### Order Information

<table>
<thead>
<tr>
<th>REF</th>
<th>CONTENT</th>
<th>Analyzer(s) on which cobas c pack(s) can be used</th>
</tr>
</thead>
<tbody>
<tr>
<td>03507432 190</td>
<td>Tina-quant IgG Gen.2 150 tests</td>
<td>System-ID 07 6787 5</td>
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<tr>
<td>11355279 216</td>
<td>Calibrator f.a.s. Proteins (5 × 1 mL)</td>
<td>Code 656</td>
</tr>
<tr>
<td>03121305 122</td>
<td>Calibrator f.a.s. PUC (5 × 1 mL)</td>
<td>Code 489</td>
</tr>
<tr>
<td>10557897 122</td>
<td>Precinorm Protein (3 × 1 mL)</td>
<td>Code 302</td>
</tr>
<tr>
<td>11333127 122</td>
<td>Precipath Protein (3 × 1 mL)</td>
<td>Code 303</td>
</tr>
<tr>
<td>10171743 122</td>
<td>Precinorm U (20 × 5 mL)</td>
<td>Code 300</td>
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<tr>
<td>03121313 122</td>
<td>Precinorm PUC (4 × 3 mL)</td>
<td>Code 240</td>
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<tr>
<td>03121291 122</td>
<td>Precipath PUC (4 × 3 mL)</td>
<td>Code 241</td>
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<tr>
<td>05117003 190</td>
<td>PreciControl ClinChem Multi 1 (20 × 5 mL)</td>
<td>Code 391</td>
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<tr>
<td>05947626 190</td>
<td>PreciControl ClinChem Multi 1 (4 × 5 mL)</td>
<td>Code 391</td>
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<td>05117216 190</td>
<td>PreciControl ClinChem Multi 2 (20 × 5 mL)</td>
<td>Code 392</td>
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<td>05947774 190</td>
<td>PreciControl ClinChem Multi 2 (4 × 5 mL)</td>
<td>Code 392</td>
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<tr>
<td>04489357 190</td>
<td>Diluent NaCl 9 % (50 mL)</td>
<td>System-ID 07 6869 3</td>
</tr>
</tbody>
</table>

### English

#### System Information

For cobas c 311/501 analyzers:

**IGG-2: ACN 674** (Standard application for serum and plasma)

**IGGC2: ACN 673** (Sensitive application for cerebrospinal fluid)

**IGGU2: ACN 625** (Sensitive application for urine)

For cobas c 502 analyzer:

**IGG-2: ACN 8674** (Standard application for serum and plasma)

**IGGC2: ACN 8673** (Sensitive application for cerebrospinal fluid)

**IGGU2: ACN 8625** (Sensitive application for urine)

#### Intended use

In vitro test for the quantitative determination of IgG in human serum, plasma, cerebrospinal fluid and urine on Roche/Hitachi cobas c systems.

**Summary**

IgG molecules are composed of two light chains (kappa or lambda) and two gamma heavy chains. Approximately 80 % of serum immunoglobulin is IgG; its main tasks are the defense against microorganisms, direct neutralization of toxins and induction of complement fixation. IgG is the only immunoglobulin that can cross the placental barrier and provide passive immune protection for the fetus and newborn. This maternal protection gradually declines until the infant’s own immunological system starts to develop (at about six months of age). Near-adult levels in serum/plasma are reached at 18 months.

Polyclonal IgG increases in serum/plasma may be present in systemic lupus erythematosis, chronic liver diseases (infectious hepatitis and Laennec’s cirrhosis), infectious diseases and cystic fibrosis. Monoclonal IgG increases in IgG-myeloma.

Decreased synthesis of IgG is found in congenital and acquired immunodeficiency diseases and selective IgG subclass deficiencies, such as Bruton type agammaglobulinemia. Decreased IgG concentrations in serum and plasma are seen in protein-losing enteropathies, nephrotic syndrome and through the skin from burns. Increased IgG metabolism is found in Wiskott-Aldrich syndrome, myotonic dystrophy and with anti-immunoglobulin antibodies.

The determination of IgG in cerebrospinal fluid (CSF) is used for evaluation of infections involving the central nervous system (CNS), neoplasms or primary neurologic diseases (in particular, multiple sclerosis). Increased CSF IgG concentrations may occur because of either increased permeability of the blood-brain barrier or local/intrathecal production of IgG, or both.

