responsibilities of the program office, Medical Facility Directors, Laboratory Directors, and HIV Lead Clinicians: removes the requirement for providing written educational material at the time of HIV testing: establishes a time frame for written local HIV Testing Policies **to be implemented within 1 year after publication of this Directive**, and updates the description of high-risk behaviors."

The VA, on the other hand, erroneously states the following in its report:

> "The Directive does not specifically outline laboratory procedures for HIV screening, but references ensuring the availability HIV testing assays that meet current CDC recommendations. There was **no required date for implementation** of the new CDC algorithm."

According to the Directive, the Facility Laboratory Director (here, the Chief of PLMS) is responsible for the following:

> (1) Ensuring procedures are in place for the timely performance of initial HIV testing and confirmatory reflex testing if necessary
>
> (2) Ensuring availability of HIV testing assays that meet current CDC recommendations

On page 5 of the report, the VA admits that the Chief of PLMS (Director, PLMS) as the person named responsble for (2) in the HSPM published on October 2015.

In order to implement the CDC recommendations and ensure the procedures were in place for HIV testing, the Chief of PLMS would have had to identify the tests available in the laboratory, evaluate the new requirements, coordinate between the units performing testing, develop a plan and strategy to comply with the new requirements (including introducing new, compliant tests or outsourcing those that could not be performed in-house), and develop a new written protocol to have all the necessary parties involved and informed.

There was no coordination, guidance, or plan for implementation by the Chief of PLMS before my disclosure outside of the facility. Even though the the Directive outlines her responsibilities, the Chief of PLMS defends her faliure to meet those obligations by claiming she was unaware of the changes in CDC recommendations despite clear language in the VHA Directive. She also denies that I told her of my concerns, as if to suggest that was necessary to trigger her responsibilities. The Directive triggered those responsibilities. Moreover, as discussed below under Allegation 3, her denials are untrue – I told her on several occasions, including in emails where I sent her the CDC Recommendations and the Directive. At the very least, this shows that the Chief of PLMS was not meeting her obligations and is willing to deny having information that I provided to her in order to avoid taking responsibility. It is remarkable that the Chief of PLMS would defend herself by claiming ignorance of her responsbilities under the VHA Directive and denying knowledge of the CDC recommendations referenced in the Directive. The Directive explicitly refers to the implementation of CDC Recommendations. To do so despite my efforts and emails is more than remarkable and neglects culpable knowledge on her part.

It is unreasonable and irresponsible for the VA to imply compliance by simply pointing to a VISN-wide contract without delineating a new protocol to comply with the VHA Directive or the appropriate tests for coordination between the Chemistry and SIS Units.

The Chemistry unit of the PLMS laboratory was responsible for the screening testing for HIV and Hepatitis. SIS was responsible for all confirmatory testing of HIV-positive screening results. On page 4, the SIS Supervisor alleges that SIS began running NATs for discordant samples to validate the WB results. The report fails to provide a date for when this practice allegedly began. I am unaware of any NATs for discordant samples before July 2016, because serum was the only type of sample that the Chemistry Unit provided to the SIS unit. The SIS Supervisor had personally stated to me that he could only run viral loads on EDTA samples, not in serum. This contradicts the SIS Supervisor's explanation that they began running NATs for discordant samples, because Chemistry did not provide SIS with EDTA samples before July 2016. Furthermore, the VA admits this so-called "alternative" process was not formalized in written policy on page 4. This is significant because the report reflects that the Medical Center only put an "alternate testing practice" in writing adding the NAT after I disclosed the VA's non-compliance to the OSC, the OIG, and the White House. NAT testing, however, is currently being outsourced to Quest Diagnostics.

The report concludes on page 8 that the October 2015 HSPM "contained the required sections that complied with the Directive." This is not supported by the evidence. The October 2015 HSPM outlined

a two-step procedure: (1) initial testing by screening EIA, and if positive, (2) confirmed by Western Blot (WB). This procedure does not meet the CDC's recommendations, which were published in June 2014. On page 3 of the report, the VA provides the 3-step algorithm the Directive and the CDC Recommendations require:

> The algorithm recommends that laboratories [1] 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. If the results of this screening test are reactive, CDC recommends [2] additional testing with an FDA-approved antibody immunoassay that differentiates HIV-1 antibodies from HIV-2 antibodies. 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), [3] should be tested with an FDA-approved HIV-1 nucleic acid test (NAT).

Western Blot does not meet the recommendations as a confirmatory test for step-2, because it does not differentiate between HIV-1 and HIV-2 antibodies. Remarkably, the Chief of ID & HIV admits that he had not read the CDC's Recommendations before writing the HSPM.

