

2015 HIV Diagnostic Testing Survey

This survey is designed to capture the current HIV testing practices in state and local public health laboratories. The results of the survey will help APHL and CDC determine the uptake of the Recommended Laboratory HIV Testing Algorithm for Serum or Plasma Specimens

1. How many full-time equivalents does your laboratory employ for HIV testing?

These questions refer to HIV diagnostic testing conducted in 2014 (January 1-December 31)

2. In 2014 (January 1-December 31), how many total specimens did your laboratory receive for HIV diagnostic testing (not including tests solely submitted for patient management e.g. viral load)?
3. How many of each of the following specimen types did your laboratory receive for HIV diagnostic testing in 2014? *Please enter "0" for specimen types not received for testing.*

_____ Plasma
_____ Serum
_____ Serum/Plasma (unable to distinguish)
_____ Oral fluid
_____ Dried blood spot
_____ Other
_____ Unknown
_____ Whole blood

4. Of all specimens received in 2014, how many of the following HIV-1 final results did your laboratory report? *Please enter "0" for results not reported by your laboratory.*

_____ Negative (e.g., IA-)
_____ Positive for HIV-1 (e.g., IA+/WB or IFA+; IA +/MultiSpot + for HIV-1; IA+/RNA+)
_____ Indeterminate/ HIV Antibodies not confirmed (e.g., indeterminate result WB, Multispot or other supplemental test and NAT not performed)
_____ Inconclusive (e.g., IA+/supplemental test -/ NAT not performed)
_____ Positive for HIV-1; Consistent with Acute or Early Infection (e.g., IA +/supplemental IA- or indeterminate/RNA +)
_____ Not Tested (specimen rejected)

- 4a. How does your laboratory report IA+/WB-?

- Negative
- Indeterminate
- Inconclusive
- Not applicable
- None of the above

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5. In 2014 (January 1-December 31), how many specimens did your laboratory report as positive for HIV-2 infection (e.g., positive for HIV-2 by Multispot)?

These questions refer to HIV diagnostic testing conducted in 2014 (January 1-December 31)

6. Does your laboratory receive specimens for confirmation of reactive rapid tests performed outside your laboratory?
- Yes, specimens use the entire laboratory based testing algorithm starting with the initial IA.
 - Yes, specimens tested using supplemental antibody assay only.
 - Yes, but perform different testing on those specimens
 - No, do not receive specimens for confirmation of reactive rapid tests performed outside our laboratory (*Please proceed to question 12*)
 - Not sure (*Please proceed to question 12*)
7. Does your laboratory USUALLY know what specimen type (oral fluid or blood) was used for the reactive rapid test result performed in the field?
- Yes (*Please proceed to questions 7a and 7b*)
 - No (*Please proceed to question 8*)

7a. If a prescreened **blood** rapid test was reactive, what specimen type(s) did your laboratory receive for follow-up HIV testing? *Please check all that apply.*

- Plasma
- Serum
- Serum/Plasma (Unable to distinguish)
- Oral fluid
- Dried blood spot
- Whole blood
- Other- please specify:
- Not applicable

7b. If a prescreened **oral fluid** rapid test was reactive, what specimen type(s) did your laboratory receive for follow-up HIV testing? *Please check all that apply.*

- Plasma
- Serum
- Serum/Plasma (Unable to distinguish)
- Oral fluid
- Dried blood spot
- Whole blood
- Other-please specify:
- Not applicable

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These questions refer to HIV diagnostic testing conducted in 2014 (January 1-December 31)

8. How many specimens prescreened as reactive by a rapid test did your laboratory receive for testing? *Please write "Not sure" if this information is not easily accessible.*

9. Of those serum and/or plasma specimens received after a reactive rapid test was performed outside of your laboratory (CLIA waived setting), how many of the following HIV-1 results did your laboratory report? *Please check all that apply and include the number each type of result reported. Please check "Not Sure" if this information is not easily accessible.*

- Negative_____
- HIV-1 Antibody Positive_____
- Indeterminate_____
- Inconclusive_____
- RNA Positive (acute infection) _____
- Not tested (specimen rejected) _____
- Not sure
- Not applicable

9a What tests are used in your laboratory for serum/plasma specimens received following a reactive rapid test? *Please check all that apply.*

- Antigen/Antibody Combo IA (e.g. Abbott Architect HIV Ag/Ab Combo)
- Antibody IA (e.g. Bio-Rad GS HIV-1/HIV-2 Plus O EIA)
- HIV-1/HIV-2 differentiation assay (e.g. Multispot)
- HIV-1 WB
- HIV-1 RNA
- Other – please indicate assay:

