

SERVICE ANNOUNCEMENT

HIV Emergency Testing Changes

HIV Testing Changes

Due to a national shortage of HIV-1/HIV-2 antibody differentiation testing reagents, Labcorp is implementing temporary changes to tests that include the HIV testing algorithm.

HIV Test Algorithm Background and Changes

The HIV testing algorithm, recommended by the U.S. Centers for Disease Control and Prevention (CDC), is a multistep process. The first step of the algorithm is the HIV p24 antigen/antibody screen. Repeated reactivity on the HIV antigen/antibody screen triggers a reflex to a secondary antibody immunoassay that detects and differentiates between HIV-1 and HIV-2 antibodies (HIV-1/HIV-2 antibody differentiation). If the secondary antibody immunoassay is negative or indeterminate, a qualitative nucleic acid test (NAT) is performed for HIV-1 and HIV-2 RNA.

As there are no other validated antibody differentiation reagents available for use, we will utilize an alternate HIV testing algorithm where HIV-1 and HIV-2 qualitative RNA detection is being substituted as the second step. This change impacts only those specimens that are positive on the HIV antigen/antibody (4th generation) screening test. In this alternate algorithm, specimens that are positive on the HIV antigen/antibody screening test will reflex directly to the HIV-1 and HIV-2 qualitative RNA test.

This emergency testing process is anticipated to remain in place for several weeks until reagent supply stabilizes.

EDI Impact

Electronic Medical Record (EMR) and Laboratory Information System (LIS) clients that manually associate specific reflex order codes to the initial order code—or link reflex result code combinations—may require changes to their compendium build. Please review the attached EDI notifications that outline the result code updates for each impacted test.

If you have questions related to build requirements for these tests, contact your local EDI support representative.

Please see the table on the reverse for a summary of testing changes. If you have further questions, contact your local Labcorp representative or call Labcorp customer service at 888-522-2677.

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Summary of HIV testing changes

Impacted Test No.	Test Name	Testing Description	Emergency Changes	Effective date
083935	HIV p24 Antigen/ Antibody With Reflex to Confirmation	CDC-recommended algorithm for laboratory diagnosis of HIV infection, including acute and primary infection	Temporary alternative algorithm; specimens positive on the HIV antigen/antibody screening test will reflex directly to the HIV-1 and HIV-2 qualitative RNA test	April 28, 2025
083955	Human Immunodeficiency Virus 1/2 (HIV-1/2) Antibody Differentiation, With Reflex to HIV-1 RNA	Intended for hospitals that perform HIV antigen/antibody screening and submit positive samples for completion of the testing algorithm	Temporarily discontinued; for specimens screening positive for HIV antigen/ antibody, consider ordering HIV-1/HIV-2 RNA (Test No. 139825) or the updated HIV algorithm (Test No. 083935)	April 25, 2025
083971	PrEP Use Only: HIV Antigen/Antibody and HIV RNA, Qualitative	Includes HIV antigen/antibody screen with reflex to antibody differentiation and HIV-1 and HIV-2 qualitative RNA	Temporarily discontinued antibody differentiation testing; HIV antigen/ antibody and HIV-1 and HIV-2 qualitative RNA will still be performed	April 28, 2025
083909	PrEP Use Only: HIV p24 Antigen/Antibody With Reflex to Confirmation	CDC-recommended algorithm for laboratory diagnosis of HIV infection, including acute and primary infection	Temporary alternative algorithm; specimens positive on the HIV antigen/antibody screening test will reflex directly to the HIV-1 and HIV-2 qualitative RNA test	April 28, 2025
254988	PrEP, Female, Injectable Baseline + HIV RNA	Includes HIV antigen/antibody screen with reflex to antibody differentiation and HIV-1 and HIV-2 qualitative RNA.	Temporarily discontinued antibody differentiation testing; HIV antigen/ antibody and HIV-1 and HIV-2 qualitative RNA will still be performed	April 28, 2025
254801	PrEP, Female, Injectable Monitor + HIV RNA			
254855	PrEP, Female, Oral Baseline + HIV RNA			
254880	PrEP, Female, Oral Monitor + HIV RNA			
254972	PrEP, Male, Injectable Baseline + HIV RNA			
254736	PrEP, Male, Injectable Monitor + HIV RNA			
254842	PrEP, Male, Oral Baseline + HIV RNA			
254868	PrEP, Male, Oral Monitor + HIV RNA			