Serazym® Astrovirus Antigen

Enzyme Immuno Assay for the detection of Astrovirus-antigen in faecal specimens

Epidemiology and Clinic

Astrovirus is a world-wide occurring single-strand RNA virus. Together with Rotavirus and Adenovirus Astrovirus is one of the most common causes of non-bacterial gastroenteritis in children under 5 years of age all over the world. The transmission is faecal-oral from person to person or via contaminated things or food. Astrovirus caused gastroenteritis in adults and nosocomial infections are observed as well. The course of the disease is usually self-limiting and of short duration. After an incubation time of 1-2 days a 1-4 days lasting gastroenteritis develops. Although occurring all over the year Astrovirus infections are mainly observed during the winter months. Astrovirus is detected in 3-9% of patients suffering an acute gastroenteritis.

Diagnosis

Direct detection of astroviruses in stool specimens is the most important method for the diagnosis of an astrovirus infection. Direct virus detection can be performed by:

- Virus Culture (special laboratory)
- Electron Microscopy (special laboratory)
- PCR (special laboratory)
- Antigen-ELISA from stool specimens (routine laboratory)

Principle of the Test

The Serazym® Astrovirus is a fast enzymometric one-step immunoassay on the basis of polyclonal and monoclonal antibodies.

Test Procedure Time

Total Incubation Time: 70 Minutes

Cut-Off Determination

The frequency distribution of the absorbances of 244 stool specimens with the Serazym Astrovirus Antigen ELISA was used to determine the cut-off.

Extinction Negative-Control + 0,10 EE
Lower Detection Limit

The lower detection limit of the Astrovirus antigen in the Serazym® Astrovirus Antigen ELISA was determined by titration of purified Astrovirus-Antigen.

Lower Detection Limit: 6 ng/ml

Specificity and Sensitivity

A total of 100 stool specimens have been examined in a parallel test run on the Serazym® Astrovirus ELISA and another commercially available ELISA.

<table>
<thead>
<tr>
<th>Serazym Astrovirus</th>
<th>Comparative-ELISA</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>negative</td>
</tr>
<tr>
<td>ELISA negative</td>
<td>47</td>
</tr>
<tr>
<td>ELISA positive</td>
<td>0</td>
</tr>
</tbody>
</table>

Specificity: 100 %
Sensitivity: 96 %

Order Number:
HW/E-045, 96 wells

Also available as automatic device version:
HW/E-045-A2, 2 x 96 wells

Precision

| I.  | 1,667 | 0.148 | 8.9 | I.  | 1,853 | 0.071 | 3.8 |
| II. | 0.994 | 0.063 | 6.4 | II. | 1.019 | 0.059 | 5.8 |
| III. | 0.443 | 0.027 | 6.1 | III. | 0.583 | 0.069 | 11.9 |
| IV.  | 0.185 | 0.018 | 9.8 | IV.  | 0.350 | 0.034 | 9.7 |

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