2024 HIV and HCV Diagnostic Testing Survey

This survey is designed to capture the 2023 HIV and HCV testing practices in state and local public health laboratories (PHLs). The results of the survey will help APHL understand the current capacity and capabilities of HIV and HCV testing in the public health laboratory, and to create resources and tools to support our members.

This survey may require inputs from other individuals in your laboratory.

At times, the numbering of the questions might not be in order as the survey has built in skips depending on how you answer questions.

1. Did your public health laboratory perform any HIV or HCV testing in 2023 (January 1, 2023 - December 31, 2023)?

- ○ Yes, HIV and HCV testing
- ○ Yes, HIV only
- ○ Yes, HCV only
- ○ No, HIV and HCV testing was not performed

Skip To: Question 24 If 1. Did your public health laboratory perform any HIV or HCV testing in 2023 (January 1, 2023 - De... = Yes, HCV only

Skip To: Question 24 If 1. Did your public health laboratory perform any HIV or HCV testing in 2023 (January 1, 2023 - De... = No, HIV and HCV testing was not performed

2. Did your laboratory provide or refer the following HIV Testing Services in 2023?

	In-House	Referral	Not Offered
HIV Ab Immunoassay for screening	○	○	○
HIV Ag/Ab Immunoassay for screening	○	○	○
HIV Antibody Differentiation Assay (e.g. Geenius, VioOne)	○	○	○
CLIA-Waived Point of Care Test/Rapid Diagnostic Test	○	○	○
HIV-1 NAT (qualitative)	○	○	○
HIV-1 NAT (quantitative/viral load)	○	○	○
HIV-1 Genotyping Assay	○	○	○
HIV-1 Western Blot	○	○	○
HIV-1/HIV-2 NAT (qualitative)	○	○	○
HIV-2 NAT (qualitative)	○	○	○
HIV-2 EIA	○	○	○
Cadaveric Testing	○	○	○
Diagnostic Testing of Exposed Infants	○	○	○
Pooled NAT Testing	○	○	○
Diagnostic NAT testing without screening by serology (this excludes viral load testing)	○	○	○

Testing for PrEP Initiation and/or Monitoring	○	○	○
Recency Testing	○	○	○
Sequencing for Cluster Identification/Molecular Surveillance (Sanger or Next Gen)	○	○	○
Other test method or service, please specify;	○	○	○

3. As of December 31, 2023 did your laboratory accept the following for HIV clinical testing? *Please check all that apply.*

☐ Serum and/or plasma to perform the entire HIV laboratory diagnostic algorithm

☐ Serum and/or plasma that was reactive on a screening assay at another laboratory for completion of the diagnostic algorithm

☐ Any sample type to confirm preliminary positive CLIA-waived point of care (single-use) tests

☐ Plasma for quantitative viral load testing

☐ Dried blood spot (DBS) to perform the diagnostic algorithm

☐ Oral fluid to perform the diagnostic algorithm

☐ Other, please specify:

_____

☐ Our laboratory no longer receives samples for clinical HIV Testing, *if testing was discontinued at any point after December 2017 please provide narrative for when the testing was discontinued and reasons (i.e. lab decision (cost/staffing), program decision, etc.)*

_____

Display This Question:

If 3. As of December 31, 2023 did your laboratory accept the following for HIV clinical testing? Ple... = Serum and/or plasma that was reactive on a screening assay at another laboratory for completion of the diagnostic algorithm

3a. When a specimen that tested reactive on a laboratory-based screening assay (i.e., reactive using a HIV Ab or HIV Ag/Ab immunoassay at a different laboratory) is referred to your laboratory for confirmation, what is the first test your laboratory would perform?

- ○ Screening IA (complete algorithm)
- ○ Supplemental test-antibody differentiation
- ○ Supplemental test-NAT
- ○ Supplemental testing with automatic reflexes-antibody and NAT if needed
- ○ Other, please describe: _____

Display This Question:

If 3. As of December 31, 2023 did your laboratory accept the following for HIV clinical testing? Ple... = Any sample type to confirm preliminary positive CLIA-waived point of care (single-use) tests

3b. When a specimen that tested reactive on a CLIA-waived point of care-based screening assay (i.e., reactive using a rapid test performed elsewhere) is referred to your laboratory for confirmation, what is the first test your laboratory would perform?

- ○ Screening IA (complete algorithm)
- ○ Supplemental test-antibody
- ○ Supplemental test-NAT
- ○ Supplemental testing with automatic reflexes-antibody and NAT if needed
- ○ Other, please describe _____

Additional Comments:

_____

Questions 4 and 5 refer to your testing practices related to HIV PrEP as of December 31, 2023 .

4. As of December 31, 2023, did your laboratory information management system or test requisition form capture information regarding if specimens are from persons on antiretrovirals or if the patient is being tested for purposes of HIV PrEP initiation or monitoring?

- ○ Yes
- ○ No
- ○ Unsure

Display This Question:

If 4. As of December 31, 2023, did your laboratory information management system or test requisition... = No

4a. Does your laboratory plan to capture this information regarding antiretroviral use in the future?

- ○ Yes
- ○ No
- ○ Unsure

5. As of December 31, 2023, did your laboratory provide or refer HIV testing for the purposes of HIV PrEP initiation and/or monitoring?

- ○ Yes, in-house
- ○ Yes, we refer this testing to another laboratory
- ○ No
- ○ Unsure

Display This Question:

If 5. As of December 31, 2023, did your laboratory provide or refer HIV testing for the purposes of... = Yes, in-house

Or 5. As of December 31, 2023, did your laboratory provide or refer HIV testing for the purposes of... = Yes, we refer this testing to another laboratory

5a. What is the approximate number of samples received in 2023 for the purposes of HIV PrEP initiation or monitoring?

_____

Display This Question:

If 5. As of December 31, 2023, did your laboratory provide or refer HIV testing for the purposes of... = Yes, in-house

Or 5. As of December 31, 2023, did your laboratory provide or refer HIV testing for the purposes of... = Yes, we refer this testing to another laboratory

5b. As of December 31, 2023, did you have a specific orderable for (select all that apply)

- ☐ HIV testing for PrEP (both initiation and monitoring)
- ☐ HIV testing for PrEP initiation
- ☐ HIV testing for PrEP monitoring (on-going PrEP usage)
- ☐ We do not have a specific orderable
- ☐ Unsure

Display This Question:

If 5. As of December 31, 2023, did your laboratory provide or refer HIV testing for the purposes of... = Yes, in-house

Or 5. As of December 31, 2023, did your laboratory provide or refer HIV testing for the purposes of... = Yes, we refer this testing to another laboratory

5c. When HIV testing is for purposes related to HIV PrEP, what tests are performed in your laboratory?