To my knowledge and belief, the VAMC did not actively pursue any solutions to the non-compliant confirmatory testing until July 2016, after I disclosed the issue outside of the facility. Significantly, the VHA Directive requires compliance with CDC Recommendations, not compliance with "alternatives" to CDC Recommendations. Even if the alternatives were "recommended", the SIS Section's use of the Western Blot as the second test in the algorithm instead of the HIV-1/HIV-2 antibody differentiation immunoassay would have required NAT testing. As I indicated above, NAT testing was not done prior to my disclosures outside of the facility and was not a step in the facility's written protocol. Moreover, reading the report was the first time I learned that SIS allegedly used ORAQUICK tests on patients with discordant results after I told the SIS Supervisor the WB confirmatory test did not align with CDC recommendations. I have never seen a log of ORAQUICK results or confirmatory ORAQUICK results reported in a patient's records. The SIS Supervisor had months of emails throughout 2016 where he could have told me that he was using ORAQUICK as a confirmatory test, but he did not. The CDC recommends reporting all assays that were used, the results of each assay, the interpretation of the results, and, where alternatives to the recommended assays or algorithm sequence were used, the assays that were used and limitations of these tests compared with the recommended algorithm. To my

knowledge, this was done neither with ORAQUICK nor with NAT. Therefore, the VA's claims that they were implementing those additional tests outside of the written protocol are dubious, to say the least.

To make matters worse, the ORAQUICK test is not an FDA-approved HIV supplemental test, and therefore, would not have met the CDC's Recommendations.

These facts illustrate deficiencies in the conclusions for Allegation 1. Those conclusions also fail to bring home management's responsibility for these deficiencies and staffing vacancies.

Allegation 2 – Patients who were tested for HIV at the Miami VAMC since October 2015 may have received inaccurate diagnosis.

After my disclosures were made outside of the VAMC, the facility believed it was necessary to recall 8 patients where confirmatory testing was not performed according to CDC Recommendations. I am aware of a high-risk patient that was screened and NAT tested at the same time at the practitioner's request. For the sake of illustrating my concerns, imagine that this same patient was sent for HIV screening but the practitioner had not requested NAT testing simultaneously. The patient sample could have had a 4th generation positive screening, and quite possibly an HIV-1 WB negative (and even a negative ORAQUICK result). In this scenario, it is possible that the patient could have been reported as negative by the facility, because NAT testing was not a part of the facility's official written protocol as admitted in the report. Therefore, the facility could fail to identify an early-stage HIV-1 patient during the most infectious period and, consequently, the patient would not receive timely treatment. In this hypothetical scenario, the patient would be put at risk because the confirmatory testing did not meet recommendations and the opportunity for a diagnosis will be missed. This was the reason for the CDC's Recommendations and was at the core of my concern for patients tested prior to my disclosures outside the facility.

As the Chemistry Supervisor in PLMS and as a healthcare professional, I fully understand that HIV is an infectious disease that should be approached seriously and to the best of the facility's ability. The VAMC owes the veterans the best treatment and testing available to us. I believe we have responsibility to look out for the patient's interests and to provide them with the best possible treatment and diagnostic tools available. I spoke up because my superiors were neglecting their duties and not meeting testing requirements. It is concerning how the VA's report downplays the possibility of inaccurate results before July 2016 when the CDC Recommendations were not followed, yet the facility felt the need to recall 8 discordant cases.

At the time of my disclosures, I perceived no attempts by the Chief of PLMS or her CMT to correct the issues related to HIV confirmatory testing. Through a GD review for HIV and Hepatitis, I saw that some 4th-generation positive screenings were reported as negative after confirmatory testing using Western Blot. Despite my attempts and discussion related to the CDC Recommended algorithm from October through November 2015, I could see that the CDC Recommendations would not be properly implemented by the deadline imposed by the VHA Directive.

Again, all of management's attempts to correct the deficiencies were made after I made my whistleblower disclosures outside the facility.

Given these facts the conclusions of Allegation 2 ignore management's failure to timely act and the consequences of that inaction.

Allegation 3 – Miami VAMC management officials ignored my repeatedly expressed concerns regarding the facility's noncompliance with Directive 1113 and continued use of outdated HIV testing.

Firstly, the report concludes on page 13 that I did not provide expressed concerns about noncompliance with VHA Directive 1113. This is demonstrably false. My concerns were expressed specifically to the Chief of PLMS and her CMT via email and in person on multiple occasions in October and November 2015 prior to the Chief of PLMS telling me to mind my own business on November 20, 2015. I am enclosing a few email strings as examples. On October 28, 2015 I sent an email to the Chief of PLMS for her review and cc'd the CMT. That email contains the following passage: "Besides that, this was part of the latest recommendation by the Center for Disease Control and Prevention (CDC) in conjunction with the Association of Public Health Laboratories (APHL) published on June 27, 2014 (see attached updated recommendations file). **I believe that our testing protocol needs to be adapted to the new proposed algorithms.** We will like to have a meeting with all the stakeholders to re-define our reporting protocols and tests to comply with the new demands." Also on October 28, 2015 I sent the Chief of PLMS (cc'd CMT) another email attaching the CDC's recommended algorithm in a pdf file. When she responded "I will not review pdf files – I have said so before," I sent her the CDC Recommended Algorithm in Word Format. In an email sent to all of the clinical laboratory supervisors nationwide on November 5, 2015, I asked how other facilities were handling discordant results. I forwarded the responses I received from the group to the Chief of PLMS. To my dismay, the Chief dismissed my concerns in her response: "Thank you. So far for the calendar year, we have only had 53 positive screen tests." Her response CC'd the SIS Supervisor and the CMT. At a meeting with the Chief of PLMS, Chief of ID & HIV, and Medical Director of

IC, I distributed a copy of the recommended algorithm from the CDC Recommendations. In an email sent to the Chief PLMS on November 9, 2015 CC'd to the SIS Supervisor and the CMT I stated the following: "**We need to adjust to new requirements and follow VHA Directive 1113.**" There are other examples as well.

