α1-Antitrypsin Clearance ELISA

Zur in-vitro-Bestimmung von α1-Antitrypsin in Serum, Plasma und Stuhl

α1-Antitrypsin Clearance ELISA

For the in vitro determination of α1-antitrypsin in serum, plasma and stool

EU: IVD / CE

Gültig ab / Valid from 04.09.2014

REF K 6752

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1. INTENDED USE
The described Enzyme-Linked-Immuno-Sorbent-Assay (ELISA) is intended for the quantitative determination of α₁-Antitrypsin in serum, plasma and stool. It is for in vitro diagnostic use only.

2. INTRODUCTION
Intestinal protein loss is a serious consequence of various systemic or local gastrointestinal diseases (e.g. allergies, chronic inflammation, malignancies). These pathologies damage the mucosal integrity and/or cause lymphostasis, thereby leading to an increased transfer of plasma proteins into the bowel lumen. Subsequently, hypoproteinemia accompanied with edema may develop. This condition is diagnosed by exclusion of other sources of protein loss and by proof of an elevated α₁-antitrypsin concentration in stool.

In serum, α₁-antitrypsin represents the majority of serine protease inhibitors and protects tissues from protease damages during inflammation. The protein is synthesized primarily in the liver but also to a small extent in intestinal macrophages, monocytes, and intestinal epithelial cells. Since α₁-antitrypsin is relatively resistant against enzymatic digestion, the secreted amount in stool reflects the internal concentration of the protein. An elevated α₁-antitrypsin stool concentration is therefore a widely recognized marker for intestinal protein loss and for an increased mucosal permeability.

In clinical routine, the α₁-antitrypsin clearance (ratio of the α₁-antitrypsin ELISA values of stool and serum samples) has been established along with the sole determination of the 24h α₁-antitrypsin secretion in stool. Thus the group of J. S. Fordtran reports that the sole determination of the α₁-antitrypsin concentration in stool yielded false positive or false negative results in 21 % of the patients compared to the α₁-antitrypsin clearance measurement (Strygler et al. 1990).

The analytical quality of Immundiagnostik’s α₁-antitrypsin ELISA surpasses by far the conventional radial immunodiffusion (RID) technique in the determination of serum, stool and tissue culture supernatants. In direct comparison, the concentrations measured with the ELISA were approximately 30 % above the corresponding RID levels. Cell culture supernatants of an intestinal cell line as well as fecal samples of lymphostasis patients yielded negative results with RID. Our ELISA could detect α₁-antitrypsin in all of these samples, in some of them even in very high concentrations.

These results clearly prove that the α₁-antitrypsin ELISA is far more sensitive than the conventional method and that it recognizes not only hepatic but also enteral α₁-antitrypsin. The discrepancy of both methods and hence the superiority of the ELISA to RID is especially striking in the analysis of extremely high enteral protein losses. The combination of two specific antibodies in our α₁-antitrypsin ELISA widely exclu-
des the possibility of false negative results thereby enabling a reliable diagnostics of enteral protein loss.

**Indications**

- Suspected enteric protein loss
- Crohn's disease
- Necrotic enterocolitis
- Chronic mesenterial ischemia
- Viral, bacterial, allergic, or autoimmune-induced gastrointestinal inflammation

