



## Biotech Clinical Laboratory Technical Bulletin

Effective 01/22/2021 Biotech Clinical Laboratories will change HIV assay to Bio-Rad Bio-Plex multiplex flow immunoassay that allows the simultaneous qualitative detection and differentiation of the individual analytes HIV-1 p24 antigen, HIV-1 antibodies, and HIV-2 antibodies in human serum or plasma.

This assay is intended as an aid in the diagnosis of infection with HIV-1 and/or HIV-2, including acute (primary) HIV-1 infection. The assay may also be used as an aid in the diagnosis of infection with HIV-1 and/or HIV-2 in pediatric subjects as young as two years of age, and pregnant women.

The BioPlex 2200 HIV Ag-Ab assay is an immunoassay that incorporates highly conserved recombinant and synthetic peptide sequences representing HIV-1 and HIV-2, as well as a monoclonal antibody specific for HIV-1 p24 antigen.

The assay's design allows results of antibody and antigen detection to be reported separately and to differentiate between HIV-1 and HIV-2 reactivity.

The BioPlex 2200 HIV Ag-Ab assay generates an Index for each of the individual HIV analytes. It outputs the Index for each analyte along with the interpretation based on that Index, and it also outputs an overall result using the highest Index and an overall interpretation based on that Index.

- A specimen is REACTIVE if **at least one analyte has an Index of  $\geq 1.00$** .
- A specimen is Non-Reactive if all analytes have Indices  $< 1.00$ .

Interpretation of Results Index (IDX)	Interpretation
$< 1.00$	NON-REACTIVE
$\geq 1.00$	REACTIVE

### HIV-1 p24 Ag Results:

When HIV-1 and/or HIV-2 antibody levels are very high the antibody may interfere with HIV-1 p24 Ag results. Therefore the output of the BioPlex 2200 will not contain HIV-1 p24 Ag results when:

- the Index for HIV-1 or HIV-2 Ab is at least 100, AND
- the HIV-1 p24 Ag Index is at least 1.00.

### Reporting Results

		Reference Range
HIVAG/AB (interpretation)		REACTIVE
HIV-1 Antibody	REACTIVE	REACTIVE
HIV-1 p24 Antigen	NON-REACTIVE	NONREACTIVE
HIV—2 Antibody	NON-REACTIVE	NONREACTIVE

Director Dr. E.Dvorin at 248-912-1700 or by e-mail [edvorin@biotechclinical.com](mailto:edvorin@biotechclinical.com).