The malfunction of the blood-brain barrier can be reliably quantified by means of the albumin CSF/serum ratio. An elevated albumin ratio is an indication of a disorder of the blood-brain barrier. If IgG and albumin are measured in CSF and serum simultaneously, differentiation between IgG originating from blood and IgG originating from intrathecal production is possible.

The determination of urine IgG aids, in combination with urinary albumin, to separate selective forms from unselective forms of tubular proteinuria, since IgG is markedly increased only in unselective forms of glomerular proteinuria (IgG/albumin > 0.03 mg/mg). Additionally, measurements of IgG in urine can be used in the monitoring and assessment of glomerular proteinuria.

The Roche IgG assay is based on the principle of immunological agglutination. In addition to the standard application (IGG-2), there are sensitive applications (IGGC2 and IGGU2) designed for the quantitative determination of IgG in CSF and urine.

It is known that the so-called paraproteins secreted in monoclonal gammapathies (monoclonal immunoglobulinemia) may differ from the respective immunoglobulins of polyclonal origin by amino acid composition and size. This may impair the binding to antibody and hence impair accurate quantitation.

#### Test principle

Immunoturbidimetric assay.

Anti-IgG antibodies react with antigen in the sample to form an antigen/antibody complex. Following agglutination, this is measured turbidimetrically. Addition of PEG allows the reaction to progress rapidly to the end point, increases sensitivity, and reduces the risk of samples containing excess antigen producing false negative results.

#### Reagents - working solutions

- **R1**
  - TRIS buffer: 20 mmol/L, pH 8.0; NaCl: 200 mmol/L; polyethylene glycol: 3.6 %; preservative; stabilizers

- **R2**
  - Anti-human IgG antibody (goat); dependent on titer; TRIS buffer: 20 mmol/L, pH 8.0; NaCl: 150 mmol/L; preservative

**R1** is in position B and **R2** is in position C.

#### Precautions and warnings

For in vitro diagnostic use.

Exercise the normal precautions required for handling all laboratory reagents.

Disposal of all waste material should be in accordance with local guidelines.

Safety data sheet available for professional user on request.

This kit contains components classified as follows in accordance with the Regulation (EC) No. 1272/2008:

**Danger**

- **H318** Causes serious eye damage.

**Prevention:**
Stability:

Samples

Spontaneous, urine

Stability:

Particles

Stability:

Serum

Centrifuge urine.

Urine

manufacturer.

From tubes

The CSF

Serum/plasma

Only collection

for specimens

in 2‑8 °C:

Shelf refrigerated

Shelf life at 2‑8 °C:

See expiration date on cobas c pack label.

On‑board in use and refrigerated on the analyzer:

Diluent NaCl 9 %

Shelf life at 2‑8 °C:

See expiration date on cobas c pack label.

On‑board in use and refrigerated on the analyzer:

Specimen collection and preparation

For specimen collection and preparation only use suitable tubes or collection containers.

Only the specimens listed below were tested and found acceptable.

Serum/plasma application (IGG‑2)

Serum.

Plasma: Li‑heparin and K2‑EDTA plasma

CSF application (IGGC2)

Cerebrospinal fluid.

The sample types listed were tested with a selection of sample collection tubes that were commercially available at the time of testing, i.e. not all available tubes of all manufacturers were tested. Sample collection systems from various manufacturers may contain differing materials which could affect the test results in some cases. When processing samples in primary tubes (sample collection systems), follow the instructions of the tube manufacturer.

Urine application (IGGU2)

Urine.

Centrifuge samples containing precipitates before performing the assay.

Serum and plasma

Stability:10

4 months at 15‑25 °C

8 months at 2‑8 °C

8 months at (-15)‑(-25) °C

CSF

Samples should be as fresh as possible. Centrifuge samples containing particles and/or cells before performing the assay.

Stability:10

1 day at 15‑25 °C

7 days at 2‑8 °C

Storage at (-15)‑(-25) °C is not recommended.

Urine

Spontaneous, 24‑hour urine or 2nd morning urine. Centrifuge the urine samples for 10 min at ≥ 800 g.

Stability:11

7 days at 15‑25 °C

1 month at 2‑8 °C

Storage at (-15)‑(-25) °C is not recommended.