3. **MATERIAL SUPPLIED**

<table>
<thead>
<tr>
<th>Cat. No.</th>
<th>Label</th>
<th>Kit components</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>K 6752MTP</td>
<td>PLATE</td>
<td>Holder with precoated strips</td>
<td>12 x 8 wells</td>
</tr>
<tr>
<td>K 6752WP</td>
<td>WASHBUF</td>
<td>ELISA wash concentrate 10x</td>
<td>2 x 100 ml</td>
</tr>
<tr>
<td>K 6752K</td>
<td>CONJ</td>
<td>Conjugate, (goat-anti-α₁-antitrypsin, peroxidase-labeled)</td>
<td>200 µl</td>
</tr>
<tr>
<td>K 6752ST</td>
<td>STD</td>
<td>Standards, ready to use (0; 3.3; 10; 30; 90 µg/l)*</td>
<td></td>
</tr>
<tr>
<td>K 6752KO1</td>
<td>CTRL</td>
<td>Control, ready to use</td>
<td>1 vial</td>
</tr>
<tr>
<td>K 6752KO2</td>
<td>CTRL</td>
<td>Control, ready to use</td>
<td>1 vial</td>
</tr>
<tr>
<td>K 6752TMB</td>
<td>SUB</td>
<td>TMB substrate (tetramethylbenzidine), ready to use</td>
<td>1 x 15 ml</td>
</tr>
<tr>
<td>K 6752AC</td>
<td>STOP</td>
<td>ELISA stop solution, ready to use</td>
<td>1 x 15 ml</td>
</tr>
<tr>
<td>K 6752EP</td>
<td>IDK Extract®</td>
<td>Extraction buffer concentrate IDK Extract® 2.5x</td>
<td>2 x 100 ml</td>
</tr>
<tr>
<td>K 6752PV</td>
<td>SAMPLEBUF</td>
<td>Sample buffer, ready to use</td>
<td>2 x 70 ml</td>
</tr>
</tbody>
</table>

* The used standards have been calibrated on the WHO reference material CRM 470.

4. **MATERIAL REQUIRED BUT NOT SUPPLIED**

- Ultra pure water*
- Laboratory balance
- Calibrated precision pipettors and 10–1000 µl tips
- Foil to cover the microtiter plate
- Horizontal microtiter plate shaker
• Multi-channel pipets or repeater pipets
• Centrifuge, 3000 g
• Vortex
• Standard laboratory glass or plastic vials, cups, etc.
• Microtiter plate reader (required filters see chapter 7)

* Immundiagnostik AG recommends the use of Ultra Pure Water (Water Type 1; ISO 3696), which is free of undissolved and colloidal ions and organic molecules (free of particles > 0.2 µm) with an electrical conductivity of 0.055 µS/cm at 25°C (≥ 18.2 MΩ cm).

5. STORAGE AND PREPARATION OF REAGENTS

• To run the assay more than once, ensure that reagents are stored at the conditions stated on the label. **Prepare only the appropriate amount necessary for each run.** The kit can be used up to 4 times within the expiry date stated on the label.

• Reagents with a volume less than 100 µl should be centrifuged before use to avoid loss of volume.

• The **ELISA wash buffer concentrate** (WASHBUF) should be diluted 1:10 in **ultra pure water** before use (100 ml concentrate + 900 ml ultra pure water), mix well. Crystals could occur due to high salt concentration in the stock solutions. The crystals must be redissolved at room temperature or 37°C before dilution of the buffer solutions. The buffer concentrate is stable at 2–8°C until the expiry date stated on the label. **Diluted buffer solution** (wash buffer) can be stored in a closed flask at 2–8°C for one month.

• The **extraction buffer concentrate IDK Extract®** must be diluted with ultra pure water 1:2.5 before use (100 ml concentrate + 150 ml ultra pure water), mix well. Crystals could occur due to high salt concentration in the stock solutions. Before dilution, the crystals must be redissolved at 37°C in a water bath. The extraction buffer concentrate IDK Extract® is stable at 2-8°C until the expiry date stated on the label. Diluted buffer solution (extraction buffer) can be stored in a closed flask at 2-8°C for three months.

• The **standards** (STD) and **controls** (CTRL) are stable at 2–8°C until the expiry date stated on the label.

• The **conjugate concentrate** (CONJ) must be diluted 1:101 in **wash buffer** (100 µl CONJ + 10 ml wash buffer). The concentrate is stable at 2–8°C until the expiry date stated on the label. **Diluted conjugate is not stable and cannot be stored.**
• All other test reagents are ready to use. Test reagents are stable until the expiry date (see label of test package) when stored at 2–8°C.