- ○ All specimens tested for purposes related to HIV PrEP receive both HIV Ag/Ab and HIV NAT testing (regardless of the results of either test) in our laboratory
- ○ Only patients that have recent or on-going antiretroviral use (i.e., person is using or has recently used HIV PrEP) are tested with both HIV Ag/Ab and HIV NAT testing (regardless of the results of either test) in our laboratory
- ○ We do not automatically perform both HIV Ag/Ab and HIV NAT (regardless of the results of either test) in our laboratory
- ○ Unsure

Display This Question:

If 5. As of December 31, 2023, did your laboratory provide or refer HIV testing for the purposes of... = Yes, in-house

Or 5. As of December 31, 2023, did your laboratory provide or refer HIV testing for the purposes of... = Yes, we refer this testing to another laboratory

5d. As of December 31, 2023, did you offer additional tests that are recommended in conjunction with HIV PrEP usage? A response is required for each row.

	In-House	Referral	Not Offered
Syphilis	☐	☐	☐
Chlamydia / Gonorrhea	☐	☐	☐
Hepatitis B testing	☐	☐	☐
Serum creatinine	☐	☐	☐
Lipid Profile	☐	☐	☐

Display This Question:

If 5. As of December 31, 2023, did your laboratory provide or refer HIV testing for the purposes of... = Yes, in-house

Or 5. As of December 31, 2023, did your laboratory provide or refer HIV testing for the purposes of... = Yes, we refer this testing to another laboratory

5e. Please indicate whether testing for the following is bundled (as a panel or an order set) with HIV test for PrEP related orders.

- [ ] Syphilis
- [ ] Chlamydia / Gonorrhea
- [ ] Serum creatinine
- [ ] Lipid Profile

6. In your laboratory, how many full-time equivalents are:
(Enter a valid number)

- ○ currently trained to perform HIV testing *(Please enter number)*

_____

- ○ routinely assigned to perform HIV testing *(Please enter number)*

_____

Additional Comments regarding HIV PrEP:

_____

Questions 7 through 18 refer to your HIV laboratory diagnostic testing algorithm for serum/plasma samples as of December 31, 2023.

7. Which HIV immunoassay did your laboratory use for initial laboratory screening of serum/plasma specimens? *Please select only one.*

- ○ Architect HIV Ag/Ab Combo (Abbott)
- ○ ALINITY i HIV Ag/Ab Combo (Abbott)
- ○ Determine HIV-1/2 Ag/Ab Combo (Alere)
- ○ HIV-1 Microelisa (Avioq)
- ○ Access HIV Ag/Ab Combo (Beckman Coulter)
- ○ BioPlex 2200 HIV Ag-Ab (Bio-Rad)
- ○ GS HIV-1/HIV-2 Plus O EIA (Bio-Rad)
- ○ GS HIV Combo Ag/Ab EIA (Bio-Rad)
- ○ Liaison XL Murex HIV Ag/AB HT (Diasorin)
- ○ VITROS Anti-HIV 1+2 Immunoassay (Ortho)
- ○ VITROS HIV Combo Test (Ortho)
- ○ Elecsys HIV Combi PT (Roche)
- ○ Elecsys HIV Duo (Roche)
- ○ ADVIA HIV Ag/AB Combo (Siemens)
- ○ ADVIA Centaur HIV 1/O/2 Enhanced (Siemens)
- ○ Our lab switched assays in 2023
- ○ Our lab does not use an immunoassay for screening, we use an HIV RNA test – please specify rationale and test sequence if screening NAT is negative _____
- ○ Other- please specify: _____
- ○ Not applicable

Display This Question:

If 7. Which HIV immunoassay did your laboratory use for initial laboratory screening of serum/plasma... = Our lab switched assays in 2023

7a. Please select the **current** HIV Immunoassay from the dropdown.

- ○ Architect HIV Ag/Ab Combo (Abbott)
- ○ ADVIA HIV Ag/AB Combo (Siemens)
- ○ ADVIA Centaur HIV 1/O/2 Enhanced (Siemens)
- ○ BioPlex 2200 HIV Ag-Ab (Bio-Rad)
- ○ ALINITY i HIV Ag/Ab Combo (Abbott)
- ○ Determine HIV-1/2 Ag/Ab Combo (Alere)
- ○ Elecsys HIV Combi PT (Roche)
- ○ Elecsys HIV Duo (Roche)
- ○ GS HIV-1/HIV-2 Plus O EIA (Bio-Rad)
- ○ GS HIV Combo Ag/Ab EIA (Bio-Rad)
- ○ HIV-1 Microelisa (Avioq)
- ○ VITROS Anti-HIV 1+2 Immunoassay (Ortho)
- ○ VITROS HIV Combo Test (Ortho)

Display This Question:

If 7. Which HIV immunoassay did your laboratory use for initial laboratory screening of serum/plasma... = Our lab switched assays in 2023

7b. Please select the **previous** HIV Immunoassay used in 2023.

- ○ Architect HIV Ag/Ab Combo (Abbott)
- ○ ADVIA HIV Ag/AB Combo (Siemens)
- ○ ADVIA Centaur HIV 1/O/2 Enhanced (Siemens)
- ○ BioPlex 2200 HIV Ag-Ab (Bio-Rad)
- ○ ALINITY i HIV Ag/Ab Combo (Abbott)
- ○ Determine HIV-1/2 Ag/Ab Combo (Alere)
- ○ Elecsys HIV Combi PT (Roche)
- ○ Elecsys HIV Duo (Roche)
- ○ GS HIV-1/HIV-2 Plus O EIA (Bio-Rad)
- ○ GS HIV Combo Ag/Ab EIA (Bio-Rad)
- ○ HIV-1 Microelisa (Avioq)
- ○ VITROS Anti-HIV 1+2 Immunoassay (Ortho)
- ○ VITROS HIV Combo Test (Ortho)

Display This Question:

If 7. Which HIV immunoassay did your laboratory use for initial laboratory screening of serum/plasma... = Our lab switched assays in 2023

7c. Approximate Date of Switch: (mm/dd/yyyy)

_____

8. After a **repeatedly reactive** laboratory screening immunoassay, what is the first supplemental HIV assay your laboratory performs on **serum/plasma specimens**? *Please select only one.*

- ○ Geenius HIV-1/2 Supplemental Assay (Bio-Rad)
- ○ VioOne HIV Profile (Avioq)
- ○ Laboratory refers supplemental antibody testing to another laboratory
- ○ We utilize an HIV RNA Test at the second step
- ○ Our lab switched assays in 2023
- ○ No supplemental test is performed
- ○ Not applicable
- ○ Other- please specify: _____

Display This Question:

If 8. After a repeatedly reactive laboratory screening immunoassay, what is the first supplemental HI... = We utilize an HIV RNA Test at the second step

8a. Please specify which HIV RNA test is used at the second step of the HIV diagnostic algorithm, following a reactive HIV screening immunoassay

_____

Display This Question:

If If 8a. Please specify which HIV RNA test is used at the second step of the HIV diagnostic algorithm,... Text Response Is Displayed

8b. When an HIV RNA test is used at the second step of the HIV diagnostic algorithm and the result is “Not Detected” (i.e., screening assay reactive, HIV RNA not detected), do you reflex to a supplemental HIV-1/HIV-2 Ab differentiation assay?

