January 14th 2023

//* To Whom It May Concern

Re: Human Immunodeficiency Virus 1 and 2
Serological Assay (Antibody / Antigen)
Serological Assay (Nucleic Acid Test)

With reference to:

Code of Federal Regulations
Title 21 – Food and Drugs
Chapter I – Food and Drug Administration
Department of Health and Human Services
Subchapter H – Medical Devices
Part 866 – Immunology and Microbiology Devices
Section 866.3956 [Serological Assay – Antibody / Antigen] and
Section 866.3957 [Serological Assay – Nucleic Acid Test]

With regards to any approved, commercially available antibody-based (serological) assay for Human Immunodeficiency Virus (HIV) -1 or HIV-2, could you please so advise as to which laboratory test is considered acceptable as a "gold-standard" for the purposes of calculating sensitivity and specificity, given that there are no [listed] FDA-approved HIV-2 assays based on nucleic acid test (NAT) methods, per the "Complete List of Donor Screening Assays for Infectious Agents and HIV Diagnostic Assays"?

Further, given that:

"Human immunodeficiency virus (HIV) serological diagnostic and supplemental tests are **prescription devices** for the qualitative detection of HIV antigen(s) and/or detection of antibodies against HIV in human body fluids or tissues. The tests are intended for use as an aid in the diagnosis of infection with HIV and are for **professional use only**",

and that:

“analytical sensitivity of [such] test[s] must be the same as or better than that of other cleared or approved tests”

It should be noted that, per Sections 866.3956, for antigen-antibody based serological tests:

“Clinical sensitivity of the test must have a lower bound of the 95 percent confidence interval of greater than or equal to 99 percent.

[and]

Clinical specificity of the test must have a lower bound of the 95 percent confidence interval of greater than or equal to 99 percent.”

Further, per Sections 866.3957 for nucleic acid based serological tests:

“Clinical sensitivity of the test must have a lower bound of the 95 percent confidence interval of greater than or equal to 99 percent.

[and]

Clinical specificity of the test must have a lower bound of the 95 percent confidence interval of greater than or equal to 99 percent.”

Reference is made to the following “FDA approved” test:

“*OraQuick* In-Home HIV Test” [oral specimen collection device]

where the reported sensitivity of the test is 91.7%.

This is but one example.

In addition to the information requested [above], I am respectfully requesting clarification as to the suitability of said HIV-1 and HIV-2 serological (antibody-antigen-based) tests, for in-vitro diagnostic use, including those tests designed for "at-home use".

Further, I am respectfully requesting clarification as to whether or not an FDA approved serological assay based on a nucleic acid test method is available for HIV-2, and perhaps is not listed on the “complete list” [see earlier].

I await your response.

Sincerely,

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