Materials provided

See "Reagents – working solutions" section for reagents.

Materials required (but not provided)

• See "Order information" section

• General laboratory equipment

Assay

For optimum performance of the assay follow the directions given in this document for the analyzer concerned. Refer to the appropriate operator’s manual for analyzer‑specific assay instructions.

The performance of applications not validated by Roche is not warranted and must be defined by the user.

Application for serum and plasma (IGG‑2)

cobas c 311 test definition

Assay type 2‑Point End

Reaction time / Assay points 10 / 6‑16

Wavelength (sub/main) 700/340 nm

Reaction direction Increase

Units g/L (µmol/L, mg/dL)

Reagent pipetting Diluent (H2O)

R1 120 µL –

R2 38 µL –

Sample volumes Sample Sample dilution

Sample Diluent (NaCl)

Normal 5 µL 9 µL 180 µL

Decreased 3.9 µL 2 µL 180 µL

Increased 9.4 µL 20 µL 85 µL

cobas c 501/502 test definition

Assay type 2‑Point End

Reaction time / Assay points 10 / 10‑46

Wavelength (sub/main) 700/340 nm

Reaction direction Increase

Units g/L (µmol/L, mg/dL)

Reagent pipetting Diluent (H2O)

R1 120 µL –

R2 38 µL –

Sample volumes Sample Sample dilution

Sample Diluent (NaCl)

Normal 5 µL 9 µL 180 µL

Decreased 3.9 µL 2 µL 180 µL

Increased 9.4 µL 20 µL 85 µL

Application for CSF (IGGC2)

cobas c 311 test definition

Assay type 2‑Point End

Reaction time / Assay points 10 / 6‑31

Wavelength (sub/main) 700/340 nm

Reaction direction Increase

Units mg/L (nmol/L)

Reagent pipetting Diluent (H2O)
### Tina-quant IgG Gen.2

<table>
<thead>
<tr>
<th>Sample volumes</th>
<th>Sample dilution</th>
<th>Sample</th>
<th>Diluent (NaCl)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>14.5 µL</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Decreased</td>
<td>2.9 µL</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Increased</td>
<td>14.5 µL</td>
<td>–</td>
<td>–</td>
</tr>
</tbody>
</table>

**cobas c 501 test definition**

- **Assay type**: 2-Point End
- **Reaction time / Assay points**: 10 / 10-46
- **Wavelength (sub/main)**: 700/340 nm
- **Reaction direction**: Increase
- **Units**: mg/L (nmol/L)
- **Reagent pipetting**: Diluent (H₂O)
  - **R1**: 120 µL
  - **R2**: 38 µL
- **Sample volumes**: Sample dilution
  - **Sample**: 14.5 µL
  - **Diluent (NaCl)**: –

**cobas c 502 test definition**

- **Assay type**: 2-Point End
- **Reaction time / Assay points**: 10 / 10-46
- **Wavelength (sub/main)**: 700/340 nm
- **Reaction direction**: Increase
- **Units**: mg/L (nmol/L)
- **Reagent pipetting**: Diluent (H₂O)
  - **R1**: 120 µL
  - **R2**: 38 µL
- **Sample volumes**: Sample dilution
  - **Sample**: 14.5 µL
  - **Diluent (NaCl)**: –

**Application for urine (IGGU2)**

**cobas c 311 test definition**

- **Assay type**: 2-Point End
- **Reaction time / Assay points**: 10 / 6-31
- **Wavelength (sub/main)**: 700/340 nm
- **Reaction direction**: Increase
- **Units**: mg/L (nmol/L)
- **Reagent pipetting**: Diluent (H₂O)
  - **R1**: 120 µL
  - **R2**: 38 µL
- **Sample volumes**: Sample dilution
  - **Sample**: 14.5 µL
  - **Diluent (NaCl)**: –

### cobas c 311 analyzer: Spline

**Calibration mode**

- **cobas c 501/502 analyzer: RCM**

**Calibration frequency**

- Full calibration
  - after reagent lot change
  - as required following quality control procedures

**CSF (IGGC2) and urine (IGGU2) applications:**

<table>
<thead>
<tr>
<th>R1</th>
<th>120 µL</th>
<th>–</th>
<th>–</th>
</tr>
</thead>
<tbody>
<tr>
<td>R2</td>
<td>10 µL</td>
<td>20 µL</td>
<td>–</td>
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</tbody>
</table>