- ○ Yes
- ○ No, please explain your course of action

_____

Display This Question:

If 8. After a repeatedly reactive laboratory screening immunoassay, what is the first supplemental HI... = Our lab switched assays in 2023

8c. Please select the **current** supplemental HIV assay from the dropdown.

- ○ Geenius HIV-1/2 Supplemental Assay (Bio-Rad)
- ○ VioOne HIV Profile (Avioq)

Display This Question:

If 8. After a repeatedly reactive laboratory screening immunoassay, what is the first supplemental HI... = Our lab switched assays in 2023

8d. Please select the **previous** supplemental HIV assay from the dropdown.

- ○ Geenius HIV-1/2 Supplemental Assay (Bio-Rad)
- ○ VioOne HIV Profile (Avioq)

Display This Question:

If 8. After a repeatedly reactive laboratory screening immunoassay, what is the first supplemental HI... = Our lab switched assays in 2023

8e. Approximate Date of Switch: (mm/dd/yyyy)

_____

9. If the laboratory screening immunoassay is **reactive** and the first supplemental test result is **nonreactive** what is your laboratory's next step? *Please select the response which reflects your laboratory's primary next step.*

- ○ Automatic reflex to in-house HIV-1 NAT
- ○ Automatic reflex to in-house HIV-1/-2 NAT
- ○ Automatic reflex to referral lab for HIV NAT (HIV 1 or HIV 1/2)
- ○ Perform additional testing upon request
- ○ Refer for additional testing upon request
- ○ Request additional specimen to perform follow-up testing in-house
- ○ Request additional specimen to refer to another laboratory for follow-up testing
- ○ Consult with CDC, state epidemiologist or laboratory expert before any further testing
- ○ No further testing
- ○ Other- please specify: _____

Display This Question:

If 9. If the laboratory screening immunoassay is reactive and the first supplemental test result is... = Perform additional testing upon request

Or 9. If the laboratory screening immunoassay is reactive and the first supplemental test result is... = Refer for additional testing upon request

Or 9. If the laboratory screening immunoassay is reactive and the first supplemental test result is... = Request additional specimen to perform follow-up testing in-house

Or 9. If the laboratory screening immunoassay is reactive and the first supplemental test result is... = Request additional specimen to refer to another laboratory for follow-up testing

9a. What additional testing is performed or referred? *Please select the response that reflects* the *most likely option.*

- ○ Repeat Initial Supplemental Test
- ○ HIV-1 NAT
- ○ HIV-2 NAT
- ○ HIV-1/2 NAT
- ○ HIV-2 EIA
- ○ Other-please specify: _____

10. If the laboratory screening immunoassay is **reactive** and the first supplemental test result is **HIV-2 antibody positive** (with or without cross-reactivity), what is your laboratory's next step? *Please select the response which reflects your laboratory's primary next step.*

- ○ Perform additional testing on automatic reflex
- ○ Refer for additional testing on automatic reflex
- ○ Perform additional testing upon request
- ○ Refer for additional testing upon request
- ○ Request additional specimen to perform additional testing
- ○ Request additional specimen to refer for additional testing
- ○ No further testing
- ○ Consult with CDC, state epidemiologist or laboratory expert before any further testing
- ○ Other- please specify: _____

Display This Question:

If 10. If the laboratory screening immunoassay is reactive and the first supplemental test result is... != No further testing

And 10. If the laboratory screening immunoassay is reactive and the first supplemental test result is... != Consult with CDC, state epidemiologist or laboratory expert before any further testing

10a. Based on your response above-what additional testing does your laboratory conduct or refer? *Please select the response that reflects the most likely option.*

- ○ Repeat Initial Supplemental Test
- ○ HIV-1 NAT
- ○ HIV-2 NAT
- ○ HIV-1/2 NAT
- ○ HIV-2 EIA
- ○ HIV-2 Western Blot
- ○ Other-please specify: _____

11. If the laboratory screening immunoassay is **reactive** and the first supplemental test result is **HIV Indeterminate** what is your laboratory's next step? *Please select the response which reflects your laboratory's primary next step.*

- ○ Automatic reflex to in-house HIV-1 NAT
- ○ Automatic reflex to in-house HIV-1/-2 NAT
- ○ Automatic reflex to referral lab for HIV NAT (HIV 1 or HIV 1/2)
- ○ Perform additional testing upon request
- ○ Refer for additional testing upon request
- ○ Request additional specimen to perform follow-up testing in-house
- ○ Request additional specimen to refer to another laboratory for follow-up testing
- ○ Consult with CDC or other laboratory expert before any further testing
- ○ No further testing
- ○ Other- please specify: _____
- ○ Not Applicable (This is not a result from the supplemental test our laboratory uses)

Display This Question:

If 11. If the laboratory screening immunoassay is reactive and the first supplemental test result is... = Perform additional testing upon request

Or 11. If the laboratory screening immunoassay is reactive and the first supplemental test result is... = Refer for additional testing upon request

Or 11. If the laboratory screening immunoassay is reactive and the first supplemental test result is... = Request additional specimen to perform follow-up testing in-house

Or 11. If the laboratory screening immunoassay is reactive and the first supplemental test result is... = Request additional specimen to refer to another laboratory for follow-up testing

11a. Based on your response above-what additional testing does your laboratory conduct or refer? *Please select the response that reflects the most likely option.*

- ○ Repeat Initial Supplemental Test
- ○ HIV-1 NAT
- ○ HIV-2 NAT
- ○ HIV-1/-2 NAT
- ○ HIV-2 EIA
- ○ Other-please specify: _____

12. If the laboratory screening immunoassay is **reactive** and the first supplemental test result is **HIV-1 Indeterminate** what is your laboratory's next step? *Please select the response which reflects your laboratory's primary next step.*

- ○ Automatic reflex to in-house HIV-1 NAT
- ○ Automatic reflex to in-house HIV-1/-2 NAT
- ○ Automatic reflex to referral lab for HIV NAT (HIV 1 or HIV 1/2)
- ○ Perform additional testing upon request
- ○ Refer for additional testing upon request
- ○ Request additional specimen to perform follow-up testing in-house
- ○ Request additional specimen to refer to another laboratory for follow-up testing
- ○ Consult with CDC or other laboratory expert before any further testing
- ○ No further testing
- ○ Other- please specify: _____
- ○ Not Applicable (This is not a result from the supplemental test our laboratory uses)

Display This Question:

If 12. If the laboratory screening immunoassay is reactive and the first supplemental test result is... = Perform additional testing upon request

Or 12. If the laboratory screening immunoassay is reactive and the first supplemental test result is... = Refer for additional testing upon request

Or 12. If the laboratory screening immunoassay is reactive and the first supplemental test result is... = Request additional specimen to perform follow-up testing in-house

Or 12. If the laboratory screening immunoassay is reactive and the first supplemental test result is... = Request additional specimen to refer to another laboratory for follow-up testing

12a. Based on your response above-what additional testing does your laboratory conduct or refer? *Please select the response that reflects the most likely option.*

- ○ Repeat Initial Supplemental Test
- ○ HIV-1 NAT
- ○ HIV-2 NAT
- ○ HIV-1/2 NAT
- ○ HIV-2 EIA
- ○ Other-please specify: _____

13. If the laboratory screening immunoassay is **reactive** and the first supplemental test is **HIV-2 indeterminate (after repeat per package insert, if applicable)** what is your laboratory's next step?

