FAQ

INNO-LIA™ Syphilis Score

- WHAT IS THE VALUE OF INNO-LIA™ SYPHILIS SCORE IN THE SEROLOGIC DIAGNOSIS OF SYPHILIS?

  In the first steps of the serologic diagnosis of syphilis, a positive non-treponemal screening test (RPR), is followed by a sensitive antibody screening assay (TPHA/TPPA, EIA). When the screening assay generates 1) discrepant results between non-treponemal and treponemal tests or 2) positive results, then a confirmatory assay is required (FTA-ABS, immunoblot). The immunoblot is the only technique that can determine the specific antibody production against essential *T. pallidum* antigens. Traditionally, the FTA-ABS test has been considered the gold standard treponemal test and still is used by some laboratories. However, the FTA-ABS test has lower specificity than other treponemal tests and probably lower sensitivity. In addition to inherent subjectivity, the FTA-ABS test also requires trained personnel and a dedicated fluorescence microscope. For these reasons, CDC recommends that the FTA-ABS test should not be used to confirm discordant treponemal screening results. The INNO-LIA™ Syphilis Score is a line immunoassay which confirms the presence of *T. pallidum* antibodies in human serum or plasma with a high sensitivity and specificity [1, 2].

1. French et al. IUSTI: 2008 European Guidelines on the Management of Syphilis. International Journal of STD & AIDS 2009;20:300-309.
2. Chuck et al. International Journal of STD & AIDS 2008;19:393-399.

- WHAT IS THE CLINICAL VALUE OF THE DIFFERENT ANTIGEN LINES ON THE INNO-LIA™ SYPHILIS STRIP?

  The INNO-LIA™ Syphilis Score can detect specific T. pallidum antibodies in a very early stage of the disease. The order of appearance of antibodies against a syphilis infection is: first TpN17, then TpN47, next TpN15 and finally TmpA. For example, when there is only reactivity on the antigen lines TpN17 and TpN47 it means that there is an initial infection. The more the antigen lines becoming reactive, the more the infection is advanced. When you see a reactivity pattern on the antigen lines that differs from the one described above, this can mean:

  - that at the moment of blood sampling, a treatment against syphilis infection has already started,
  - or that the patient has been recently infected and the titer of IgG antibodies is low while the titer of IgM antibodies is high. The antibody titers to TmpA decline rapidly following treatment for syphilis, thus making it possible to differentiate between past versus current syphilis treatment[3].

3. Ran et al. Chin Med J 2013;126(2)

FAQ

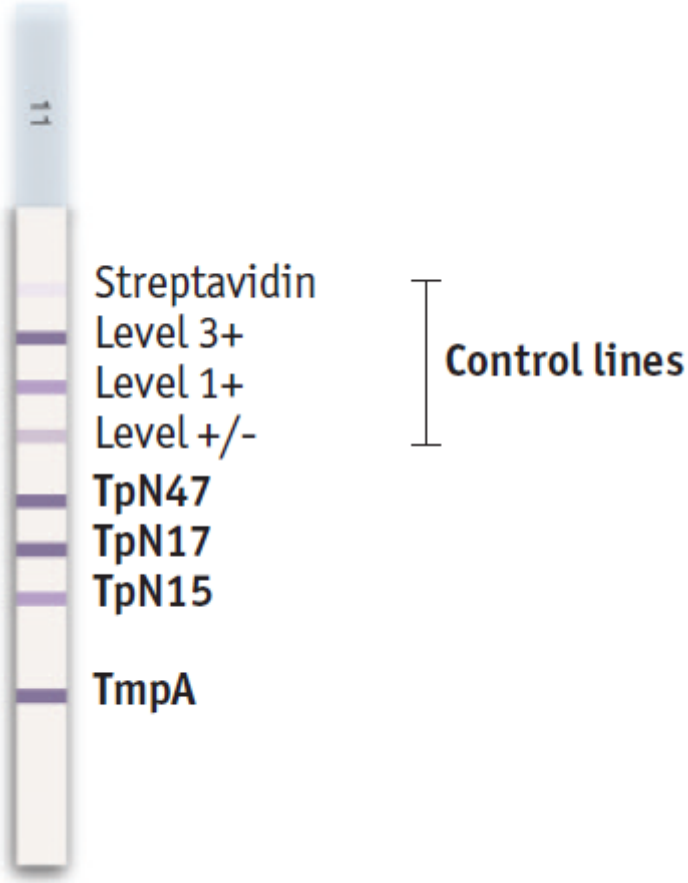
INNO-LIA™ Syphilis Score

- IS THE PRODUCT REGISTERED IN MY COUNTRY?

  For more information, please contact Fujirebio Europe N.V. Customer Support (Customer.support@fujirebio-europe.com) or your local distributor.

- WHAT DOES A 'NORMAL' STRIP LOOK LIKE?

  A 'normal' strip shows reactivity on the three control lines: level 3+, 1+ and +/-. The strip can be interpreted as positive, negative or indeterminate for syphilis antibodies.



- WHERE IS THE PRODUCT USED?

  The INNO-LIA™ Syphilis Score is used in blood banks, clinical and hospital laboratories.

- CAN THE ASSAY BE AUTOMATED?

  Yes, Fujirebio Europe N.V. has 2 automation options with different throughput.

  - *Auto*-LIA™ 48 and *Auto*-LiPA™ 48 (48 samples)

- AutoBlot 3000 (H) (20 samples)

The interpretation of the strips can be done by visual analysis (reading card included in the kit) or by the LiRAS™ for Infectious Diseases interpretation software. With the LiRAS™ for Infectious Diseases, the interpretation for all infectious diseases INNO-LIA™ Score products (HCV, HIV, Syphilis and HTLV) can be automated

- CAN I RUN DIFFERENT INNO-LIA™ SCORE PRODUCTS TOGETHER?

  Yes, the INNO-LIA™ Score reagents are interchangeable except the sample diluent (assures high sensitivity/specificity) but reagents with different lot numbers should not be mixed.