6. STORAGE AND PREPARATION OF SAMPLES

Storage

Stool samples
The sample stability is as follows:

- **Raw stool**: over night at room temperature (15–30°C), 3 days at 2–8°C or at least 4 weeks at -20°C
- **Stool extracts**: 9 days at room temperature, 2–8°C or -20°C, maximum 3 freeze-thaw cycles

Serum and plasma samples
Fresh collected blood should be centrifuged within one hour. Store samples at -20°C if not assayed on the same day. Lipemic or hemolytic samples may give erroneous results. Samples should be mixed well before assaying.

**Extraction of the stool samples**

Diluted extraction buffer **IDK Extract**® is used as a sample extraction buffer. We recommend the following sample preparation:

Stool Sample Application System (SAS) (Cat. No.: K 6998SAS)

**Stool sample tube – Instructions for use**

Please note that the dilution factor of the final stool suspension depends on the amount of stool sample used and the volume of the buffer.

**SAS with 1.5 ml extraction buffer:**

Applied amount of stool: 15 mg
Buffer Volume: 1.5 ml
Dilution Factor: 1:100

Please follow the instructions for the preparation of stool samples using the SAS as follows:

a) The raw stool sample has to be thawed. For particularly heterogeneous samples we recommend a mechanical homogenisation using an applicator, inoculation loop or similar device.
b) Fill the empty sample tube with **1.5 ml** of ready to use *IDK Extract®* extraction buffer before using it with the sample. Important: Allow the extraction buffer to reach room temperature.

c) Unscrew the tube (orange part of cap) to open. Insert the orange dipstick into the sample. The lower part of the dipstick has notches which need to be covered completely with stool after inserting it into the sample. Place dipstick back into the tube. When putting the stick back into the tube, excess material will be stripped off, leaving 15 mg of sample to be diluted. Screw tightly to close the tube.

d) Shake the tube well until no stool sample remains in the notches. Important: Please make sure that you have a maximally homogenous suspension after shaking. Especially with more solid samples, soaking the sample in the tube with buffer for ~10 minutes improves the result.

e) Allow sample to stand for ~10 minutes until sediment has settled. Floating material like shells of grains can be neglected.

f) Carefully unscrew the complete cap of the tube including the blue ring plus the dipstick. Discard cap and dipstick. Make sure that the sediment will not be dispersed again.

**Dilution I:**  **1:100**

**Dilution of samples**

**Stool samples**

The supernatant of the **sample** preparation procedure (dilution I) is further diluted **1:250 in wash buffer**. For example:

- **20 µl** supernatant (dilution I) + **980 µl** wash buffer, mix well = **dilution II** (1:50)
- **200 µl** dilution II + **800 µl** wash buffer, mix well = **dilution III** (1:5)

This results in a **final dilution of 1:25 000**.

For analysis, pipet **100 µl** of **dilution III** per well.

**Serum and plasma samples**

Normal samples are diluted **1:40000**. Samples from patients with Morbus Crohn etc. are diluted **1:250000 and 1:1000000**. Use the corresponding dilution factor to calculate the $\alpha_1$-antitrypsin concentration.
1:40000 dilution
For example:
- 10µl serum + 990 µl SAMPLEBUF (sample buffer), mix well (dilution I)
- 100 µl of dilution I + 900µl SAMPLEBUF (sample buffer), mix well (dilution II)
- 25 µl of dilution II + 975µl SAMPLEBUF (sample buffer) (1: 40000)

1:250000 dilution
For example:
- 10µl serum + 990 µl SAMPLEBUF (sample buffer), mix well (dilution I)
- 10 µl of dilution I + 990µl SAMPLEBUF (sample buffer), mix well (dilution II)
- 20 µl of dilution II + 480µl SAMPLEBUF (sample buffer) (1:250000)

For analysis, pipette 100 µl of the supernatant of the final dilution step per well.