- ○ No further testing
- ○ Perform HIV-1 NAT
- ○ Perform HIV-1/-2 NAT
- ○ Consult with CDC or other laboratory expert before any further testing
- ○ Request additional specimen to perform additional testing
- ○ Request additional specimen to refer for additional testing
- ○ Perform additional testing on automatic reflex
- ○ Refer for additional testing on automatic reflex
- ○ Perform additional testing upon request
- ○ Refer for additional testing upon request
- ○ Other- please specify: _____

Display This Question:

If 13. If the laboratory screening immunoassay is reactive and the first supplemental test is HIV-2... = Request additional specimen to perform additional testing

Or 13. If the laboratory screening immunoassay is reactive and the first supplemental test is HIV-2... = Request additional specimen to refer for additional testing

Or 13. If the laboratory screening immunoassay is reactive and the first supplemental test is HIV-2... = Perform additional testing on automatic reflex

Or 13. If the laboratory screening immunoassay is reactive and the first supplemental test is HIV-2... = Refer for additional testing on automatic reflex

Or 13. If the laboratory screening immunoassay is reactive and the first supplemental test is HIV-2... = Perform additional testing upon request

Or 13. If the laboratory screening immunoassay is reactive and the first supplemental test is HIV-2... = Refer for additional testing upon request

13a. Based on your response above-what additional testing does your laboratory conduct or refer? *Please select the response that reflects the most likely option.*

- ○ Repeat Initial Supplemental Test
- ○ HIV-1 NAT
- ○ HIV-2 NAT
- ○ HIV-1/2 NAT
- ○ HIV-2 EIA
- ○ Other-please specify: _____

14. Does your laboratory perform any HIV-1 Nucleic Acid Testing (NAT) for any sample type?

- ○ Yes, we perform testing in-house using an HIV-1 NAT
- ○ No, we refer out specimens for HIV-1 NAT
- ○ No, HIV-1 NAT testing is neither performed nor referred
- ○ Other, please describe: _____

Display This Question:

If 14. Does your laboratory perform any HIV-1 Nucleic Acid Testing (NAT) for any sample type? = Yes, we perform testing in-house using an HIV-1 NAT

14a. What specimen types does your laboratory accept for HIV-1 NAT? *Please check all that apply.*

- ☐ Serum
- ☐ Plasma
- ☐ Dried Blood Spot (DBS)
- ☐ Whole Blood
- ☐ Other-please specify:

_____

Display This Question:

If 14a. What specimen types does your laboratory accept for HIV-1 NAT? Please check all that apply. , Serum Is Displayed

14b. For each HIV-1 NAT method listed select the purpose(s) that it is used for by selecting the box. If you don't perform HIV-1 NAT for that purpose, please select "don't use method." *For each row, at least one answer must be selected.*

	Don't Use Method	Diagnosis/detect acute infection (Final Step in Algorithm and /or when used for purposes related to HIV PrEP)	Supplemental test for HIV-1 p24 Ag positive samples (Following screening test only results)	Clinical management/ Viral Load	Other purpose, please describe below **(14bii)**
Alinity m HIV-1 (Abbott)	☐	☐	☐	☐	☐
APTIMA HIV-1 Quant Assay-Panther (Hologic)	☐	☐	☐	☐	☐
COBAS HIV-1/HIV-2 Qualitative (Roche)	☐	☐	☐	☐	☐
COBAS Ampli-Prep/COBAS TaqMan HIV-1 Test on 48/96 (Roche)	☐	☐	☐	☐	☐
COBAS HIV-1 on 5800/6800/8800 (Roche)	☐	☐	☐	☐	☐
RealTime HIV-1 Amplification Kit, m2000 (Abbott)	☐	☐	☐	☐	☐
Other HIV-1 NAT Method, **Please describe below (14bi)**	☐	☐	☐	☐	☐

Display This Question:

If 14b. For each HIV-1 NAT method listed select the purpose(s) that it is used for by selecting the... = Other HIV-1 NAT Method, Please describe below (14bi)

14bi. Please specify the method used including whether it detects RNA or DNA, is qualitative or quantitative, and FDA cleared or LDT.

_____

Display This Question:

If 14b. For each HIV-1 NAT method listed select the purpose(s) that it is used for by selecting the... [Other purpose, please describe below (14bii)] (Recode) Is Not Empty

14bii. Please specify any other purpose that HIV-1 NAT is performed.

_____

Display This Question:

If 14. Does your laboratory perform any HIV-1 Nucleic Acid Testing (NAT) for any sample type? = No, we refer out specimens for HIV-1 NAT

14c. Where does your laboratory refer HIV-1 NAT?

- ○ Refer to APHL HIV NAT Reference Center Laboratory (Florida Bureau of Laboratories or NY-Wadsworth Center)
- ○ Refer to another public health laboratory
- ○ Refer to commercial laboratory (e.g. Quest, Lab Corp)
- ○ Refer to clinical or hospital laboratory in your jurisdiction
- ○ Other – please specify: _____

15. Has your laboratory encountered specimens or patients that test positive for HIV antibody (i.e. HIV Ab or HIV Ab/Ag Immunoassay Positive and Confirmed with Ab Differentiation method) but negative for HIV RNA?

- ○ Yes
- ○ No
- ○ Unsure

Display This Question:

If 15. Has your laboratory encountered specimens or patients that test positive for HIV antibody (i.... = Yes

15a. What are your next steps when you encounter this situation? (select all that apply)

- ☐ Review antibody S/CO to determine if possible false positive Ab result
- ☐ Review patient records for past or present antiretroviral use
- ☐ Retest new sample for retesting
- ☐ Suggest that submitter send specimen to a laboratory with a different screening assay
- ☐ Suggest submitter send for HIV DNA testing
- ☐ Send specimen to CDC for Western Blot testing

16. How many total specimens did your laboratory receive for HIV laboratory diagnostic testing in **2023**? Notes: Do not include proficiency testing specimens or specimens submitted solely for patient management (e.g. viral load) *Please enter a valid number in the box.*

_____

17. Of the total specimens submitted, how many of each of the following specimen types did your laboratory receive for HIV diagnostic testing? Please enter “0” for specimen types not received for testing.

The total number of specimens in this question should equal the total number of specimens reported in Question 16.

Sample Type

	2023
Plasma	
Serum	
Serum/Plasma (unable to distinguish)	
Oral fluid	
Dried blood spot	
Other (please specify)	
Unknown	
Whole blood	
Total	

18. Of all **serum/plasma specimens** received how many of the following HIV results did your laboratory report?

Note: Select the results that you report and then report an integer for the number tested. The total number of results in this question should equal the sum of specimens listed for Serum, Plasma and Serum/Plasma (unable to distinguish).