10. Of those oral fluid specimens received after a reactive rapid test performed outside of your laboratory, how many of the following HIV-1 antibody results did your laboratory report? *Please check all that apply and include the number each type of result reported. Please check "Not Sure" if this information is not easily accessible.*

- Negative_____
- Antibody Positive_____
- Indeterminate_____
- Inconclusive_____
- Not tested (specimen rejected) _____
- Not sure
- Not applicable

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11. Of those dried blood spot specimens received after a reactive rapid test performed outside of your laboratory, how many of the following HIV-1 antibody results did your laboratory report? *Please check all that apply and include the number each type of result reported. Please check "Not Sure" if this information is not easily accessible.*

- Negative_____
- Antibody Positive_____
- Indeterminate_____
- Inconclusive_____
- Not tested (specimen rejected) _____
- Not sure
- Not applicable

These questions are intended to outline the testing algorithm used by your laboratory at the END OF 2014 for SERUM/PLASMA specimens.

12. Has your laboratory adopted the [Recommended Laboratory HIV Testing Algorithm for Serum or Plasma Specimens](#)? (say "yes" even if RNA is referred)

- Yes
- No (proceed to question 13)

12a. Please provide the approximate date of algorithm adoption.

13. Which HIV immunoassay does your laboratory use for initial laboratory screening of serum/plasma specimens?

- Abbott Architect HIV Ag/Ab Combo
- Alere Determine™ HIV Combo
- Avioq HIV-1 Microelisa
- ADVIA Centaur HIV 1/O/2 Enhanced
- Bio-Rad GS HIV-1/HIV-2 Plus O EIA
- Bio-Rad GS HIV Combo Ag/Ab EIA
- Ortho VITROS Anti-HIV 1+2 Immunoassay
- Other- please specify:
- Not applicable

14. After a reactive laboratory initial immunoassay, what supplemental test do you perform?

Please check only one.

- HIV-1 Western blot (*Please proceed to questions 14a, 14c*)
- IFA (*Please proceed to questions 14a, 14c*)
- Bio-Rad Multispot HIV-1/HIV-2 Rapid Test (*Please proceed to questions 14a, 14b, 14c*)
- Hologic APTIMA HIV-1 RNA Qualitative Assay (*Please proceed to questions 14a, 14c*)
- Other NAT (*Please proceed to questions 14a, 14c*)
- Laboratory refers supplemental testing to another laboratory. Please specify tests referred_____ (*Please proceed to question 15*)
- Other- please specify: (*Please proceed to 14a, 14c*)

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14a. If the first supplemental test is nonreactive for HIV, what is your laboratory's next step? *Please check all that apply.*

- Report overall result/interpretation as negative
- Perform additional testing (*Please proceed to question 14a1*)
- Refer for HIV-1 RNA NAT (*Please proceed to question 14a2*)
- Report negative result and request additional specimen
- Report reactive IA and negative supplemental results and request additional specimen
- Report as inconclusive
- Other- please specify:

14a1. What additional tests does your laboratory conduct? *Please check all that apply.*

- Hologic APTIMA HIV-1 RNA Qualitative Assay
- RNA assay other than the APTIMA HIV-1 RNA Qualitative Assay
- Bio-Rad Multispot HIV-1/HIV-2 Rapid Test
- HIV-1 Western blot
- HIV-2 Western blot
- HIV-1IFA
- HIV-2 EIA
- HIV-2 NAA
- Other-please specify:

14a2. Where do you refer specimens for supplemental HIV-1 RNA NAT?

- APHL NAT demonstration referral laboratory (Florida Bureau of Laboratories or Wadsworth Center)
- Commercial laboratory (e.g. Quest, Lab Corp)
- Another public health laboratory
- Clinical or hospital laboratory in your jurisdiction
- Other-please specify:

14b. If the Bio-Rad Multispot is reactive for HIV-2 only, what does your laboratory do? *Please check all that apply.*

- Report HIV-2 positive result
- Refer specimen to or consult with CDC
- Perform additional test (*Please proceed to question 14b1*)
- Other- please specify:

14b1. What additional tests does your laboratory conduct? *Please check all that apply.*

- HIV-2 EIA
- HIV-2 Nucleic Acid
- HIV-2 Western blot
- Other-please specify:

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14c. If the supplemental test is indeterminate, what is your laboratory's next step? *Please check all that apply.*

- Report results
- Perform additional testing (*Please proceed to question 14c1*)
- Refer for HIV-1 RNA NAT (*Please proceed to question 14c2*)
- Report indeterminate result and request additional specimen
- Other-please specify:

14c1. What additional tests does your laboratory conduct? *Please check all that apply.*

- Hologic APTIMA HIV-1 RNA Qualitative Assay
- RNA assay other than Hologic APTIMA HIV-1 RNA Qualitative Assay
- Bio-Rad Multispot HIV-1/HIV-2 Rapid Test
- HIV-1 Western blot
- HIV-2 Western blot
- HIV-1 IFA
- HIV-2 EIA
- HIV-2 Nucleic Acid Test
- Other-please specify:

14c2. Where do you refer specimens for supplemental HIV-1 RNA NAT?

