Serazym® Clostridium difficile Toxin A+B

Enzyme Immunoassay for direct detection of Clostridium difficile toxin A and B in faecal specimens and culture suspensions

Pathogen and Clinical Picture

The anaerobic spores-forming Clostridium difficile is considered as a cause of nosocomial diarrhoea in adults after antibiotic treatment. The exotoxins A and B are responsible for expression of the clinical picture of

- antibiotic-associated diarrhoea,
- antibiotic-associated colitis (AAC) and
- pseudomembranous colitis (PMC).

Transmission

Although 2–3% of healthy adults and 20-50% of healthy children are colonised with Clostridium difficile, the infection is usually of exogenous origin and results from the contact either to hospital staff or equipment contaminated with Clostridium difficile spores.

Diagnosis

The diagnosis of a Clostridium difficile associated disease is based mainly on a direct detection of the toxins in stool specimens by:

- Cytological Examination
- Cytotoxicity Test
- Enzyme Immuno Assay

Principle of the Test

The Serazym® Clostridium difficile Toxin A+B ELISA is an indirect two-site enzyme immunoassay based on immobilised monoclonal and biotinylated polyclonal anti-toxin A and B antibodies and with a streptavidin peroxidase as detection system.

The Serazym® Clostridium difficile Toxin A + B ELISA can be proceeded in two versions:

1) Incubation without shaking
   Total Incubation Time: 2 hours 15 minutes

2) Incubation with shaking
   Total Incubation Time: 1 hour 15 minutes
Cut-Off Determination

The cut-off has been determined based on the frequency distribution of the extinctions of 226 stool specimens with the Serazym® ELISA.

![Extinction Negative-Control + 0,20 EE](image)

Cross-Reactivities

The examination of stool specimen with the following pathogens did not show cross-reactivities with the Serazym® Clostridium difficile Toxin A+B Antigen ELISA: Staphylococcus aureus, EHEC, Pseudomonas aeruginosa, Salmonella typhimurium, Salmonella enteritidis, Salmonella spec., Aeromonas hydro-phila, Campylobacter spec., Hafnia alvei, Yersinia enterocolitica O:3.

Specificity and Sensitivity

Specificity and Sensitivity of the Serazym® Clostridium difficile Toxin A+B ELISA have been determined compared with another commercially available ELISA.

<table>
<thead>
<tr>
<th></th>
<th>Comparative-ELISA positive</th>
<th>Comparative-ELISA negative</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serazym® ELISA positive</td>
<td>103</td>
<td>4</td>
</tr>
<tr>
<td>Serazym® ELISA negative</td>
<td>2</td>
<td>45</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Sample</th>
<th>Extinction-Average Value</th>
<th>Standard-Deviation</th>
<th>Variation-Coefficient (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>1,386</td>
<td>0,042</td>
<td>3,0</td>
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<tr>
<td>II</td>
<td>0,506</td>
<td>0,017</td>
<td>3,3</td>
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<tr>
<td>III</td>
<td>0,332</td>
<td>0,028</td>
<td>8,5</td>
</tr>
</tbody>
</table>

Specificity: 91,8 %
Sensitivity: 98,0 %

Order Number:
HW/E-040, 96 wells

On demand also available as automatic device version!
HW/E-040-A2, 2 x 96 wells

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