



SERION ELISA *classic*

Candida albicans IgA/IgG/IgM

Intended Use

- Qualitative and quantitative detection of human IgA, IgG and IgM antibodies in serum or plasma directed against *Candida albicans*
- Demonstration of systemic mycosis
- Support in the diagnosis at an early stage of infection

Diagnostic Efficiency

For the evaluation of the SERION ELISA *classic* Candida albicans IgA and IgG tests more than 80 serum samples from blood donors, pregnant women and from patients with suspected candidiasis were analyzed in comparison to three commercially available immunoassays of other European manufacturers.

In another study the performance characteristics of the SERION ELISA *classic* Candida albicans IgM test was assessed by the analysis of 133 serum samples from healthy blood donors and patients with suspected candidiasis using the test of a European manufacturer as a reference.

| Product | Sensitivity | Specificity |
|--|-------------|-------------|
| SERION ELISA <i>classic</i> Candida albicans IgA | 83.3 % | 98.5 % |
| SERION ELISA <i>classic</i> Candida albicans IgG | 93.3 % | >99 % |
| SERION ELISA <i>classic</i> Candida albicans IgM | >99 % | >99 % |

Precision

SERION ELISA *classic* Candida albicans IgA

| Sample | Mean value (OD) | Intraassay CV (%) (n=20) | Mean value (OD) | Interassay CV (%) (n=10) |
|---------|-----------------|--------------------------|-----------------|--------------------------|
| Serum 1 | 0.555 | 2.4 | 0.627 | 9.2 |
| Serum 2 | 1.483 | 2.2 | 1.595 | 6.3 |
| Serum 3 | 1.613 | 2.6 | 1.747 | 6.0 |

SERION ELISA *classic* Candida albicans IgG

| Sample | Mean value (OD) | Intraassay CV (%) (n=20) | Mean value (OD) | Interassay CV (%) (n=10) |
|---------|-----------------|--------------------------|-----------------|--------------------------|
| Serum 1 | 0.272 | 3.8 | 0.245 | 8.9 |
| Serum 2 | 0.994 | 3.5 | 0.910 | 9.8 |
| Serum 3 | 1.166 | 2.7 | 1.087 | 9.4 |

Pathogens

Candida albicans is an ubiquitous yeast which, like all *Candida spp.*, belongs to the family of yeast-like fungi. Apart from the yeast form, which primarily causes superficial infections, so-called pseudo mycelia are a further morphologic manifestation of the pathogen. Germ tubes and the development of pseudo-mycelia mainly occur in cases of systemic mycosis. *Candida spp.* produce and excrete a range of destructive enzymes, that enable the facultative pathogenic microorganisms to penetrate mucous membrane barriers and blood vessels.

Disease

In general, *Candida spp.* are transmitted from person to person by smear contamination. The primary entry site is the oral cavity. Changes in the fungistatic properties of the skin, which are a consequence of a slightly acidic pH value and the antagonistic bacterial flora, can facilitate the establishment of superficial candidiasis of the skin surface. Systemic mycosis results from colonization of mucous membranes, particularly in the gastrointestinal tract.

SERION ELISA *classic* Candida albicans IgM

| Sample | Mean value (OD) | Intraassay CV (%) (n=20) | Mean value (OD) | Interassay CV (%) (n=10) |
|---------|-----------------|--------------------------|-----------------|--------------------------|
| Serum 1 | 0.701 | 3.0 | 0.764 | 6.1 |
| Serum 2 | 1.020 | 3.4 | 1.088 | 5.0 |
| Serum 3 | 1.610 | 1.3 | 1.682 | 3.3 |

Diagnosis

The diagnosis of candidiasis on the basis of serological methods is not easy: On the one hand transient yeast colonization may induce an antibody response, on the other hand systemic Candida mycosis in immunosuppressed patients may only lead to minor changes in antibody activities. Such situations make critical interpretation of serological findings necessary. In addition, systemic Candida infections may not cause typical symptoms. Currently, no single technique in isolation allows for a definitive serological diagnosis of candidiasis. Surveillance of at risk patients and therapy control requires the use of a variety of methods including serology and antigen detection.

Highlights

- Support in the diagnosis of systemic candidiasis as well as of early stage infections
- Confirmation of infections, particularly when HAT titers remain constant by individual demonstration of all relevant immunoglobulin classes
- Quantification of antibody activities for mycological monitoring of at risk patients
- Exclusion of background seroprevalence of IgA and IgG antibodies resulting in the specific detection of clinically relevant antibody activities

| Product | Order No. |
|--|-----------|
| SERION ELISA <i>classic</i> Candida albicans IgA | ESR117A |
| SERION ELISA <i>classic</i> Candida albicans IgG | ESR117G |
| SERION ELISA <i>classic</i> Candida albicans IgM | ESR117M |

SERION ELISA *control*

Please visit our website for more information.

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