Sample Results

	2023
Negative (e.g. Screening test nonreactive with no further testing)	
Negative (e.g. Screening test reactive, supplemental Ab negative/indeterminate and HIV RNA NOT detected)	
Acute HIV-1 Positive (e.g. Screening test reactive, supplemental Ab negative/indeterminate and HIV-1 RNA detected)	
HIV-1 Positive (e.g. Screening test reactive, supplemental Ab testing confirms HIV-1)	
HIV-2 Positive (e.g. Screening test reactive, supplemental Ab testing confirms HIV-2)	
HIV Positive (e.g. Screening test reactive, supplemental Ab testing untypeable or undifferentiated)	
HIV-1 Negative, HIV-2 Inconclusive (e.g. Screening test reactive, supplemental Ab testing was either repeatedly HIV-2 indeterminate or HIV indeterminate and not detected by HIV-1 NAT or HIV-1/-2 NAT)	
Inconclusive (e.g. Screening test reactive, supplemental Ab test negative or indeterminate and HIV-1 NAT or HIV -1/-2 NAT was invalid, quantity not sufficient, or otherwise not performed)	
Not tested (e.g. sample rejected)	
Total	

Questions 19 and 20 refer to confirmation of preliminary positive point of care (single-use) tests conducted in 2023 (January 1, 2023- December 31, 2023)

19. Does your laboratory receive specimens for confirmation of preliminary positive point of care (single-use) tests performed outside your laboratory (in a CLIA-waived setting)?

- ○ Yes and samples are identifiable as being submitted for this purpose
- ○ Yes but we are unable to determine which samples we receive are being submitted for this purpose
- ○ No
- ○ Not sure

Display This Question:

If 19. Does your laboratory receive specimens for confirmation of preliminary positive point of ca... = Yes and samples are identifiable as being submitted for this purpose

19a. Please answer the following questions regarding whole blood/serum/plasma specimens received following a preliminary positive rapid test performed outside of your laboratory.

Please enter a number (Enter 0 if you receive specimens for confirmation but are not able to determine the number of samples)

How many whole blood/serum/plasma specimens were received following a preliminary positive rapid test performed outside of your laboratory (CLIA waived setting)?

Please enter a number (Enter 0 if you receive specimens for confirmation but are not able to determine the number of samples)

Of those received, how many were reported as HIV Negative following confirmatory testing by your laboratory?

Please enter a number (Enter 0 if you receive specimens for confirmation but are not able to determine the number of samples)

Display This Question:

If 19. Does your laboratory receive specimens for confirmation of preliminary positive point of ca... = Yes and samples are identifiable as being submitted for this purpose

19b. Please complete the table below for each specimen type that you receive for confirmation of a preliminary positive rapid test by selecting the first HIV test conducted in your laboratory to diagnose HIV. Each row of the table must have a response.

Sample Type Used for Confirmatory Testing	**What is the first HIV Test conducted to confirm a preliminary positive?**			
	Not Applicable/ Don't receive sample type	HIV Ag/Ab or HIV Ab	Supplemental HIV Test (Ab differentiation)	HIV-1 NAT or HIV-1/-2 NAT (Dx claim)
Plasma	○	○	○	○
Serum	○	○	○	○
Plasma/Serum (indistinguishable)	○	○	○	○
Oral Fluid	○	○	○	○
Dried Blood Spot	○	○	○	○
Whole Blood	○	○	○	○
Other, please describe in comment box	○	○	○	○

Additional Comments regarding confirmation of preliminary positive point of care (single-use) tests:

_____

Questions 20 to 21 concern your laboratory's testing practices for ORAL FLUID specimens ONLY as of December 31, 2023.

20. Did your laboratory receive specimens for **screening oral fluid** specimens in 2023?

- ○ Yes
- ○ No

Skip To: Question 23 If 20. Did your laboratory receive specimens for screening oral fluid specimens in 2023? = No

21. What test did your laboratory use for the screening of **oral fluid** specimens as of December 31, 2023?

- ○ Avioq HIV-1 Microelisa
- ○ Chembio DPP® HIV 1/2 Assay
- ○ OraQuick ADVANCE Rapid HIV-1/2 Antibody Test
- ○ Our lab switched assays in 2023
- ○ Our lab only receives oral fluid for confirmation of preliminary positives
- ○ Other- please specify: _____

Display This Question:

If 21. What test did your laboratory use for the screening of oral fluid specimens as of December 31... = Our lab switched assays in 2023

21a. Please select the **current** assay from the dropdown. 1

- ○ 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

Display This Question:

If 21. What test did your laboratory use for the screening of oral fluid specimens as of December 31... = Our lab switched assays in 2023

21b. Please select the **previous** assay from the dropdown.

- ○ 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

Display This Question:

If 21. What test did your laboratory use for the screening of oral fluid specimens as of December 31... = Our lab switched assays in 2023

21c. Approximate Date of Switch: (mm/dd/yyyy)

_____

22. There are no FDA-approved methods for confirmation of HIV in Oral Fluid specimens. How does your laboratory handle confirmation? *Please describe in the comment box:*

_____

_____

_____

_____

_____

Additional Comments regarding testing practices for ORAL FLUID specimens ONLY:

_____

Questions 23 through 28 concern your laboratory's potential changes in HIV testing practices.

Display This Question:

If 1. Did your public health laboratory perform any HIV or HCV testing in 2023 (January 1, 2023 - De... = Yes, HIV and HCV testing

Or 1. Did your public health laboratory perform any HIV or HCV testing in 2023 (January 1, 2023 - De... = Yes, HIV only

23. Did your laboratory eliminate any HIV testing methods between January 1, 2023, and December 31, 2023?

- ○ Yes, please specify _____
- ○ No

24. Does your laboratory have any plans to change any HIV testing services (including any clinical testing or molecular surveillance) before December 31, 2024?

- ○ Yes
- ○ No
- ○ Unsure

Display This Question:

If 24. Does your laboratory have any plans to change any HIV testing services (including any clinica... = Yes

HIV Screening Assay *(Please select at least one response per section)*

☐ Add screening assay to be performed on site, specify new assay in comments

☐ Replace existing screening assay with a new screening assay; specify old and new assays in comments _____

☐ Modify an existing screening assay (including specimen types); specify modification in comments _____

☐ Eliminate an existing screening assay; specify rationale in comments _____

☐ Refer screening assay to another laboratory; specify rationale in comments _____

☐ ⊗ No changes planned for HIV Screening Assay

HIV Supplemental Antibody Assay *(Please select at least one response per section)*

☐ Add supplemental assay to be performed on site, specify new assay in comments _____

☐ Replace existing supplemental assay with a new assay; specify old and new assays in comments _____

☐ Modify an existing supplemental antibody assay (including specimen types); specify modification in comments _____

☐ Eliminate an existing supplemental assay; specify rationale in comments _____

☐ Refer supplemental antibody assay to another laboratory; specify rationale in comments _____

☐ ⊗ No changes planned for HIV Supplemental Antibody Assay

HIV NAT *(Please select at least one response per section)*

- ☐ Add an HIV NAT to be performed on site, specify new assay in comments

_____

- ☐ Replace existing HIV NAT performed on site with a new HIV-1 NAT, please specify old and new assays in comments

_____

- ☐ Modify existing HIV NAT; specify modification in comments

_____

- ☐ Eliminate HIV NAT; specify rationale in comments

_____

- ☐ Refer HIV NAT to another laboratory; specify rationale in comments

_____

- ☐ Add or change other HIV NAT, specify in comments

_____

- ☐ ⊗ No changes planned for HIV NAT

Other HIV Testing Services (Genotyping, Monitoring, etc.)