- APHL NAT demonstration referral laboratory (Florida Bureau of Laboratories or Wadsworth Center)
- Commercial laboratory (e.g. Quest, Lab Corp)
- Another public health laboratory
- Clinical or hospital laboratory in your jurisdiction
- Other-please specify:

The following questions concern your laboratory's CURRENT testing practices for ORAL FLUID specimens ONLY.

15. What test does your laboratory currently use for screening of **oral fluid** specimens?

- Avioq HIV-1 Microelisa
- Bio-Rad HIV-1/HIV-2 Plus O EIA
- Chembio DPP® HIV 1/2 Assay
- OraQuick ADVANCE Rapid HIV-1/2 Antibody Test
- Other- please specify:
- No primary oral fluid screening performed (*Please proceed to question 17*)

16. What does your laboratory do after a reactive oral fluid screening test result?

- OraSure Western blot
- Other- please specify:

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The following questions concern your laboratory's CURRENT testing practices for HIV-1 Nucleic Acid (Amplification) Testing (NAT) only

17. Does your laboratory currently perform HIV-1 NAT?

- Yes (*Please proceed to questions 17a, 17b, 17c, and 18*)
- No (*Please proceed to questions 17d, 17e*)

17a. For what purpose(s) does your laboratory perform HIV-1 NAT ? *Please check all that apply.*

- Detect acute infection
- Clinical management
- Follow-up for discordant results
- Other-please specify:

17b. Which of the following does your laboratory perform? *Please check all that apply.*

- Roche Amplicor HIV-1 Monitor Test (PCR)
- NucliSens HIV-1 QT (NASBA)
- Versant HIV-1 RNA 3.0 (bDNA)
- Hologic APTIMA HIV-1 RNA Qualitative Assay (TMA)
- Abbott RealTime HIV-1 Amplification Kit (PCR)
- COBAS Ampli-Prep/COBAS TaqMan HIV-1 Test (PCR)
- NAT assay developed and validated in house
- Other-please specify:

17c. What specimen types does your laboratory accept for HIV-1 NAT?

- Serum
- Plasma
- Other-please specify:

17d. Does your laboratory refer (send out) specimens for HIV-1 NAT?

- Yes (*Please proceed to question 17d1, 17e*)
- No (*Please proceed to question 17e*).

17d1. Where does your laboratory refer HIV-1 NAT? *Please check all that apply.*

- Commercial laboratory (e.g. Quest, Lab Corp)
- Other public health laboratory
- Clinical (e.g. hospital) laboratory
- Other-please specify:

17e. Does your laboratory plan to offer HIV-1 NAT in the next 12 months?

- Yes (*please proceed to question 17f and 18*)
- No (*please proceed to question 17g and 18*)
- Not sure (*please proceed to question 18*)

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17f. What type of HIV-1 NAT assay does your laboratory plan to offer?

- Qualitative
- Quantitative
- Both
- Unsure

17g. What are your laboratory's greatest impediments to implementing HIV-1 NAT? Please **rank** up to three with 1 being the greatest impediment.

- ___ Physical/Laboratory space
- ___ Workforce
- ___ Cost/Funding
- ___ Regulatory issues
- ___ Low volume
- ___ No perceived need
- ___ None
- ___ Difficulty in performing test
- ___ Other-please specify:

18. Does your laboratory routinely conduct pooled RNA (NAT) screening?

- Yes, routinely on seronegative specimens – How many specimens are included in each pool? _____
- No
- Other- please specify:

19. Please indicate the number of days per week that the following tests are conducted. Indicate "as needed" for tests that are only performed on an as-needed basis.

- Serum/Plasma Immunoassays (IA) _____
- Oral fluid immunoassays _____
- Serum/Plasma Western blots _____
- Oral fluid Western blots _____
- IFA _____
- Multispot HIV-1/HIV-2 Rapid Test _____
- NAT qualitative (diagnosis/identification of acute infection) _____
- NAT quantitative (patient management) _____

20. Has your laboratory implemented a 4th generation HIV Antibody Test as your initial screening test?

- Yes (*please proceed to question 21*)
- No (*please proceed to question 20a*)

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20a. What are your laboratory's greatest impediments to implementing 4th generation testing? Please **rank** up to three with 1 being the greatest impediment.

