Immunoglobulin A FS*

Diagnostic reagent for quantitative in vitro determination of immunoglobulin A (IgA) in serum or plasma on DiaSys respons® 910

Order Information
Cat. No. 1 7202 99 10 921
4 twin containers for 80 tests each

Method
Immunoturbidimetric test

Principle
Determination of the IgA concentration by photometric measurement of antigen-antibody-reaction of antibodies to human IgA with IgA present in the sample.

Reagents
Components and Concentrations
R1: TRIS pH 7.5 100 mmol/L
NaCl 150 mmol/L
R2: TRIS pH 8.0 100 mmol/L
NaCl 300 mmol/L
Anti-human IgA antibody (goat) ≤ 1%

Storage Instructions and Reagent Stability
The reagents are stable up to the end of the indicated month of expiry, if stored at 2 – 8°C, protected from light and contamination is avoided. DiaSys responders containers provide protection from light. Do not freeze the reagents!

Warnings and Precautions
1. The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes!
2. Reagent 2 contains animal material: Handle the product as potentially infectious according to universal precautions and good clinical laboratory practices.
3. In very rare cases, samples of patients with gammopathy might give falsified results [8].
4. Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents. For diagnostic purposes, the results should always be assessed with the patient’s medical history, clinical examinations and other findings.
5. For professional use only!

Waste Management
Please refer to local legal requirements.

Reagent Preparation
The reagents are ready to use. The bottles are placed directly into the reagent rotor.

Specimen
Serum, heparin plasma or EDTA plasma
Stability [1]:
3 months at 20 – 25°C
3 months at 4 – 8°C
6 months at −20°C

Only freeze once!

Discard contaminated specimens.

Calibrators and Controls
For the calibration DiaSys TruCal Protein calibrator set is recommended. The assigned values of the calibrators have been made traceable to the Reference Material ERM-DA470k/IFCC. For internal quality control DiaSys TruLab Protein controls should be assayed. Each laboratory should establish corrective action in case of deviations in control recovery.

Performance Characteristics
Measuring range up to 900 mg/dL IgA (at least up to the concentration of the highest calibrator in case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function).

Limit of detection** 3 mg/dL IgA
No prozone effect up to 5000 mg/dL IgA
On-board stability 21 days
Calibration stability 10 days

Interfering substance Interferences IgA
< 10% [mg/dL]
Hemoglobin up to 1200 mg/dL 74.8
Bilirubin, conjugated up to 60 mg/dL 279
Bilirubin, unconjugated up to 60 mg/dL 382
Lipemia triglycerides up to 2000 mg/dL 85.2
up to 2000 mg/dL 386
up to 2000 mg/dL 352

For further information on interfering substances refer to Young DS [2].

Precision
Within run (n=20)
<table>
<thead>
<tr>
<th>Sample 1</th>
<th>Sample 2</th>
<th>Sample 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean [mg/dL]</td>
<td>83.3</td>
<td>107</td>
</tr>
<tr>
<td>Coefficient of variation [%]</td>
<td>3.39</td>
<td>3.86</td>
</tr>
</tbody>
</table>

Between run (n=20)
<table>
<thead>
<tr>
<th>Sample 1</th>
<th>Sample 2</th>
<th>Sample 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean [mg/dL]</td>
<td>84.5</td>
<td>102</td>
</tr>
<tr>
<td>Coefficient of variation [%]</td>
<td>3.26</td>
<td>3.32</td>
</tr>
</tbody>
</table>

Method comparison (n=140)

<table>
<thead>
<tr>
<th>Test x</th>
<th>Test y</th>
</tr>
</thead>
<tbody>
<tr>
<td>DiaSys Immunoglobulin A FS Hitachi 917</td>
<td>DiaSys Immunoglobulin A FS respons® 910</td>
</tr>
<tr>
<td>Slope</td>
<td>0.963</td>
</tr>
<tr>
<td>Intercept</td>
<td>1.032 mg/dL</td>
</tr>
<tr>
<td>Coefficient of correlation</td>
<td>0.995</td>
</tr>
</tbody>
</table>

** according to NCCCLS document EP17-A, vol. 24, no. 34

Conversion factor
Immunoglobulin A [mg/dL] x 0.0625 = Immunoglobulin A [µmol/L]