- ☐ Add service; specify new assay in comments

_____

- ☐ Replace; please specify old and new service/ in comments

_____

- ☐ Modify, specify modification in comments

_____

- ☐ Eliminate an existing service; specify rationale in comments

_____

- ☐ ⊗ No changes planned

25. With respect to HIV, what changes are your laboratory considering as a direct result of the FDA Rule regarding regulation of laboratory developed tests? (select all that apply)

- ○ We are considering how to generate the data needed for FDA submission, please specify _____
- ○ We are considering elimination of a specific test/specimen type/practice, please specify _____
- ○ Not Applicable, we do not perform HIV testing
- ○ Not Applicable, we do not utilize LDTs for HIV testing
- ○ Not Applicable, we utilize an LDT that would remain under enforcement discretion, please specify _____
- ○ Unsure/Undecided

Display This Question:

If 25. With respect to HIV, what changes are your laboratory considering as a direct result of the F... = We are considering how to generate the data needed for FDA submission, please specify

25a. Would your laboratory be interested in collaborating with other laboratories to generate a group submission for the FDA?

- ○ Yes
- ○ No
- ○ Unsure

Additional Comments regarding potential changes in HIV testing practices:

_____

26. New HIV testing technologies are on the horizon. If any of the following new technologies became FDA approved and/or included in the APHL/CDC HIV Laboratory Algorithm, which would your laboratory be interested in bringing on? *(This in no way means that it will happen, but this information is useful to understand the needs) Please check all that apply.*

- ☐ Rapid HIV-1/2 Ag/Ab Combination Immunoassay
- ☐ Alternative HIV-1/2 Ag/Ab Differentiating Combination Immunoassay (for Step 1 screening)
- ☐ Alternative supplemental HIV-1/2 antibody differentiation assay
- ☐ Rapid HIV NAT (HIV-1 and/or HIV-2)
- ☐ HIV-1/HIV-2 NAT (Quantitative)
- ☐ HIV-2 NAT
- ☐ HIV-1 p24 Ag confirmatory assay
- ☐ HIV-1 NGS Method
- ☐ HIV-1 RNA dual claim (serum and plasma)
- ☐ HIV-1 RNA dual claim (Dried Blood Spots or microtainers)
- ☐ HIV-1 RNA dual claim (self-collected in a non-clinical setting)
- ☐ Other, please specify: _____
- ☐ ⊗ None of the above

27. Has your laboratory implemented or been approached about implementing testing to support a ‘self-collection' strategy for HIV? *Please select the most accurate response and we encourage you to use the comment box to provide more details if you selected one of the “Yes” responses. Note: The term ‘self-testing is used to reflect any practice where a person is collecting their own specimen for testing and either bringing it to a laboratory or mailing it into the laboratory.*

- ○ Yes, we have validated alternative specimen types (e.g. dried blood spot) for HIV testing to support a ‘self-collection’ strategy
- ○ Yes, we have been approached by our health department and are planning on validating alternative specimen types for HIV testing
- ○ Yes, we have been approached by our health department but are still in the planning phases of how to address the needs
- ○ No, we have neither implemented nor been approached to implement any HIV testing to support ‘self-collection’ strategies

28. Did staff from your laboratory provide outreach training education or consultation regarding HIV diagnostic testing in 2023 (Including the following entities: providers, submitters, epidemiologists, public health/department of health program staff, laboratory personnel, community-based organizations, etc.)?

- ○ Yes
- ○ No

Display This Question:

If 28. Did staff from your laboratory provide outreach training education or consultation regarding... = Yes

28a. Please identify the 5 most common topics your laboratory provides outreach, including training education or consultation regarding HIV diagnostic testing in 2023. Consider requests for assistance through phone calls, emails, hotlines, meetings, or other mechanisms and entities including providers, submitters, epidemiologists, public health/department of health program staff, laboratory personnel, community-based organizations, etc.

- [ ] Algorithm Interpretation
- [ ] At-home Testing/Self-Collection
- [ ] Cost of Tests
- [ ] Evaluating Alternative Testing Strategies
- [ ] Guidance on Verifying FDA approved method
- [ ] Guidance on Validating a modification to an FDA approved method/laboratory developed tests (LDT)
- [ ] HIV-1 NAT/RNA for Diagnosis (performance or platforms)
- [ ] HIV1-NAT/RNA for Viral Load/Monitoring
- [ ] Implementing recommended diagnostic algorithm (appropriate tests, sequence)
- [ ] Rapid Tests (performance and selection of test kit)
- [ ] Rapid Tests (implementation and quality assurance)
- [ ] Result Interpretation
- [ ] Result Reporting
- [ ] Specimen Handling/Requirements

- [ ] Specimen Collection-Traditional Samples and Methods
- [ ] Screening Methods: HIV Ag/Ab or HIV Ab Immunoassays (performance or platforms for screening tests)
- [ ] Supplemental HIV Ab differentiation tests (performance or platforms)
- [ ] Test and Treat Programs
- [ ] Testing for PrEP Enrollment or PrEP Maintenance
- [ ] Other, please describe: _____

Display This Question:

If 28. Did staff from your laboratory provide outreach training education or consultation regarding... = Yes

28b. Please identify the 3 entities your laboratory has provided the most outreach, training education, or consultation to regarding HIV diagnostic testing in 2023.

- [ ] HIV Surveillance Program (Health Department)
- [ ] HIV Prevention Program (Health Department)
- [ ] HIV Patient Care (Health Department)
- [ ] Clinicians/Providers
- [ ] Hospital Laboratories
- [ ] Commercial Laboratories
- [ ] Other Public Health Laboratories
- [ ] CLIA-Waived testing sites
- [ ] Other, please describe:

_____

Display This Question:

If 28. Did staff from your laboratory provide outreach training education or consultation regarding... = Yes

28c. What modalities did you use for outreach, training, education, or consultation you provided on HIV Diagnostic testing? *Please check all that apply.*

- ☐ Web-based seminar/meeting
- ☐ Web-based training
- ☐ In-person seminar/meeting
- ☐ In-person training
- ☐ On-line (self-guided) training
- ☐ Written guidance or information (e.g. newsletter, policy update, template procedures)
- ☐ Informal consultation via phone, email, or other
- ☐ Other, please specify: _____

Hepatitis C Testing

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

- ○ Yes
- ○ No

Skip To: Question 37 If 29. Does your laboratory offer any testing services for the diagnosis or management of Hepatitis... = No

30. In your laboratory, how many full-time equivalents are:

	Number of FTE
Currently trained to perform HCV testing?	
Routinely assigned to perform HCV testing?	