- Physical/Laboratory space
- Workforce
- Cost/Funding
- Regulatory issues
- No perceived need
- Low volume
- None
- Other-please specify:

21. Has your laboratory implemented a HIV ½ differentiation assay as your routine supplemental test?

- Yes (please proceed to question 22)
- No (please proceed to question 21a)

21a. What are your laboratory's greatest impediments to implementing an HIV 1/2 antibody differentiation assay as a routine supplemental test? Please **rank** up to three with 1 being the greatest impediment.

- Workforce
- Cost/Funding
- State regulations require WB
- HIV Testing Volume Too Low to Warrant a Change
- No perceived need
- None
- Other-please specify:

22. Has your laboratory provided any outreach, training or education on the Recommended Laboratory HIV Testing Algorithm for Serum or Plasma Specimens?

- Yes (please proceed to question 22a and 22b)
- No (please proceed to question 23)

22a. Please identify which entities your laboratory has provided outreach to regarding the Recommended Laboratory HIV Testing Algorithm for Serum or Plasma Specimens. Please *please check all that apply*.

- HIV program(s)
- Clinicians
- Hospital laboratories
- Commercial laboratories
- Point of care testing sites
- Other -please specify:

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22b. What was the nature of the outreach or training you provided on the new algorithm?

Please please check all that apply

- Webinar
- Individual meetings
- Sent literature
- Item(s) in newsletter
- Promoted CDC or APHL publications or webinars
- Other -please specify:

These questions refer to reimbursement methods utilized by public health laboratories for HIV diagnostic testing conducted in 2014 (January 1-December 31)

23. Is your laboratory currently seeking reimbursement from Medicaid, Medicare or other third-party payers for HIV diagnostic testing? *Please check one.*

- Yes, currently billing for HIV testing services (*Please proceed to questions 23 a-d*)
- No, but plan to implement billing within the next 12 months (*Please proceed to question 24*)
- No plans to implement billing in the next 12 months (*Please proceed to questions 24*).
- Don't know (*Please proceed to question 24*)

23a. From which of the following payers does your health department currently seek reimbursement for HIV testing services? *Please check all that apply.*

- Medicaid
- Medicare
- Private insurance
- Other - please specify:
- Not Sure

23b. By what mechanism does your laboratory seek reimbursement from Medicaid and/or other third-party payers for HIV testing services? *Please check one.*

- Health department bills insurers directly
- Health department bills providers
- Other - please specify:
- Not Sure

23c. Does your laboratory use an intermediary (e.g. insurance benefits manager) to seek reimbursement?

- Yes
- No
- Not Sure

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23d. If your laboratory is receiving reimbursement from third-party payers for HIV testing services, where does that revenue go? *Please check one.*

- To the laboratory – earmarked for HIV testing
- To the laboratory – other
- To the health department – HIV/AIDS program
- To the health department – general or other fund
- To the state general fund
- Other - please specify:
- Not Sure

24. What factors or issues prevent your laboratory from not billing for HIV testing services ?

Please rank the top 3 choices, 1-3.

- Lack of staff lack knowledge about billing and reimbursement
- Lack capacity to support providers in implementation
- Lack of mechanism to collect revenue obtained through third party reimbursement
- Lack of IT infrastructure needed to pursue reimbursement (e.g., billing software)
- Not cost effective to invest in infrastructure and personnel to begin billing
- Statutory/regulatory prohibitions
- Poor reimbursement rates
- Laboratory lacks capacity to follow-up on unpaid bills
- Challenges in contracting with third-party payers
- Majority of clients do not have insurance
- Other - please specify:
- Not Sure

Hepatitis C

25. Does your laboratory offer any testing services for the diagnosis or management of Hepatitis C Virus (HCV)

- Yes (*Please proceed to question 26*)
- No (*Please proceed to question 25a and end survey*)

25a. Does your laboratory have plans to add HCV testing services in the next year?

- Plan to add HCV Antibody testing
- Plan to add HCV NAT testing
- Plan add both HCV Antibody and HCV NAT testing
- No plans to add HCV testing services
- Not sure

26. What types of HCV testing services do you offer in-house? *Please check all that apply.*

- HCV Antibody IA; laboratory based
- HCV Antibody IA; point of care
- Supplemental RIBA for IA Confirmation
- HCV RNA; Qualitative
- HCV RNA; Quantitative
- HCV Genotyping
- Other- please specify:

Thank you for completing the survey!