### cobas 501 test definition

- **Assay type**: 2-Point End
- **Reaction time / Assay points**: 10 / 10-46
- **Wavelength (sub/main)**: 700/340 nm
- **Reaction direction**: Increase
- **Units**: mg/L (nmol/L)
- **Reagent pipetting**: Diluent (H₂O)
  - **R1**: 120 µL
  - **R2**: 38 µL
- **Sample volumes**: Sample dilution
  - **Sample**: 14.5 µL
  - **Diluent (NaCl)**: –

<table>
<thead>
<tr>
<th>Sample</th>
<th>Sample dilution</th>
<th>Sample</th>
<th>Diluent (NaCl)</th>
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<td>135 µL</td>
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<tr>
<td>Increased</td>
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</table>

### cobas 502 test definition

- **Assay type**: 2-Point End
- **Reaction time / Assay points**: 10 / 10-46
- **Wavelength (sub/main)**: 700/340 nm
- **Reaction direction**: Increase
- **Units**: mg/L (nmol/L)
- **Reagent pipetting**: Diluent (H₂O)
  - **R1**: 120 µL
  - **R2**: 38 µL
- **Sample volumes**: Sample dilution
  - **Sample**: 14.5 µL
  - **Diluent (NaCl)**: –

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<tr>
<td>Decreased</td>
<td>14.5 µL</td>
<td>15 µL</td>
<td>135 µL</td>
</tr>
<tr>
<td>Increased</td>
<td>14.5 µL</td>
<td>–</td>
<td>–</td>
</tr>
</tbody>
</table>

### Serum/plasma application (IGG-2):

**Calibrators**

- S1: H₂O
- S2-S6: C.f.a.s. Proteins

Multiply the lot-specific C.f.a.s. Proteins calibrator value by the factors below to determine the standard concentrations for the 6-point calibration curve:

<table>
<thead>
<tr>
<th>S2</th>
<th>S3</th>
<th>S5</th>
<th>S6</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.100</td>
<td>0.250</td>
<td>1.00</td>
<td>3.14</td>
</tr>
<tr>
<td>0.501</td>
<td>1.00</td>
<td>3.14</td>
<td>6.34</td>
</tr>
</tbody>
</table>

**Calibration mode**

- **cobas c 311 analyzer: Spline**

**Calibration frequency**

- Full calibration
  - after reagent lot change
  - as required following quality control procedures

**CSF (IGGC2) and urine (IGGU2) applications:**

<table>
<thead>
<tr>
<th>Sample</th>
<th>Sample dilution</th>
<th>Sample</th>
<th>Diluent (NaCl)</th>
</tr>
</thead>
<tbody>
<tr>
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<td>135 µL</td>
</tr>
<tr>
<td>Increased</td>
<td>14.5 µL</td>
<td>–</td>
<td>–</td>
</tr>
</tbody>
</table>
Calibrators

S1: H₂O
S2-S6: C.f.a.s. PUC

Multiply the lot-specific C.f.a.s. PUC calibrator value by the factors below to determine the standard concentrations for the 6-point calibration curve:

S2: 0.0431
S3: 0.0862
S4: 0.166
S5: 0.331
S6: 1.00

Calibration mode: RCM

Calibration frequency:
- Full calibration
- as required following quality control procedures

Traceability: This method has been standardized against the certified reference material in human serum of the IRMM (Institute for Reference Materials and Measurements) ERMA-DA470x/IFCC.

Quality control

For quality control, use control materials as listed in the “Order information” section.

IGG-2: Precinorm Protein, Precipath Protein, Precinorm U, PreciControl ClinChem Multi 1, PreciControl ClinChem Multi 2
IGGC2 and IGGU2: Precinorm PUC, Precipath PUC

In addition, other suitable control material can be used.

The control intervals and limits should be adapted to each laboratory’s individual requirements. Values obtained should fall within the defined limits. Each laboratory should establish corrective measures to be taken if values fall outside the defined limits.

Follow the applicable government regulations and local guidelines for quality control.

Calculation

Roche/Hitachi cobas c systems automatically calculate the analyte concentration of each sample.