It is absurd for the VA to have concluded that I did not provide repeated expressed concerns to management about noncompliance with VHA Directive 1113 or the CDC's Recommendations and that I delayed reporting my concerns to the VAMC's leadership. The Chief of PLMS is undoubtedly part of management and a member of the VAMC's leadership. Instead of responding to my concerns, the Chief of PLMS called me in for a "Behavior Evaluation" on November 20, 2015 and told me to "stick to my own business" when I again raised my concerns after I pointed out SIS confirmatory testing was not in compliance with the new testing requirements. Once I again, the VA only modified their policies and procedures in response to my disclosures outside of the facility in May 2016. Furthermore, it is inconceivable that the Chief of PLMS would choose not to carry out her responsibilities set forth in VHA Directive 1113 or implement the CDC recommendations without telling the Chief of Staff and the Director of the Hospital.

Given these facts the conclusions for Allegation 3 are in key respects erroneous and seem to shift responsibility from an unresponsive management to an innocent whistleblower.

Thank you for your attention to these matters.

Sincerely,

Roman Miguel

Miguel, Roman A. (MIAMI VA)

From: Miguel, Roman A. (MIAMI VA)
Sent: Wednesday, October 28, 2015 11:26 AM
To: [redacted] (Miami VA)
Cc: [redacted] (MIAMI VA); Miguel, Roman A. (MIAMI VA)
Subject: NEW HIV MEETING INVITATION
Attachments: cdc_23447_DS1.pdf

Importance: High

Dr. [redacted],
Please review the contents of the below email before I send it to Dr. [redacted] and Dr. [redacted].
Thanks.

Dr. [redacted] Dr. [redacted]:

On October 8th, we introduced the Architect HIV 1/2 Antibody/Antigen Combo from Abbott. This test identifies anti-HIV-1, anti-HIV-2 and p24 antigen (4th generation testing system). This would be an improvement compared to our previous screening test which only detected anti-HIV-1, anti-HIV-2 . Besides that, this was part of the latest recommendation by the Centers for Disease Control and Prevention (CDC) in conjunction with the Association of Public Health Laboratories (APHL) published on June 27th, 2014 (see attached updated recommendations file). I believe that our testing protocol needs to be adapted to the new proposed algorisms.

We will like to have a meeting with all the stakeholders to re-define our reporting protocols and tests to comply with the new demands.

Please provide us with a day and time to schedule this meeting.

Thank you

Roman A. Miguel, MS
Chemistry Department Supervisor
Miami VA Healthcare System
P&LMS

Phone (305) 324-4455 ext 4414
Mobile phone: (786) 299-1771
Fax Number (305) 575-7188
E-mail: Roman.Miguel@va.gov

Miguel, Roman A. (MIAMI VA)

From: [redacted] (Miami VA)
Sent: Wednesday, October 28, 2015 3:16 PM
To: Miguel, Roman A. (MIAMI VA)
Cc: [redacted] (MIAMI VA); [redacted] (Miami VA)
Subject: RE: Memorandum HIV 1_2 Combo

Follow Up Flag: Follow up
Flag Status: Completed

I will not review pdf files – I have said so before

[redacted], MD
Chief, Pathology and Laboratory Medicine Service
Bruce W. Carter VAMC
1201 NW 16th Street (113)
Miami, FL 33125
O – 305-575-3158
F – 305-575-3222
M – 786-400-5068

From: Miguel, Roman A. (MIAMI VA)
Sent: Wednesday, October 28, 2015 9:49 AM
To: [redacted] (Miami VA)
Cc: Miguel, Roman A. (MIAMI VA); [redacted] (MIAMI VA)
Subject: Memorandum HIV 1_2 Combo

Please review

Thanks

Roman A. Miguel, MT
Chemistry Department Supervisor
Miami VA Healthcare System
P&LMS

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Department of Veterans Affairs

Memorandum

Date: Wednesday, October 28th, 2015

From: Chief, Pathology & Laboratory Medicine Service (113)

Subj: Changes to Hepatitis and HIV Testing

To: All Clinical Service Chiefs

Thru: Chief of Staff (11)

1. As October 8th, 2015; P&LMS changed the detection system from Ortho-Diagnostics to Abbott Architect i1000 for our Hepatitis and Human Immunodeficiency Virus (HIV) testing.

2. The new methodology allows for the detection of p24 HIV antigen that was not available with the previous testing system.

3. The Architect HIV Ag/Ab Combo assay principle is a chemiluminescent microparticle immunoassay (CMIA) for the simultaneous qualitative detection of human immunodeficiency virus (HIV) p24 antigen and antibodies to HIV type 1 (HIV-1 group M and group O) and/or type 2 (HIV-2) in human serum and plasma (EDTA and heparin).

4. Any positive result will be referred for confirmation as our protocol indicates.

5. The specimen of choice will continue to be serum with or without separator, and the test availability remain the same from Monday to Friday from 8:00 am to 4:00 pm.

