

SERION ELISA *classic*

Aspergillus fumigatus IgA / IgG / IgM

SERION ELISA *classic* Aspergillus fumigatus IgA, IgG and IgM tests are quantitative and qualitative immunoassays for the detection of human antibodies in serum or plasma directed against *Aspergillus fumigatus*. The separate detection of individual immunoglobulin classes offers a more detailed view for the mycological monitoring of the risk patients' immune response.



Micrograph of an *Aspergillus* conidiospore (Source: Centers for Disease Control and Prevention, United States Department of Health and Human Services)

Pathogens

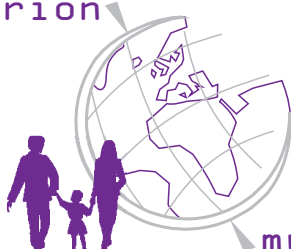
The fungus *Aspergillus* belongs to the group of *ascomycetes*. These organisms develop branched mycelia and spread through conidiospores which are released from mycelia as extremely resistant lasting spores. 20 species of *Aspergillus* are opportunistic infectious agents affecting humans. The most important species is *Aspergillus fumigatus*.

Disease

Aspergillus fumigatus causes a range of allergic and invasive diseases in humans. Bronchopulmonary diseases belong to the most common manifestations of invasive aspergillosis. Patients with a persisting immune suppression after bone marrow transplantation or organ transplantation can develop a severe clinical picture of aspergillosis, e. g. an invasive aspergillosis of the lungs (IAL), which appears as an acute pneumonia, accompanied by high fever and increasing pulmonary infiltrates.

The fungal spores are transmitted through the air and inhaled by the lungs where due to their small size of about 3 μm they reach the lung alveoli. In the case of an invasive aspergillosis, fungal hyphae penetrate the bronchial mucosa and the surrounding lung parenchyma with the aid of released proteases. The *Aspergillus* spores tend to penetrate the blood vessels and settle down in remote tissues after dissemination.

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Diagnosis

For diagnosis of invasive aspergillosis indirect haemagglutination assays are widely used for the detection of *Aspergillus* specific antibodies, however, due to their low sensitivity they are not suitable as a screening assay.

ELISA techniques enable a differentiated analysis of the antibody response in the process of risk-patient monitoring by using immunoglobulin class-specific enzyme conjugates. For a further diagnosis of an invasive aspergillosis the lungs of a risk-patient should be examined for possible damage by biopsy.

Validation of SERION ELISA *classic* *Aspergillus fumigatus*

The SERION ELISA *classic* *Aspergillus fumigatus* IgA, IgG and IgM were validated by the analysis of serum samples from 86 risk patients with a suspicion of an aspergillosis. The SERION ELISA *classic* *Aspergillus fumigatus* were compared to an indirect haemagglutination test (IHAT) of a competitor. An IHAT mainly detects IgM antibodies as well as IgG antibodies so that the results of SERION ELISA *classic* *Aspergillus fumigatus* IgM and SERION ELISA *classic* *Aspergillus fumigatus* IgG were combined during the validation process and compared to the IHAT results. Sera classified as borderline were not included in the calculation.

SERION ELISA <i>classic</i>	Sensitivity	Specificity
<i>Aspergillus fumigatus</i> IgG/M	89,7 %	95 %

Precision

The intra- and interserial precisions were determined by the analysis of serum samples of different reactivities.

SERION ELISA *classic* *Aspergillus fumigatus* IgA

Sample	Mean value OD	Intraassay CV (%) (n=20)	Mean Value OD	Interassay CV (%) (n=10)
negative	0,052	4,1	0,033	11,8
negative	0,249	6,0	0,152	9,9
positive	0,901	8,3	1,199	5,9

SERION ELISA *classic* *Aspergillus fumigatus* IgG

Sample	Mean value OD	Intraassay CV (%) (n=20)	Mean value OD	Interassay CV (%) (n=10)
negative	0,054	7,6	0,042	19,9
positive	0,628	4,3	0,479	10,9
positive	2,284	3,1	0,596	7,2

SERION ELISA *classic* *Aspergillus fumigatus* IgM

Sample	Mean value OD	Intraassay CV (%) (n=20)	Mean value OD	Interassay CV (%) (n=10)
negative	0,037	9,8	0,043	19,5
weak pos.	0,725	4,5	0,288	11,2
positive	1,339	6,7	0,495	6,0

Order Information

SERION ELISA *classic* *Aspergillus fumigatus* IgA

SERION ELISA *classic* *Aspergillus fumigatus* IgG

SERION ELISA *classic* *Aspergillus fumigatus* IgM

Reference serum *Aspergillus fumigatus* IgA

Reference serum *Aspergillus fumigatus* IgG

Reference serum *Aspergillus fumigatus* IgM

Order Nr.: ESR 132 A

Order Nr.: ESR 132 G

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Order Nr.: BR 132 A

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