INSTI™ HIV-1 Antibody Test Customer Letter

Dear Customer,

Thank you for using the INSTI™ HIV-1 Antibody Test. The sale, distribution and use of this product are restricted as described in the package insert. By purchasing this device, you are doing so as an agent of a clinical laboratory and agree that you or any of your consignees will abide by the following restrictions on the sale, distribution, and use of the device:

1. Sale of the INSTI™ HIV-1 Antibody Test is restricted to clinical laboratories
    - That have an adequate quality assurance program, including planned systematic activities to provide adequate confidence that requirements for quality will be met[1-3], and
    - Where there is assurance that operators will receive and use the instructional materials.
2. The INSTI™ HIV-1 Antibody Test is approved for use only by an agent of a clinical laboratory.
3. Test subjects must receive the "Subject Information" brochure prior to specimen collection, and appropriate counselling when test results are provided.
4. The INSTI™ HIV-1 Antibody Test is not approved for use to screen donors of blood, plasma, cells or tissues.

The package insert for the INSTI™ HIV-1 Antibody Test contains warnings and precautions, restrictions on the sale, distribution and use of the device, and information about how the device works. It also provides details on procedures to follow, how to interpret results, and the limitations of the procedure. The "Subject Information" brochure provides subjects with information about the INSTI™ HIV-1 Antibody Test and the meaning of a Reactive or Non-Reactive INSTI test result, as well as general information about HIV and AIDS. You should review all of these materials yourself.

If you have any questions, please call us at 1-866-674-6784.

Sincerely,

bioLytical Laboratories' Customer Service

References:

1. NCCLS Document GP2-A4, Clinical Laboratory Technical Procedure Manuals
2. NCCLS Document GP27-A, Using Proficiency Testing (PT) to Improve the Clinical Laboratory
3. NCCLS Document AST2-A, Point-of-Care In Vitro (IVD) Testing.

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