6. A CDC Quick Reference Guide for Laboraotry HIV testing is provided.

7. For additional information, please contact Mr. Roman Miguel, Chemistry Supervisor at extension 4414.

5. Please disseminate this information in your Service.

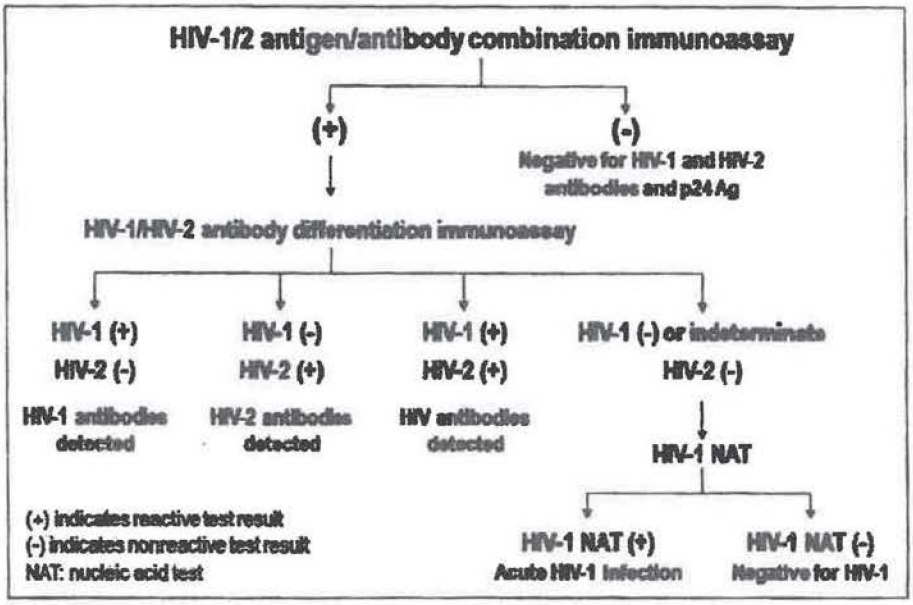
[redacted], MD

Concur: _____ Yes _____ No

[redacted], MD

Cc: Lab Manager (113)
Pathologists (113)
Chemistry Supervisor (113)
Lab Information Manager (113)

Recommended Laboratory HIV Testing Algorithm for Serum or Plasma Specimens



1. Laboratories should conduct initial testing for HIV with an FDA-approved antigen/antibody combination immunoassay* that detects HIV-1 and HIV-2 antibodies and HIV-1 p24 antigen to test for established HIV-1 or HIV-2 infection and for acute HIV-1 infection. No further testing is required for specimens that are nonreactive on the initial immunoassay.
2. Specimens with a reactive antigen/antibody combination immunoassay result (or repeatedly reactive, if repeat testing is recommended by the manufacturer or required by regulatory authorities) should be tested with an FDA-approved antibody immunoassay that differentiates HIV-1 antibodies from HIV-2 antibodies. Reactive results on the initial antigen/antibody combination immunoassay and the HIV-1/HIV-2 antibody differentiation immunoassay should be interpreted as positive for HIV-1 antibodies, HIV-2 antibodies, or HIV antibodies, undifferentiated.
3. Specimens that are reactive on the initial antigen/antibody combination immunoassay and nonreactive or indeterminate on the HIV-1/HIV-2 antibody differentiation immunoassay should be tested with an FDA-approved HIV-1 nucleic acid test (NAT).
    - A reactive HIV-1 NAT result and nonreactive HIV-1/HIV-2 antibody differentiation immunoassay result indicates laboratory evidence for acute HIV-1 infection.
    - A reactive HIV-1 NAT result and indeterminate HIV-1/HIV-2 antibody differentiation immunoassay result indicates the presence of HIV-1 infection confirmed by HIV-1 NAT.
    - A negative HIV-1 NAT result and nonreactive or indeterminate HIV-1/HIV-2 antibody differentiation immunoassay result indicates a false-positive result on the initial immunoassay.
4. Laboratories should use this same testing algorithm, beginning with an antigen/antibody combination immunoassay, with serum or plasma specimens submitted for testing after a reactive (preliminary positive) result from any rapid HIV test.

* *Exception: As of April 2014, data are insufficient to recommend use of the FDA-approved single-use rapid HIV-1/HIV-2 antigen/antibody combination immunoassay as the initial assay in the algorithm.*

Reporting results from the HIV diagnostic testing algorithm to persons ordering HIV tests and public health authorities

