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)
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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.
- **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