Conversion factors:
mg/dL × 0.01 = g/L
mg/L × 6.67 = μmol/L
μmol/L × 10 = mg/dL
μmol/L × 0.15 = g/L
mg/L × 6.67 = mmol/L
mmol/L × 0.15 = mg/L

Limitations - interference

Serum/plasma application (IGG-2):

Criterion: Recovery within ± 10 % of initial value at an IgG concentration of 7.00 g/L (46.7 μmol/L, 700 mg/dL).

Icterus: No significant interference up to an index of 60 for conjugated and unconjugated bilirubin (approximate conjugated and unconjugated bilirubin concentration: 1026 μmol/L or 60 mg/dL).

Hemolysis: No significant interference up to an index of 1000 (approximate hemoglobin concentration: 821 μmol/L or 1000 mg/dL).

Lipemia (intralipid): No significant interference up to an index of 2000 (approximate intralipid concentration: 2000 mg/dL). There is poor correlation between the index (corresponds to turbidity) and triglycerides concentration.

Rheumatoid factors < 1200 IU/mL do not interfere.

High dose hook-effect: No false result up to an IgG concentration of 400 g/L (2668 μmol/L, 40000 mg/dL) occurs due to an antigen excess within polycolonal specimens.

There is no cross-reaction between IgG and IgA or IgM under the assay conditions.

Drugs: No interference was found at therapeutic concentrations using common drug panels.

As with other turbidometric or nephelometric procedures, this test may not provide accurate results in patients with monoclonal gammopathy, due to individual sample characteristics which can be assessed by electrophoresis.

CSF application (IGGC2):

Criterion: Recovery within ± 10 % of initial value at an IgG concentration of 15.00 mg/L (100 nmol/L).

Icterus: No significant interference up to a conjugated and unconjugated bilirubin concentration of 257 μmol/L (15 mg/dL).

Hemolysis: No significant interference up to a hemoglobin concentration of 124 μmol/L (200 mg/dL).

High dose hook-effect: No false result up to an IgG concentration of 2500 mg/L (16675 nmol/L) occurs due to an antigen excess within polycolonal specimens.

There is no cross-reaction between IgG and IgA or IgM under the assay conditions.

Urine application (IGGU2):

Criterion: Recovery within ± 2 mg/L (± 13.3 nmol/L) of initial value at an IgG concentration of ≤ 10 mg/L (≤ 66.7 nmol/L) and within ± 10 % of initial value at an IgG concentration of > 10 mg/L (> 66.7 nmol/L).

Icterus: No significant interference up to a conjugated and unconjugated bilirubin concentration of 257 μmol/L (15 mg/dL).

Hemolysis: No significant interference up to a hemoglobin concentration of 93.2 μmol/L (150 mg/dL).

High dose hook-effect: No false result occurs up to an IgG concentration of 6000 mg/L (40020 nmol/L).

Drugs: No interference was found at therapeutic concentrations using common drug panels.

Exception: N-acetyl cysteine and ascorbic acid cause artificially low IgG results.

No interference by h-albumin ≤ 5000 mg/L, glucose ≤ 111 nmol/L, creatinine ≤ 44 mmol/L, urea ≤ 900 mmol/L, uric acid ≤ 6 mmol/L, oxalate ≤ 2.2 mmol/L, calcium ≤ 40 mmol/L, citrate ≤ 10 mmol/L, magnesium ≤ 75 mmol/L and phosphate ≤ 40 mmol/L.

For diagnostic purposes, the results should always be assessed in conjunction with the patient’s medical history, clinical examination and other findings.

ACTION REQUIRED

Special Wash Programming: The use of special wash steps is mandatory when certain test combinations are run together on Roche/Hitachi cobas c systems. The latest version of the carry-over evasion list can be found with the NaOHDS-SmpClin1-2-SCCS Method Sheets. For further instructions refer to the operator’s manual. cobas c 502 analyzer: All special wash programming necessary for avoiding carry-over is available via the cobas link, manual input is not required.

Where required, special wash/carry-over evasion programming must be implemented prior to reporting results with this test.

Limits and ranges

Measuring range

Serum/plasma application (IGG-2):
3.00-50.0 g/L (20.0-334 μmol/L, 300-5000 mg/dL)

Determine samples having higher concentrations via the rerun function. Dilution of samples via the rerun function is a 1:5.5 dilution. Results from samples diluted using the rerun function are automatically multiplied by a factor of 5.5.

