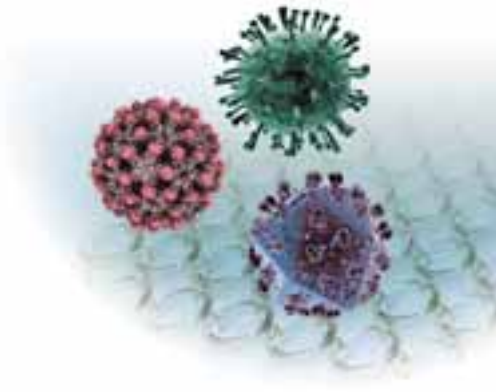


ICE* Syphilis

ELISA Infectious disease



■ Technical Assay Details

Article Number:	8E04-02 (96 tests, 1 plate), 8E04-01 (480 tests, 5 plates)
Coating:	Recombinant TpN15, 17 and 47 proteins, together with anti human IgG and IgM.
Incubation Time:	30 min sample / 60min conjugate / 30 min substrate (total 2 hours)
Incubation Temp.:	37°C / 37°C / 37°C
Assay Volumes:	50µl diluent / 50µl sample / 50µl conjugate 100µl substrate (TMB) / 50µl stop solution
Wash Steps:	Two wash steps with 5x washes each. Each wash using 500µl of wash buffer

■ Quality Control Criteria and Cut Off

Controls (C):	2 controls included: 3 x NC, 1 x PC (4 wells of C required per run)
QC Neg. Cont. (NC):	Mean Value of NC < 0.15 OD (optical density)
QC Pos. Cont. (PC):	Mean Value of PC > 0.8 OD above mean value of NC
Cut off Definition:	Mean value of NC + 0.2 OD
Result negative:	OD value of the sample < cut off
Result positive:	OD value of the sample ≥ cut off

■ Assay Performance

Specificity:

A total of 8032 routine donor specimens from four European blood transfusion centers were screened with ICE* Syphilis. In the study, 8027/8032 of specimens were non-reactive and 5/8032 were repeatedly reactive. One of the repeatedly reactive specimens was confirmed positive by testing with other commercial assays for the detection of *Treponema pallidum* infection. The screening specificity of the ICE Syphilis assay was **99,95 %**.

Sensitivity:

A total of 407 specimens from patients with known syphilis infection were tested and found to be reactive with ICE* Syphilis. The specimens were taken from patients at various stages of syphilis infection and included 37 specimens from patients with primary syphilitic disease. The diagnostic sensitivity of ICE* Syphilis on this population of specimens is therefore estimated to be **100 % (407/407)**



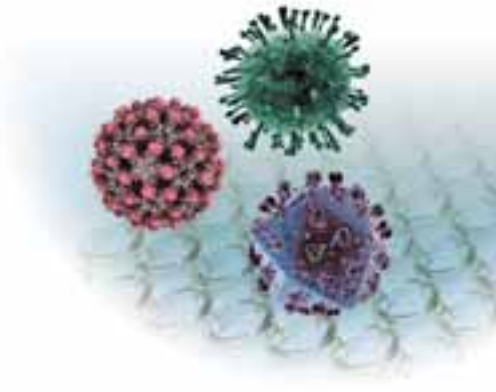
The Diagnostic Specialist



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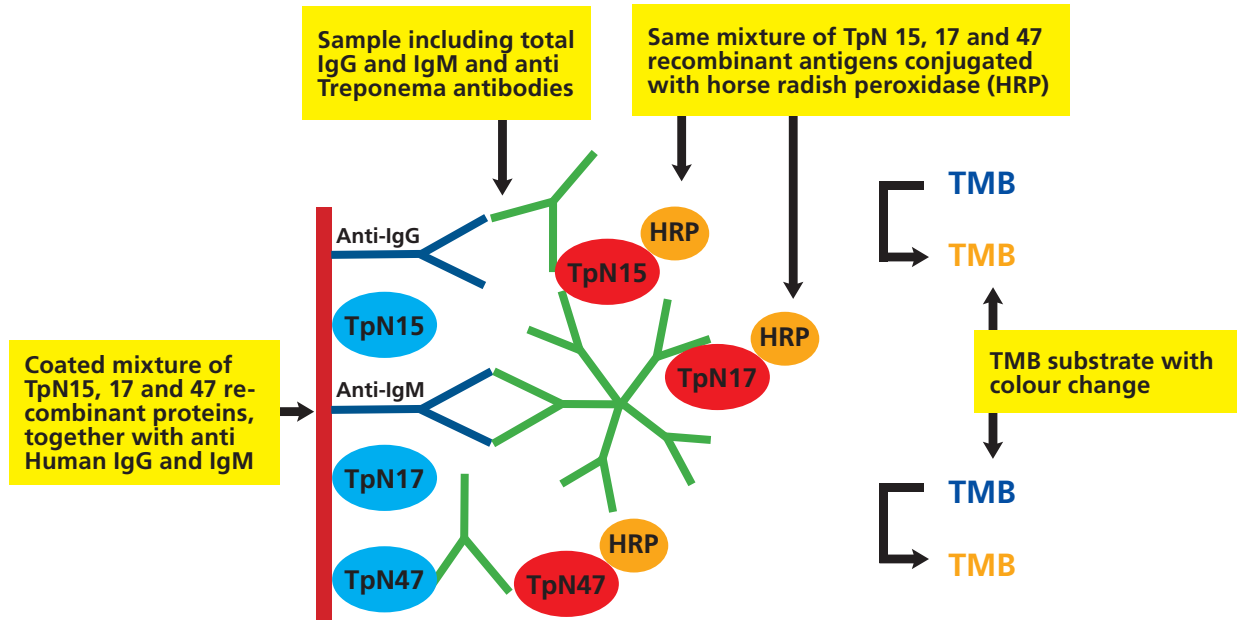
ICE* Syphilis

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Assay Principle

Combination of human IgG and IgM capture assay and a total antibody assay by using recombinant TpN15, 17, 47 proteins to detect antibodies against *Treponema pallidum*.



Your Advantages

- **High security** for the operator. Each pipetting step is completely monitored by a colour change (full sample monitoring included).
- **Ease of use and better standardization** by performing the ICE Syphilis assay in manual, semi-automated or fully automated way relative to the TPHA assay.
- **High sensitivity** because the ICE Syphilis test was proven to be one of the most sensitive assays.
- **More sensitive** and better standardized than the TPHA assay (H. Young et al., Journal of Clin. Microbiol. April 1998, p. 913-917).
- **Reliability** in detecting all different stages of the Syphilis infection and suitable to be used as a first line screening assay for blood donations.
- **Less extra work by increased specificity** by using anti human capture antibodies and recombinant TpN proteins (less false positive results).
- **Reduction of laboratory costs** because with the ELISA a low number of retests can be expected.

Product availability subject to required regulatory approval

FOR OUTSIDE THE US AND CANADA ONLY



The Diagnostic Specialist

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