Test performed	Test results	Final interpretation for provider report	Test results to be reported to public health authorities
1. HIV-1/2 Ag/Ab combination immunoassay	1. Nonreactive	Negative for HIV-1 antigen and HIV-1/HIV-2 antibodies. No laboratory evidence of HIV infection. If acute HIV infection is suspected, consider testing for HIV-1 RNA.	Reporting this test result is not required.
1. HIV-1/2 Ag/Ab combination immunoassay 2. HIV-1/HIV-2 antibody differentiation immunoassay	1. Reactive 2. HIV-1 reactive and HIV-2 nonreactive	Positive for HIV-1 antibodies. Laboratory evidence consistent with established HIV-1 infection is present.	Report test results 1 and 2.
1. HIV-1/2 Ag/Ab combo immunoassay 2. HIV-1/HIV-2 antibody differentiation immunoassay	1. Reactive 2. HIV-1 nonreactive and HIV-2 reactive	Positive for HIV-2 antibodies. Laboratory evidence of HIV-2 infection is present.	Report test results 1 and 2.
1. HIV-1/2 Ag/Ab combination immunoassay 2. HIV-1/HIV-2 antibody differentiation immunoassay 3. HIV-1 RNA assay	1. Reactive 2. Nonreactive or indeterminate 3. RNA not detected	HIV antibodies were not confirmed and HIV-1 RNA was not detected. No laboratory evidence of HIV-1 infection. Follow-up testing for HIV-2 should be performed if clinically indicated.	Reporting this test result is not required.
1. HIV-1/2 Ag/Ab combination immunoassay 2. HIV-1/HIV-2 antibody differentiation immunoassay 3. HIV-1 RNA assay	1. Reactive 2. Nonreactive 3. RNA detected	Positive for HIV-1. Laboratory evidence consistent with acute HIV-1 infection is present.	Report test results 1, 2, and 3.
1. HIV-1/2 Ag/Ab combination immunoassay 2. HIV-1/HIV-2 antibody differentiation immunoassay 3. HIV-1 RNA assay	1. Reactive 2. Indeterminate 3. RNA detected	Positive for HIV-1 antibodies. Laboratory evidence of HIV-1 infection confirmed by HIV-1 RNA.	Report test results 1, 2, and 3.
1. HIV-1/2 Ag/Ab combination immunoassay 2. HIV-1/HIV-2 antibody differentiation immunoassay	1. Reactive 2. HIV-1 and HIV-2 reactive	Positive for HIV antibodies. Laboratory evidence of HIV infection is present. HIV antibodies could not be differentiated as HIV-1 or HIV-2. Additional testing for HIV-1 RNA or HIV-2 RNA should be performed if clinically indicated.	Report test results 1 and 2.
1. HIV-1/2 Ag/Ab combination immunoassay 2. HIV-1/HIV-2 antibody differentiation immunoassay	1. Reactive 2. Nonreactive or indeterminate	HIV-1 antibodies were not confirmed and HIV-1 RNA testing was not performed. Testing of this specimen is incomplete. Follow-up testing for HIV antibodies and HIV-1 RNA is recommended as soon as possible.	Report test results 1 and 2.

Abbreviations: Ag/Ab, antigen/antibody; RNA, ribonucleic acid.

Adapted from *Interim Guidelines for Laboratories on the Use of a New Diagnostic Testing Algorithm for Human Immunodeficiency Virus (HIV) Infection*. New York State Department of Health (http://www.health.ny.gov/diseases/aids/providers/regulations/testing/docs/guidelines_diagnostic_testing.pdf).

Miguel, Roman A. (MIAMI VA)

From: Miguel, Roman A. (MIAMI VA)
Sent: Wednesday, October 28, 2015 3:19 PM
To: [redacted] (Miami VA)
Cc: [redacted] (MIAMI VA); Miguel, Roman A. (MIAMI VA)
Subject: RE: Memorandum HIV 1_2 Combo
Attachments: Hepatitis and HIV Abbott 10012015.docx

Tracking:

Recipient	Delivery	Read
[redacted] (Miami VA)	Delivered: 10/28/2015 3:20 PM	
[redacted] (MIAMI VA)	Delivered: 10/28/2015 3:20 PM	Read: 11/2/2015 11:22 AM
Miguel, Roman A. (MIAMI VA)	Delivered: 10/28/2015 3:19 PM	Read: 10/28/2015 3:20 PM

Here is the Word format, I sent the one in PDF because is the only way to send both document in one.

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Miami VA Healthcare System
P&LMS

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E-mail: Roman.Miguel@va.gov

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Sent: Wednesday, October 28, 2015 3:16 PM
To: Miguel, Roman A. (MIAMI VA)
Cc: [redacted] (MIAMI VA); [redacted] (Miami VA)
Subject: RE: Memorandum HIV 1_2 Combo

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[redacted]
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M - 786-400-5068

From: Miguel, Roman A. (MIAMI VA)
Sent: Wednesday, October 28, 2015 9:49 AM
To: [redacted]. (Miami VA)
Cc: Miguel, Roman A. (MIAMI VA); [redacted] (MIAMI VA)
Subject: Memorandum HIV 1_2 Combo

Please review

Thanks

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P&LMS

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Roman Miguel

From: Miguel, Roman A. (MIAMI VA)
Sent: Thursday, November 05, 2015 11:59 AM
To: VHAASH SPVRMEDTECHS
Cc: Miguel, Roman A. (MIAMI VA)
Subject: HIV 1/2 Supplemental tests

Tracking:

Recipient	Delivery	Read
VHAASH SPVRMEDTECHS		
Miguel, Roman A. (MIAMI VA)	Delivered: 11/5/2015 11:59 AM	Read: 11/5/2015 1:39 PM

Hello everyone, we at Miami VA are using a 4th Generation test to screen our patients for HIV, I will like to have a feedback for what supplemental tests are you using to differentiate within HIV-1 antibody and HIV-2 antibody, and also how are you handling when you have a HIV screening positive and the antibody supplemental negative, are you doing a p24 NAT or a HIV viral Load.

