

Intended Use

- Quantitative and qualitative immunoassay for the detection of *Candida* antigen in human serum or plasma
- · Recommended for the detection of systemic candidosis

Diagnostic Efficiency

The SERION ELISA *antigen* Candida test was validated by the analysis of 148 serum samples from blood donors and 93 specimens from patients, who showed signs of candidiasis during intensive care treatment, in comparison to the results obtained with a commercially available assay of a leading European manufacturer. Sera classified as borderline were not included in the calculation of sensitivity and specificity values.

Product	Sensitivity	Specificity
SERION ELISA <i>antigen</i> Candida	>99 %	97.8 %

Precision

SERION ELISA antigen Candida

Sample	Mean value (OD)	Intraassay CV (%) (n=20)	Mean value (OD)	Interassay CV (%) (n=10)
Serum 1	0.507	2.4	0.476	5.3
Serum 2	1.413	2.5	1.356	2.7
Serum 3	2.851	2.0	2.442	8.1

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 portal of 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.

Diagnosis

The diagnosis of candidiasis on the basis of serological methods is not straight forward: 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

- · Sensitive detection of different Candida subspecies
- Support in detection of systemic candidiasis, also in immunocompromised patients
- Quantitative detection of Candida antigen for mycological monitoring of at risk patients and for therapeutic follow up
- No cross-reactivity with the plasma expander hydroxyethyl starch (HES) and *Aspergillus fumigatus*

Product	Order No.
SERION ELISA <i>antigen</i> Candida	ESR200

SERION ELISA control

Please visit our website for more information.