CHEMBIO
DIAGNOSTIC SYSTEMS, INC.

DPP® HIV 1 / 2 Assay

CUSTOMER LETTER

Dear Customer,

Thank you for choosing to use Chembio's DPP® HIV 1 / 2 Assay. The restrictions for sale, distribution and use of this product are described in the Product Insert. You are purchasing a device as an agent of the clinical laboratory and understand that you or any of your consignees will abide by the following restrictions on the sale, distribution and use of the device:

A. Sale of the DPP® HIV 1 / 2 Assay is restricted to clinical laboratories
   - where there is assurance that operators will receive and use the Product Insert,
   - that have an adequate quality assurance program, including planned systematic activities to provide adequate confidence to meet quality standards.[1-3]

B. The DPP® HIV 1 / 2 Assay is approved to be used only by a clinical laboratory agent.

C. Test Subjects must receive the "Subject Information Notice" and pre-test counseling prior to specimen collection and appropriate counseling when test results are approved.

D. The DPP® HIV 1 / 2 Assay is not approved for use to screen blood, plasma, cell or tissue donors.

The Product Insert for the DPP® HIV 1 / 2 Assay describes warnings and precautions, restrictions for sale, distribution and use of the device, and information about how it functions, instructions for use, interpretation of the results, and limitations of the procedure. The "Subject Information Notice" contains the information about the limitations of the assay and definition of a preliminary positive or negative test result with the DPP® HIV 1 / 2 Assay along with general information about HIV and AIDS. It is your responsibility to review and understand all of this information and materials.

Please contact Customer Service, either toll free 1-800-327-3635 or at 1-631-924-1135, with any questions.

Sincerely,

Chembio Customer Service

References:

1. CLSI Document QMS02-A6, Quality Management System: Development and Management of Laboratory Documents; Approved Guideline – Sixth Edition
2. CLSI Document GP27-A2, Using Proficiency Testing (PT) to Improve the Clinical Laboratory; Approved Guideline – Second Edition
3. CLSI Document POCT04-A2 , Point-of-Care *In Vitro* (IVD) Testing; Approved Guideline – Second Edition
4. DPP HIV 1/2 Assay Product Insert Document No. 10-6273-0

10-6229-0 Rev 2
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