Thank you

Roman A. Miguel, MS
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P&LMS

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E-mail: Roman.Miguel@va.gov

Roman Miguel

From: Miguel, Roman A. (MIAMI VA)
Sent: Thursday, November 05, 2015 12:32 PM
To: [redacted] (Miami VA)
Cc: Miguel, Roman A. (MIAMI VA)
Subject: FW: HIV 1/2 Supplemental tests

Tracking:

Recipient	Delivery	Read
[redacted] (Miami VA)	Delivered: 11/5/2015 12:33 PM	Read: 11/6/2015 6:56 AM
Miguel, Roman A. (MIAMI VA)	Delivered: 11/5/2015 12:32 PM	Read: 11/5/2015 1:38 PM

FYI·

Roman A. Miguel, MS
Chemistry Department Supervisor
Miami VA Healthcare System
P&LMS

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Fax Number (305) 575-7188
E-mail: Roman.Miguel@va.gov

From: [redacted]
Sent: Thursday, November 05, 2015 12:14 PM
To: Miguel, Roman A. (MIAMI VA)
Subject: RE: HIV 1/2 Supplemental tests

Roman,

At VA Nashville, TN, we use Abbott HIV Combo to screen and BioRad Multispot to differentiate. A unique accession is generated for the Multispot after the pos screen is obtained. If we have a pos screen, but a neg Multispot, we report the results as such, but comment the Multispot result: "follow-up RNA testing is recommended". The assumption is that there is an early infection and/or the positive is due to the P24 ag, however that is not included in the Multispot comment.

[redacted]

From: Miguel, Roman A. (MIAMI VA)
Sent: Thursday, November 05, 2015 10:59 AM
To: VHAASH SPVRMEDTECHS

Cc: Miguel, Roman A. (MIAMI VA)
Subject: HIV 1/2 Supplemental tests

Hello everyone, we at Miami VA are using a 4th Generation test to screen our patients for HIV, I will like to have a feedback for what supplemental tests are you using to differentiate within HIV-1 antibody and HIV-2 antibody, and also how are you handling when you have a HIV screening positive and the antibody supplemental negative, are you doing a p24 NAT or a HIV viral Load.

Thank you

Roman A. Miguel, MS
Chemistry Department Supervisor
Miami VA Healthcare System
P&LMS

Phone (305) 324-4455 ext 4414
Mobile phone: (786) 299-1771
Fax Number (305) 575-7188
E-mail: Roman.Miguel@va.gov

Roman Miguel

From: Miguel, Roman A. (MIAMI VA)
Sent: Thursday, November 05, 2015 12:33 PM
To: [redacted]
Cc: Miguel, Roman A. (MIAMI VA); [redacted] (Miami VA)
Subject: RE: HIV 1/2 Supplemental tests

Tracking:

Recipient	Delivery	Read
[redacted]	Delivered: 11/5/2015 12:34 PM	Read: 11/5/2015 1:09 PM
Miguel, Roman A. (MIAMI VA)	Delivered: 11/5/2015 12:33 PM	Read: 11/5/2015 1:38 PM
[redacted] (Miami VA)	Delivered: 11/5/2015 12:34 PM	

Thank you very much [redacted] for you information.

Roman A. Miguel, MT
Chemistry Department Supervisor
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P&LMS

Phone (305) 324-4455 ext 4414
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Fax Number (305) 575-7188
E-mail: Roman.Miguel@va.gov

From: [redacted]
Sent: Thursday, November 05, 2015 12:14 PM
To: Miguel, Roman A. (MIAMI VA)
Subject: RE: HIV 1/2 Supplemental tests

Roman,

At VA Nashville, TN, we use Abbott HIV Combo to screen and BioRad Multispot to differentiate. A unique accession is generated for the Multispot after the pos screen is obtained. If we have a pos screen, but a neg Multispot, we report the results as such, but comment the Multispot result: "follow-up RNA testing is recommended". The assumption is that there is an early infection and/or the positive is due to the P24 ag, however that is not included in the Multispot comment.

[redacted]

From: Miguel, Roman A. (MIAMI VA)
Sent: Thursday, November 05, 2015 10:59 AM
To: VHAASH SPVRMEDTECHS

Cc: Miguel, Roman A. (MIAMI VA)
Subject: HIV 1/2 Supplemental tests

Hello everyone, we at Miami VA are using a 4th Generation test to screen our patients for HIV, I will like to have a feedback for what supplemental tests are you using to differentiate within HIV-1 antibody and HIV-2 antibody, and also how are you handling when you have a HIV screening positive and the antibody supplemental negative, are you doing a p24 NAT or a HIV viral Load.

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Roman Miguel

From: Miguel, Roman A. (MIAMI VA)
Sent: Thursday, November 05, 2015 1:10 PM
To: [redacted] (STL)
Cc: Miguel, Roman A. (MIAMI VA); [redacted] (Miami VA)
Subject: RE: HIV 1/2 Supplemental tests

Tracking:

Recipient	Delivery	Read
[redacted] (STL)	Delivered: 11/5/2015 1:10 PM	Read: 11/5/2015 1:14 PM
Miguel, Roman A. (MIAMI VA)	Delivered: 11/5/2015 1:10 PM	Read: 11/5/2015 1:23 PM
[redacted] (Miami VA)	Delivered: 11/5/2015 1:10 PM	

Thank you [redacted] very helpful your information, have you seen the Geenius? I had a demo today by Bio-Rad and seems to be very easy, and TAT is around 45 minutes. I request a quote for information purposes. Will keep you posted.