Determine samples having lower concentrations via the rerun function. For samples with lower concentrations, the re-run function increases the sample volume by a factor of 7.5. The results are automatically divided by this factor.

CSF application (IGGC2):
4.00-200 mg/L (26.7-1334 nmol/L)

Determine samples having higher concentrations via the rerun function. Dilution of samples via the rerun function is a 1:5.5 dilution. Results from samples diluted using the rerun function are automatically multiplied by a factor of 5.

Urine application (IGGU2):
4.00-200 mg/L (26.7-1334 nmol/L)
Determine samples having higher concentrations via the rerun function. Dilution of samples via the rerun function is a 1:10 dilution. Results from samples diluted using the rerun function are automatically multiplied by a factor of 10.

**Lower limits of measurement**

*Lower detection limit of the test*

**Serum/plasma application (IGG-2):**

0.30 g/L (2.00 µmol/L, 30 mg/dL)

The lower detection limit represents the lowest measurable analyte level that can be distinguished from zero. It is calculated as the value lying 3 standard deviations above that of the lowest standard (standard 1 + 3 SD, repeatability, n = 21).

**CSF application (IGGC2):**

4.00 mg/L (26.7 nmol/L)

The lower detection limit represents the lowest measurable analyte level that can be distinguished from zero. It is calculated as the value lying 3 standard deviations above that of the lowest standard (standard 1 + 3 SD, repeatability, n = 21).

**Urine application (IGGU2):**

*Limit of Blank, Limit of Detection and Limit of Quantitation*

Limit of Blank = 3 mg/L (20.0 nmol/L)

Limit of Detection = 4 mg/L (26.7 nmol/L)

Limit of Quantitation = 7 mg/L (46.7 nmol/L)

The Limit of Blank and Limit of Detection were determined in accordance with the CLSI (Clinical and Laboratory Standards Institute) EP17-A requirements.

The Limit of Blank is the 95th percentile value from n ≥ 60 measurements of analyte-free samples over several independent series. The Limit of Blank corresponds to the concentration below which analyte-free samples are found with a probability of 95%.

The Limit of Detection is determined based on the Limit of Blank and the standard deviation of low concentration samples.

The Limit of Detection corresponds to the lowest analyte concentration which can be detected (value above the Limit of Blank with a probability of 95%).

The Limit of Quantitation is the lowest analyte concentration that can be reproducibly measured with a total error of 30%. It has been determined using low concentration IgG samples.

**Expected values**

**Serum/plasma**

<table>
<thead>
<tr>
<th>Adults16</th>
<th>Children and juveniles17</th>
</tr>
</thead>
<tbody>
<tr>
<td>7-16 g/L</td>
<td>46.7-107 µmol/L</td>
</tr>
</tbody>
</table>

| 0-1 year | 2.32-14.11 g/L | 15.94-91 µmol/L | 232-1411 mg/dL |
| 1-3 years | 4.53-9.16 g/L | 30.2-61.1 µmol/L | 453-916 mg/dL |
| 4-6 years | 5.04-14.65 g/L | 33.6-97.7 µmol/L | 504-1465 mg/dL |
| 7-9 years | 5.72-14.74 g/L | 38.1-98.3 µmol/L | 572-1474 mg/dL |
| 10-11 years | 6.98-15.60 g/L | 46.5-104 µmol/L | 698-1560 mg/dL |
| 12-13 years | 7.59-15.50 g/L | 50.6-103 µmol/L | 759-1550 mg/dL |
| 14-15 years | 7.16-117.114 g/L | 47.7-114 µmol/L | 716-1711 mg/dL |
| 16-19 years | 5.49-15.84 g/L | 36.6-106 µmol/L | 549-1584 mg/dL |

**CSF**

10-30 mg/L (66.7-200 nmol/L)

**Urine**

The upper normal 97.5th percentile limit was found to be 8.5 mg/24 h for IgG (0.90 confidence interval: 7.7-10.1 mg/24 h).19

Each laboratory should investigate the transferability of the expected values to its own patient population and if necessary determine its own reference ranges.

**Specific performance data**

Representative performance data on the analyzers are given below. Results obtained in individual laboratories may differ.

**Precision**

*Serum/plasma and CSF:*

Precision was determined using human samples and controls in an internal protocol with repeatability (n = 21) and intermediate precision (3 aliquots per run, 1 run per day, one lot of reagent, 21 days).

