

BIONOR™ HIV-1&2 CONFIRMATORY TEST

A NEW PEPTIDE-BASED MAGNETIC PARTICLE EIA for individual detection of IgG antibodies against recombinant p24 (CORE), synthetic peptides to gp41 (TM1), synthetic peptides to gp120/recombinant gp41 (ENV) and synthetic peptides to gp36 (TM2)

The assay:

The principle of this new assay is a Magnetic Particle Enzyme Immuno Assay. It gives individual reactions to all four above-mentioned antigens. Turn around time is only 45 minutes! Can be used with serum, plasma and whole blood. A saliva protocol is being developed.

Reagents:

Everything needed for performing the assay is included in the kit. The reagents are supplied "ready to use" in droppers. Very robust reagents. 12 months shelf life. No reduction in shelf life after opening the kit. No temperature critical steps.



Testing station:

The testing station to be used with the Bionor™ HIV-1&2 Confirmatory Test, consists of a rocking platform with magnets, aspirator, lamp and waste container and is self-contained.

It can be operated on 230 V, optionally 115 V or 12 V.

Very robust device which needs minimum maintenance.



Interpretation of results:

Reading of results is simple and clear cut. Positive results give a clear and distinct red colour. Since each of the four antigen/antibody reactions can be read separately, the interpretation of results is very easy.

Following the ASTPHLD/CDC criteria for interpretation of results, studies have shown that the number of indeterminate can be significantly reduced compared to western blot assays. Examples of test results are shown overleaf.

Ref: Sommerfelt M.A., Ohlsson I., Flolid I., Thorstensson R., Sørensen B. (2003). A Simple Semi-rapid HIV-1&2 Confirmatory Immunoassay Using Magnetic Particles. J. Virol. Methods. In press

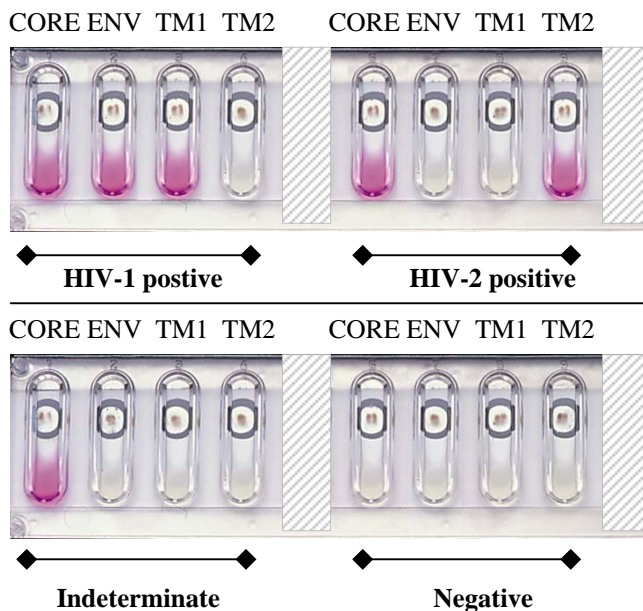


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BIONOR™ HIV-1&2 CONFIRMATORY TEST

The Bionor™ HIV-1&2 Confirmatory Test gives you a clear answer on patient HIV status in only 45 minutes!

Bionor AS (www.bionor.com) has developed a simple and semi-rapid test for confirming HIV-1 and HIV-2 serological status. The Bionor™ HIV-1&2 Confirmatory Test is based on an EIA principle using magnetic beads as a solid support where antibody responses to individual viral proteins are visualised separately. Recombinant HIV-1 core protein (CORE), synthetic peptides to HIV-1 transmembrane glycoproteins gp41 (TM1) and HIV-2 transmembrane glycoproteins gp36 (TM2) as well as synthetic peptides to gp120 together with recombinant gp41 (ENV) are used as a source of antigen. The results are interpreted easily and serological status is determined based on ASTPHLD/ CDC guidelines. The use of peptides as a source of antigen minimises non-specific responses that can often complicate the interpretation of western blot assays normally used to confirm HIV serological status. The Bionor™ HIV-1&2 Confirmatory Test is sensitive and provides greater specificity than western blot assays due to significantly fewer indeterminate results. By combining the Bionor™ rapid HIV-1&2 screening/confirmatory tests, HIV serological status can be both detected and confirmed within hours. The speed, specificity and ease of interpretation of the Bionor™ HIV-1&2 Confirmatory Test renders it an attractive and cost-effective method for confirming HIV serological status worldwide.



Examples of test results

The core and envelope antigens take advantage of serological cross reactivity between HIV-1 and HIV-2 whereas the transmembrane glycoprotein antigens are type-specific and can distinguish between antibody responses to HIV-1 and HIV-2.

The Bionor™ HIV-1&2 Confirmatory Test can confirm serological status to all HIV-1 subtypes within the major group M. Only the p24 core antigens used in this test can detect reactivity to HIV-1 subtype O. Infection with this rare subtype will therefore provide an indeterminate result and require further investigation.



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