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Mobile phone: (786) 299-1771
Fax Number (305) 575-7188
E-mail: Roman.Miguel@va.gov

From: [redacted] (STL)
Sent: Thursday, November 05, 2015 12:38 PM
To: Miguel, Roman A. (MIAMI VA)
Subject: RE: HIV 1/2 Supplemental tests

We currently perform the Multispot test from BioRad to confirm our 4th generation screens (on Abbott Architect), but BioRad is discontinuing the Multispot product and promoting their new product the Geenius HIV 1/2 Assay – which we will likely try to use, but it will have to go through contracting because it requires a reader and a computer. Currently if our Multispot assay is negative or invalid we sent to Quest for HIV PCR.

[redacted], *MLS(ASCP)CM, M(ASCP)CM*
Supervisory Medical Technologist
St. Louis VAMC
Office Phone: (314) 652-4100 ext. 5-3140
Lab Phone: (314) 289-6353
Fax: (314) 289-7920

From: Miguel, Roman A. (MIAMI VA)
Sent: Thursday, November 05, 2015 10:59 AM
To: VHAASH SPVRMEDTECHS
Cc: Miguel, Roman A. (MIAMI VA)
Subject: HIV 1/2 Supplemental tests

Hello everyone, we at Miami VA are using a 4th Generation test to screen our patients for HIV, I will like to have a feedback for what supplemental tests are you using to differentiate within HIV-1 antibody and HIV-2 antibody, and also how are you handling when you have a HIV screening positive and the antibody supplemental negative, are you doing a p24 NAT or a HIV viral Load.

Thank you

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Roman Miguel

From: Miguel, Roman A. (MIAMI VA)
Sent: Thursday, November 05, 2015 1:15 PM
To: [redacted]; VHAASH SPVRMEDTECHS
Cc: [redacted] (Miami VA)
Subject: RE: HIV 1/2 Supplemental tests

Tracking:

Recipient	Delivery	Read
[redacted]	Delivered: 11/5/2015 1:15 PM	Read: 11/5/2015 1:40 PM
[redacted]	Delivered: 11/5/2015 1:16 PM	
VHAASH SPVRMEDTECHS		
[redacted]	Delivered: 11/5/2015 1:16 PM	Deleted: 12/21/2015 1:08 PM
[redacted] (Miami VA)	Delivered: 11/5/2015 1:16 PM	

Thank you for your advice, I already request a quote from Bio-Rad, for the Geenius, today I had a demo and seems easy to work and according to them is more sensitive that the Multispot, TAT is ~45 min.

Roman A. Miguel, MS
Chemistry Department Supervisor
Miami VA Healthcare System
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E-mail: Roman.Miguel@va.gov

From: [redacted]
Sent: Thursday, November 05, 2015 12:43 PM
To: [redacted]; Miguel, Roman A. (MIAMI VA); VHAASH SPVRMEDTECHS
Cc: [redacted]
Subject: RE: HIV 1/2 Supplemental tests

We use the Abbott Architect 4th gen screen, reflex to BioRad Multispot for positives, perform HIV-1 RNA for those Multispots that result as HIV-1 indeterminate/HIV-1 negative/HIV-1/HIV-2 undifferentiated. We validated our Abbott m2000 HIV-1 viral load assay for use as an HIV-1 RNA assay to be used as part of the diagnostic algorithm for HIV. For those assays that are positive with the HIV-1 RNA assay, we concomitantly release the HIV-1 viral load result.
The BioRad Multispot is being discontinued, BioRad will only offer HIV-1/HIV-2 confirmation/differentiation assays using the Geenius. It wouldn't be worth bringing on the Multispot now, you should just start with the Geenius.

From: [redacted]
Sent: Thursday, November 05, 2015 12:24 PM
To: Miguel, Roman A. (MIAMI VA); VHAASH SPVRMEDTECHS
Cc: [redacted]
Subject: RE: HIV 1/2 Supplemental tests

We use the CDC recommendations and chart for reporting, see attached.

4th gen screen, positive to multispot, Negative multisport to HIV-1 RNA assay

[redacted] *BS(MT,ASCP), EdM*
Lead Medical Technologist
(Blood Bank/Serology/Send Outs/Specimen Procurement)
VA WNY Healthcare System
Buffalo, NY
Phone: 716-862-3165
Fax: 716-862-8679

From: Miguel, Roman A. (MIAMI VA)
Sent: Thursday, November 05, 2015 11:59 AM
To: VHAASH SPVRMEDTECHS
Cc: Miguel, Roman A. (MIAMI VA)
Subject: HIV 1/2 Supplemental tests

Hello everyone, we at Miami VA are using a 4th Generation test to screen our patients for HIV, I will like to have a feedback for what supplemental tests are you using to differentiate within HIV-1 antibody and HIV-2 antibody, and also how are you handling when you have a HIV screening positive and the antibody supplemental negative, are you doing a p24 NAT or a HIV viral Load.