*Urine:*

Precision was determined using human samples and controls in accordance with the CLSI (Clinical and Laboratory Standards Institute) EP5 requirements with repeatability (n = 84) and intermediate precision (4 aliquots per run, 1 run per day, 21 days on Roche/Hitachi cobas c 501 analyzer). The following results were obtained:

**Serum/plasma application (IGG-2):**

<table>
<thead>
<tr>
<th>Repeatability</th>
<th>Mean</th>
<th>SD</th>
<th>CV</th>
</tr>
</thead>
<tbody>
<tr>
<td>g/L (µmol/L, mg/dL)</td>
<td>g/L (µmol/L, mg/dL)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Precinorm Protein</td>
<td>8.25 (55.0, 825)</td>
<td>0.08 (0.5, 8)</td>
<td>1.0</td>
</tr>
<tr>
<td>Precipath Protein</td>
<td>14.2 (94.7, 1420)</td>
<td>0.2 (1.3, 20)</td>
<td>1.2</td>
</tr>
</tbody>
</table>

**Intermediate precision**

<table>
<thead>
<tr>
<th>Mean</th>
<th>SD</th>
<th>CV</th>
</tr>
</thead>
<tbody>
<tr>
<td>g/L (µmol/L, mg/dL)</td>
<td>g/L (µmol/L, mg/dL)</td>
<td></td>
</tr>
<tr>
<td>Precinorm Protein</td>
<td>8.19 (54.6, 819)</td>
<td>0.12 (0.8, 12)</td>
</tr>
<tr>
<td>Precipath Protein</td>
<td>14.2 (94.7, 1420)</td>
<td>0.2 (1.3, 20)</td>
</tr>
</tbody>
</table>

**CSF application (IGGC2):**

<table>
<thead>
<tr>
<th>Repeatability</th>
<th>Mean</th>
<th>SD</th>
<th>CV</th>
</tr>
</thead>
<tbody>
<tr>
<td>mg/L (nmol/L)</td>
<td>mg/L (nmol/L)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Precinorm PUC</td>
<td>18.8 (125)</td>
<td>0.3 (2)</td>
<td>1.6</td>
</tr>
<tr>
<td>Precipath PUC</td>
<td>150 (1001)</td>
<td>2 (13)</td>
<td>1.1</td>
</tr>
</tbody>
</table>

**Intermediate precision**

<table>
<thead>
<tr>
<th>Mean</th>
<th>SD</th>
<th>CV</th>
</tr>
</thead>
<tbody>
<tr>
<td>mg/L (nmol/L)</td>
<td>mg/L (nmol/L)</td>
<td></td>
</tr>
<tr>
<td>Precinorm PUC</td>
<td>20.1 (134)</td>
<td>0.5 (3)</td>
</tr>
<tr>
<td>Precipath PUC</td>
<td>160 (1067)</td>
<td>2 (13)</td>
</tr>
</tbody>
</table>

**Urine application (IGGU2):**

<table>
<thead>
<tr>
<th>Repeatability</th>
<th>Mean</th>
<th>SD</th>
<th>CV</th>
</tr>
</thead>
<tbody>
<tr>
<td>mg/L (nmol/L)</td>
<td>mg/L (nmol/L)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Precinorm PUC</td>
<td>17.2 (115)</td>
<td>0.3 (2)</td>
<td>1.5</td>
</tr>
<tr>
<td>Precipath PUC</td>
<td>140 (934)</td>
<td>1 (7)</td>
<td>0.9</td>
</tr>
<tr>
<td>Urine 1</td>
<td>7.52 (50.2)</td>
<td>0.28 (1.9)</td>
<td>3.7</td>
</tr>
<tr>
<td>Urine 2</td>
<td>89.9 (600)</td>
<td>0.6 (4)</td>
<td>0.7</td>
</tr>
</tbody>
</table>
Urinary Protein

<table>
<thead>
<tr>
<th>Method</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>Positive Predictive Value</th>
<th>Negative Predictive Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum</td>
<td>0.957</td>
<td>0.995</td>
<td>0.982</td>
<td>0.967</td>
</tr>
<tr>
<td>Urine</td>
<td>0.907</td>
<td>0.994</td>
<td>0.989</td>
<td>0.967</td>
</tr>
</tbody>
</table>

**References**

**Symbols**

- **GTIN**
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