31. Did your laboratory provide or refer the following HCV testing services in 2023? Please indicate the primary practice for each category. A response is required for each row.

	In-House	Referral	Not Offered
HCV Ab (Anti-HCV); laboratory based	○	○	○
HCV Ab (Anti-HCV); rapid test	○	○	○
HCV RNA (quantitative or qualitative)	○	○	○
HCV Core antigen	○	○	○
HCV genotyping	○	○	○
HCV sequencing	○	○	○
Cadaveric Testing	○	○	○
Diagnostic Testing of Exposed Infants	○	○	○
Pooled NAT Testing	○	○	○
Diagnostic NAT testing without screening by serology (this excludes viral load testing)	○	○	○
Acceptance of dried blood spots (DBS) for HCV testing	○	○	○
Utilization of a hepatitis screening panel to include screening for HCV and other hepatitis viruses	○	○	○
Other test method or service, please specify;	○	○	○

32. What HCV Ab (Anti-HCV) assay does your laboratory offer for Hepatitis C **screening**?

- ○ We do not offer HCV Ab testing
- ○ ADVIA Centaur Anti-HCV (Siemens)
- ○ ALINITY I Anti-HCV (Abbott)
- ○ Architect Anti HCV (Abbott)
- ○ Elecsys Anti-HCV (Roche)
- ○ HCV Version 3.0 ELISA (Ortho)
- ○ OraQuick HCV Rapid Antibody Test (OraSure)
- ○ VITROS Anti-HCV (Ortho)
- ○ Other Anti-HCV assay, please specify: _____

Display This Question:

If 32. What HCV Ab (Anti-HCV) assay does your laboratory offer for Hepatitis C screening? != We do not offer HCV Ab testing

32a. If the specimen is reactive on the HCV Ab (Anti-HCV) Assay our laboratory:

- ○ Automatically reflexes to perform HCV RNA testing in-house (using the same sample)
- ○ Automatically reflexes to perform HCV RNA testing in-house (using an additional sample already submitted)
- ○ Automatically refers to another laboratory for HCV RNA testing (using the same sample)
- ○ Automatically refers to another laboratory for HCV RNA testing (using an additional sample already submitted)
- ○ Performs an HCV RNA testing in-house upon request (using the same sample)
- ○ Performs an HCV RNA testing method in-house upon request (using an additional sample already submitted)
- ○ Requests submission of another sample to perform HCV RNA testing in-house
- ○ Requests submission of another sample to refer to another laboratory for HCV RNA testing
- ○ Recommends provider submit a specimen for HCV RNA testing to another laboratory
- ○ Other, please specify: _____

33. Please indicate for each HCV RNA method whether it is used in your PHL and if so, whether it is primarily used for the Diagnosis of current HCV infection or monitoring. *Each row must have a selection.* **Method**

	Method Not Used	**Diagnosis of Current Infection**	**Used for Monitoring (Viral Load)**
ALINITY m HCV (Abbott)	○	○	○
APTIMA HCV RNA Qual (Hologic)	○	○	○
cobas HCV (Roche)	○	○	○
COBAS Ampliprep/COBAS Taqman HCV Test, v2.0 (Roche)	○	○	○
COBAS Taqman HCV Test (Roche)	○	○	○
Hepatitis C APTIMA HCV Quant Dx Assay (Hologic)	○	○	○
RealTime HCV (Abbott)	○	○	○
Other HCV RNA Assay, please specify	○	○	○

34. Does your laboratory accept specimens from perinatally exposed infants for HCV RNA testing?

- ○ Yes
- ○ Yes, for referral to another laboratory only
- ○ No
- ○ Unsure

Display This Question:

If 34. Does your laboratory accept specimens from perinatally exposed infants for HCV RNA testing? = Yes

Or 34. Does your laboratory accept specimens from perinatally exposed infants for HCV RNA testing? = Yes, for referral to another laboratory only

34a. How are specimens from perinatally exposed infants tested?

- ○ We utilize an FDA cleared test, please specify _____
- ○ We utilize an LDT, please specify _____
- ○ We utilize a disclaimer on the report
- ○ They are tested at another laboratory using and FDA cleared test, please specify _____
- ○ They are tested at another laboratory using and LDT, please specify _____
- ○ Other, please explain _____

35. What HCV genotyping assay does your laboratory offer?

- ○ We do not offer HCV genotyping
- ○ Realtime HCV Genotype II (Abbott)
- ○ VERSANT HCV Genotype 2.0 (LiPA) (Siemens)
- ○ Laboratory Developed-HCV Genotyping Assay
- ○ Other HCV Genotyping, please specify: _____

36. Does your laboratory perform HCV sequencing in-house?

- ○ Yes
- ○ No

Display This Question:

If 36. Does your laboratory perform HCV sequencing in-house? = Yes

36a. How is HCV sequencing data utilized?

- ○ Results are provided to submitters for clinical decision making
- ○ Results are utilized for surveillance purposes only
- ○ Results are used for both clinical decision making and surveillance
- ○ Unsure

37. Does your laboratory have any plans to change any HCV testing services (including any clinical testing or molecular surveillance) before December 31, 2024?

- ○ Yes
- ○ No
- ○ Unsure

Display This Question:

If 37. Does your laboratory have any plans to change any HCV testing services (including any clinica... = Yes

37a. Which of the following HCV testing services is your laboratory considering adding or changing? *Please check all that apply.*

HCV Antibody (Anti-HCV) Screening Assay *(Please select at least one response per section)*

- ☐ Add screening assay to be performed on site, specify new assay in comments _____
- ☐ Replace existing screening assay with a new screening assay; specify old and new assays in comments _____
- ☐ Modify an existing screening assay (including specimen types); specify modification in comments _____
- ☐ Eliminate an existing screening assay; specify rationale in comments _____
- ☐ Refer screening assay to another laboratory; specify rationale in comments _____
- ☐ ⊗ No changes planned for HCV Antibody Screening Assay

HCV RNA Testing *(Please select at least one response per section)*

- ☐ Add an HCV NAT to be performed on site, specify new assay in comments

  _____

- ☐ Replace existing HCV NAT performed on site with a new HIV-1 NAT, please specify old and new assays in comments

  _____

- ☐ Modify existing HCV NAT; specify modification in comments

  _____

- ☐ Eliminate an existing HCV NAT; specify rationale in comments

  _____

- ☐ Refer HCV NAT to another laboratory; specify rationale in comments

  _____

- ☐ Add or change other HCV NAT, specify in comments

  _____

- ☐ ⊗ No changes planned for HCV NAT

Other HCV Testing Services (Genotyping, Sequencing, etc.)