Thank you

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Roman Miguel

From: Miguel, Roman A. (MIAMI VA)
Sent: Thursday, November 05, 2015 3:28 PM
To: [redacted] (Miami VA)
Cc: Miguel, Roman A. (MIAMI VA); [redacted] (MIAMI VA)
Subject: HIV Supplemental

Tracking:

Recipient	Delivery	Read
[redacted] (Miami VA)	Delivered: 11/5/2015 3:28 PM	Read: 11/6/2015 6:52 AM
Miguel, Roman A. (MIAMI VA)	Delivered: 11/5/2015 3:28 PM	Read: 11/5/2015 3:48 PM
[redacted] (MIAMI VA)	Delivered: 11/5/2015 3:28 PM	

Gainesville, Tampa, Orlando do Multispot from Bio-Rad and will move to the Geenius, Bay Pine, and WPB very low number of positive 1 or two a month, they refer to Quest. And so far Nationally the responses that I have all them do Multispot and uses the Abbott HIV 1/2 Ag/Ab Combo.

Thank you

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Chemistry Department Supervisor
Miami VA Healthcare System
P&LMS

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Fax Number (305) 575-7188
E-mail: Roman.Miguel@va.gov

Roman Miguel

From: [redacted] (Miami VA)
Sent: Friday, November 06, 2015 6:56 AM
To: Miguel, Roman A. (MIAMI VA)
Cc: [redacted] (MIAMI VA); [redacted] (MIAMI VA); [redacted] (Miami VA)
Subject: RE: HIV Supplemental

Thank you.
So far for the calendar year, we have only had 53 positive screen tests.

[redacted], MD
Chief, Pathology and Laboratory Medicine Service
Bruce W. Carter VAMC
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Miami, FL 33125
O - 305-575-3158
F - 305-575-3222
M - 786-400-5068

From: Miguel, Roman A. (MIAMI VA)
Sent: Thursday, November 05, 2015 3:28 PM
To: [redacted] (Miami VA)
Cc: Miguel, Roman A. (MIAMI VA); [redacted] (MIAMI VA)
Subject: HIV Supplemental

Gainesville, Tampa, Orlando do Multispot from Bio-Rad and will move to the Geenius, Bay Pine, and WPB very low number of positive 1 or two a month, they refer to Quest. And so far Nationally the responses that I have all them do Multispot and uses the Abbott HIV 1/2 Ag/Ab Combo.

Thank you

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E-mail: Roman.Miguel@va.gov

Roman Miguel

From: Miguel, Roman A. (MIAMI VA)
Sent: Monday, November 09, 2015 8:44 AM
To: [redacted]
Cc: Miguel, Roman A. (MIAMI VA); [redacted] (Miami VA); [redacted] (MIAMI VA); [redacted] (MIAMI VA)
Subject: RE: HIV 1/2 Supplemental tests

Tracking:

Recipient	Delivery	Read
[redacted]	Delivered: 11/9/2015 8:44 AM	Read: 11/9/2015 9:20 AM
Miguel, Roman A. (MIAMI VA)	Delivered: 11/9/2015 8:44 AM	Read: 11/9/2015 10:33 AM
[redacted] (Miami VA)	Delivered: 11/9/2015 8:44 AM	Read: 11/9/2015 5:44 PM
[redacted] (MIAMI VA)	Delivered: 11/9/2015 8:44 AM	Read: 11/9/2015 11:24 AM
[redacted] (MIAMI VA)	Delivered: 11/9/2015 8:44 AM	

Hello [redacted], after Blood Borne exposure they order the OraQuick HIV and they follow with HIV screen (we have now the 4th generation from Abbott). We are doing HIV WB in our Immunology unit after HIV screen is positive. We need to adjust to new requirements and follow VHA Directive 1113.

Thank you for your information and help.

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Miami VA Healthcare System
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Mobile phone: (786) 299-1771
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E-mail: Roman.Miguel@va.gov

From: [redacted]
Sent: Monday, November 09, 2015 7:19 AM
To: Miguel, Roman A. (MIAMI VA)
Subject: RE: HIV 1/2 Supplemental tests

Miguel:
We are currently using the BioRad Multispot. We use this kit for rapid HIV and supplemental testing. We are considering the Genius from BioRad in the near future since BioRad is discontinuing Multispot in December 2016. But we will still need a rapid HIV. How are you handling the rapid HIV after Blood borne exposures?
Infectious control clinic decided to just order HIV Viral Load if the screen is positive and supplemental negative.

Let me know if you have any questions and can you share your findings with the group?
Thanks

[redacted] *B.S.M.T.(ASCP)*
P&LMS Supervisor
Processing, Immunology & Send Out
Lean Six Sigma Green Belt
NFSGVHS - P&LMS 113
1601 SW Archer Road - Gainesville, FL 32608
☎ (352) 376-1611 Ext. 5336
Fax: (352) 374-6125
✉ [redacted]@med.va.gov

From: Miguel, Roman A. (MIAMI VA)
Sent: Thursday, November 05, 2015 11:59 AM
To: VHAASH SPVRMEDTECHS
Cc: Miguel, Roman A. (MIAMI VA)
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