Reference Range
Adults [3]
70 – 400 mg/dL (4.38 – 25.0 µmol/L)

Children [4]
1 < 1 month
7 – 94 mg/dL (0.44 – 5.88 µmol/L)
1 – 12 month(s)
10 – 131 mg/dL (0.63 – 8.19 µmol/L)
1 – 3 year(s)
19 – 220 mg/dL (1.19 – 13.8 µmol/L)
4 – 5 years
48 – 345 mg/dL (3.00 – 21.6 µmol/L)
6 – 7 years
41 – 297 mg/dL (2.56 – 18.6 µmol/L)
8 – 10 years
51 – 297 mg/dL (3.19 – 18.6 µmol/L)
11 – 13 years
44 – 395 mg/dL (2.75 – 24.7 µmol/L)

Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

Literature

Manufacturer
DiaSys Diagnostic Systems GmbH
Alte Strasse 9
65558 Holzheim
Germany
Immunoglobulin A FS

Application for serum and plasma samples

This application was set up and evaluated by DiaSys. It is based on the standard equipment at that time and does not apply to any equipment modifications undertaken by unqualified personnel.

**Identification**

This method is usable for analysis: Yes
Twin reaction: No
Name: IGA
Shortcut: 714
Reagent barcode reference: 714
Host reference:

**Technic**

Type: End point
First reagent [µL]: 180
Blank reagent: Yes
Sensitive to light: No
Second reagent [µL]: 36
Blank reagent: Yes
Sensitive to light: No
Main wavelength [nm]: 570
Secondary wavelength [nm]: 570
Polychromatic factor:
1 st reading time [min:sec]: (04:24)
Last reading time [min:sec]: 10:00
Reaction way: Increasing
Linear Kinetics
Substrate depletion: Absorbance II
Linearity: Maximum deviation [%]
Fixed Time Kinetics
Substrate depletion: Absorbance limit
Endpoint
Stability: Largest remaining slope
Prozone Limit [%]

**Reagents**

Decimals
Units

**Sample**

Diluent: DIL A (NaCl)
Hemolysis: 0 (no hemolysis)
Cleaner
Sample [µL]: 0

**Technical limits**

Concentration technical limits-Lower
Concentration technical limits-Upper
SERUM
Normal volume [µL]: 3
Normal dilution (factor): 1
Below normal volume [µL]: 6
Below normal dilution (factor): 1
Above normal volume [µL]: 2
Above normal dilution (factor): 1

URINE
Normal volume [µL]: 3
Normal dilution (factor): 1
Below normal volume [µL]: 6
Below normal dilution (factor): 1
Above normal volume [µL]: 2
Above normal dilution (factor): 1

PLASMA
Normal volume [µL]: 3
Normal dilution (factor): 1
Below normal volume [µL]: 6
Below normal dilution (factor): 1
Above normal volume [µL]: 2
Above normal dilution (factor): 1

CSF
Normal volume [µL]: 3
Normal dilution (factor): 1
Below normal volume [µL]: 6
Below normal dilution (factor): 1
Above normal volume [µL]: 2
Above normal dilution (factor): 1

Whole blood
Normal volume [µL]: 3
Normal dilution (factor): 1
Below normal volume [µL]: 6
Below normal dilution (factor): 1
Above normal volume [µL]: 2
Above normal dilution (factor): 1

**Results**

Decimals: 1
Units: mg/dL
Correlation factor-Offset: 0.000
Correlation factor-Slope: 1.000

**Range**

Gender: All
Age: Adults
SERUM
URINE
PLASMA
CSF
Whole blood

**Contaminants**

Please refer to r910 Carryover Pair Table

**Calibrators details**

Calibrator list | Concentration
--- | ---
Cat. 1/Blank | 0
Cat. 2 | *
Cat. 3 | *
Cat. 4 | *
Cat. 5 | *
Cat. 6 | *

Max delta abs.
Cat. 1 | 0.1000
Cat. 2 | 0.0100
Cat. 3 | 0.0100
Cat. 4 | 0.0200
Cat. 5 | 0.0300
Cat. 6 | 0.0500

Drift limit [%]: 5.0

**Calculations**

Model: Akima Spline
Degree: Auto

* Enter calibrator value