- ☐ Add service; specify new assay in comment

  _____

- ☐ Replace service; please specify old and new service/ in comment

  _____

- ☐ Modify service, specify modification in comment

  _____

- ☐ Eliminate service; specify rationale in comment

  _____

- ☐ ⊗ No changes

38. With respect to HCV, what changes is your laboratory considering as a direct result of the FDA Rule regarding regulation of laboratory developed tests? (select all that apply)

- ☐ We are considering how to generate the data needed for FDA submission, please specify _____
- ☐ We are considering elimination of a specific test, specimen type or practice, please specify _____
- ☐ Not Applicable, we do not perform HCV testing
- ☐ Not Applicable, we do not utilize LDTs for HCV testing
- ☐ Not Applicable, we utilize an LDT that would remain under enforcement discretion, please specify
- ☐ Unsure/Undecided

Display This Question:

If 38. With respect to HCV, what changes is your laboratory considering as a direct result of the FD... = We are considering how to generate the data needed for FDA submission, please specify

38a. Would your laboratory be interested in collaborating with other laboratories to generate a group submission for the FDA?

- ○ Yes
- ○ No
- ○ Unsure

39. Has your laboratory implemented or been approached about implementing testing to support a ‘self-collection’ strategy for HCV?

*Please select the most accurate response and we encourage you to use the comment box to provide more details if you selected one of the “Yes” responses. Note: The term **‘self-collection’** is used to reflect any practice where a person is collecting their own specimen for testing and either bringing it to a laboratory or mailing it in to the laboratory.*

- ○ Yes, we have validated alternative specimen types (e.g. dried blood spot) for HCV testing to support a ‘self-collection’ strategy
- ○ Yes, we have been approached by our health department and are planning on validating alternative specimen types for HCV testing
- ○ Yes, we have been approached by our health department but are still in the planning phases of how to address the needs
- ○ No, we have neither implemented nor been approached to implement any HCV testing to support ‘self-testing’ strategies.

40. For which HIV and HCV topic areas would it be most useful to have additional tools/resources for your laboratory in the upcoming year? *Please check all that apply.*

- [ ] Implementing diagnostic algorithm-HIV
- [ ] Implementing diagnostic algorithm-HCV
- [ ] New/emerging diagnostic technologies-HIV
- [ ] New/emerging diagnostic technologies-HCV
- [ ] Integrated screening for multiple pathogens
- [ ] Educating clinical laboratories on diagnostic algorithms
- [ ] Validation of new or modified FDA-approved assays
- [ ] Development of in house assays
- [ ] Utilization of alternative sample types - DBS, vacutainer, microtainer
- [ ] Incidence testing
- [ ] Genotype testing
- [ ] LIMS/informatics infrastructure
- [ ] 3rd party billing – basics
- [ ] 3rd party billing – policy/regulation
- [ ] 3rd party billing – contracting with insurers
- [ ] Reporting language for HIV and HCV algorithms
- [ ] Laboratory overall interpretations for PrEP monitoring algorithms

☐ Other – please specify: _____

☐ ⊗ None of the above

Additional Comments regarding Hepatitis C testing:

_____

_____

_____

_____

_____

The next (two) question(s) ask about public health laboratory capacity to submit claims to Medicaid, Medicare, Private Health Insurers and/or Submitting Providers for HIV and/or HCV diagnostic testing conducted in 2023.

41. Is your laboratory currently seeking reimbursement from Medicaid, Medicare or other health insurers (i.e. third-party payers) or submitting providers (clinical) for HIV and/or HCV diagnostic testing? *Note this does not include billing to grants. *User must select one response per category (HIV and HCV).*

HIV

- ☐ Yes, currently billing
- ☐ No, but plan to implement by 12/31/24
- ☐ No plans to implement
- ☐ Don't offer testing
- ☐ Don’t know - Please provide additional information: _____
- ☐ Not Applicable

HCV

- ☐ Yes, currently billing
- ☐ No, but planning to implement by 12/31/24
- ☐ No plans to implement
- ☐ Don’t offer testing
- ☐ Don’t know - Provide additional information _____
- ☐ Not Applicable

Display This Question:

If 41. Is your laboratory currently seeking reimbursement from Medicaid, Medicare or other health in... = Yes, currently billing

Or 41. Is your laboratory currently seeking reimbursement from Medicaid, Medicare or other health in... = Yes, currently billing

41a. Do you seek reimbursement for diagnostic and/or prognostic (i.e., viral load) testing? (go to Q41b)

- ○ We bill for both diagnostic and prognostic testing
- ○ We only bill for diagnostic testing
- ○ We only bill for prognostic testing
- ○ Unsure

Display This Question:

If 41a. Do you seek reimbursement for diagnostic and/or prognostic (i.e., viral load) testing? (go t... , We bill for both diagnostic and prognostic testing Is Displayed

41b. From which of the following payers does your health department currently seek reimbursement for HIV and/or HCV testing services?
*Note this does not include billing to grants. *The user must select at least one response per category (HIV and HCV).*

HIV

- ☐ Medicaid
- ☐ Medicare
- ☐ Private Insurance
- ☐ Submitting Providers (Clinical)
- ☐ Other - Please specify: _____
- ☐ Not Sure - Please provide additional information: _____
- ☐ Not Applicable

HCV

- ☐ Medicare
- ☐ Medicaid
- ☐ Private Insurance
- ☐ Submitting Providers (Clinical)
- ☐ Other-Please specify _____
- ☐ Not Sure - Provide additional information _____
- ☐ Not Applicable

Display This Question:

If 41. Is your laboratory currently seeking reimbursement from Medicaid, Medicare or other health in... = Yes, currently billing

Or 41. Is your laboratory currently seeking reimbursement from Medicaid, Medicare or other health in... = Yes, currently billing

41c. By what mechanism does your laboratory seek reimbursement from Medicaid and/or other third-party payers for HIV and/or HCV testing services? *The user must select at least one response per category (HIV and HCV).*

HIV

- ☐ Laboratory bills insurers directly
- ☐ Laboratory bills providers
- ☐ Other - please specify: _____
- ☐ Not Sure - Please provide additional information: _____
- ☐ Not Applicable

HCV

- ☐ Laboratory bills insurers directly
- ☐ Laboratory bills providers
- ☐ Other - Please specify _____
- ☐ Not Sure - Provide additional information _____
- ☐ Not Applicable

Display This Question:

If 41c. By what mechanism does your laboratory seek reimbursement from Medicaid and/or other third-p... , Laboratory bills insurers directly Is Displayed

41d. If your laboratory is receiving reimbursement from Medicaid, Medicare, health insurers, or submitting providers for HIV and/or HCV testing services, where does that revenue go? *The user must select only one response per category (HIV and HCV).*

HIV

- ☐ To the laboratory – specifically earmarked for laboratory
- ☐ 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 - Please provide additional information: _____
- ☐ Not Applicable

HCV

- ☐ To the laboratory – specifically earmarked for laboratory
- ☐ 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 - Provide additional information _____
- ☐ Not Applicable