For Immediate Release

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Germantown, MD - On July 20, bioLytical Laboratories (BC, Canada) received a CLIA waiver from the FDA for their INSTI HIV-1 Antibody Test, opening the door for a wider range of laboratory facilities to administer the test.

Amarex Clinical Research managed a pivotal clinical trial for bioLytical that demonstrated the necessary evidence needed to obtain the CLIA waiver.

Rick Galli, Chief Technical Officer at bioLytical, praised Amarex's work as integral to the application's success, "the statistical support [Amarex provided] proved to be invaluable and completely accurate in the final review by FDA. The cornerstone of this milestone achievement was the data from the clinical study, including the limit of detection study, and we came through all the review with solid outcome throughout."

The INSTI HIV-1 Antibody Test is a new, single use rapid test for the detection of antibodies to Human Immunodefinciency Virus Type 1 (HIV-1). The INSTI delivers results in 60 seconds, an improvement upon previously approved rapid HIV tests, which typically provide results in 10-20 minutes. Rapid HIV tests allow people to learn their HIV status in a single visit to a testing site, and allow for testing outside traditional laboratory settings. Consequently, rates of testing and diagnosis and care are improved.

The INSTI HIV-1 Antibody Test can be used in clinical laboratories, in public health laboratories and in point-of-care settings. The test is classified as Moderate Complexity under CLIA (Clinical Laboratory Improvements Amendments).

Amarex congratulates bioLytical Laboratories on their success, and looks forward to working together as the successful INSTI platform is applied to other diagnostic device developments in the future.

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