7. ASSAY PROCEDURE

Principle of the test
The assay utilizes the sandwich technique with two selected polyclonal antibodies that bind to human α₁-antitrypsin.

Standards, controls and prediluted samples which are assayed for human α₁-antitrypsin are added into the wells of a micro plate coated with a high affine polyclonal anti-human α₁-antitrypsin antibody. During the first incubation step, α₁-antitrypsin is bound by the immobilized antibody. Then a peroxidase-conjugated polyclonal anti-human α₁-antitrypsin antibody is added into each microtiter well and a sandwich of capture antibody – human α₁-antitrypsin – peroxidase-conjugate is formed. Tetramethylbenzidine (TMB) is used as peroxidase substrate. Finally, an acidic stop solution is added to terminate the reaction. The colour changes from blue to yellow. The intensity of the yellow colour is directly proportional to the concentration of α₁-antitrypsin. A dose response curve of the absorbance unit (optical density, OD at 450 nm) vs. concentration is generated, using the values obtained from the standard. α₁-antitrypsin present in the samples is determined directly from this curve.

Test procedure
Bring all reagents and samples to room temperature (15–30 °C) and mix well.
Take as many microtiter strips as needed from kit. Store unused strips covered at 2–8 °C. Strips are stable until expiry date stated on the label.
Mark the positions of STD (Standard) SAMPLE (Sample) CTRL (Controls) on a protocol sheet.
We recommend to carry out the tests in duplicate.

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Wash each well 5 times by dispensing 250 µl of diluted wash buffer into each well. After the final washing step remove residual buffer by tapping the plate on absorbent paper.</td>
</tr>
<tr>
<td>2.</td>
<td>Add 100 µl of STD (standard), SAMPLE (sample) and CTRL (controls) into respective well.</td>
</tr>
<tr>
<td>3.</td>
<td>Cover the plate tightly and incubate for 1 hour at room temperature (15–30 °C) on a horizontal shaker.</td>
</tr>
<tr>
<td>4.</td>
<td>Discard the contents of each well. Wash each well 5 times by dispensing 250 µl of diluted wash buffer into each well. After the final washing step remove residual buffer by tapping the plate on absorbent paper.</td>
</tr>
<tr>
<td>5.</td>
<td>Add 100 µl CONJ (conjugate) into each well.</td>
</tr>
<tr>
<td>6.</td>
<td>Cover the plate tightly and incubate for 1 hour at room temperature (15–30 °C) on a horizontal shaker.</td>
</tr>
<tr>
<td>7.</td>
<td>Discard the contents of each well. Wash each well 5 times by dispensing 250 µl of diluted wash buffer into each well. After the final washing step remove residual buffer by tapping the plate on absorbent paper.</td>
</tr>
<tr>
<td>8.</td>
<td>Add 100 µl of SUB (substrate) into each well.</td>
</tr>
<tr>
<td>9.</td>
<td>Incubate for 10–20 minutes at room temperature (15–30 °C) in the dark*.</td>
</tr>
<tr>
<td>10.</td>
<td>Add 100 µl of STOP (stop solution) into each well, mix thoroughly.</td>
</tr>
<tr>
<td>11.</td>
<td>Determine absorption immediately with an ELISA reader at 450 nm against 620 nm (or 690 nm) as a reference. If no reference wavelength is available, read only at 450 nm. If the extinction of the highest standard exceeds the range of the photometer, absorption must be measured immediately at 405 nm against 620 nm as a reference.</td>
</tr>
</tbody>
</table>

* The intensity of the color change is temperature sensitive. We recommend observing the color change and stopping the reaction upon good differentiation.
8. RESULTS
The following algorithms can be used alternatively to calculate the results. We recommend using the “4 parameter algorithm”.

1. 4 parameter algorithm
   It is recommended to use a linear ordinate for the optical density and a logarithmic abscissa for the concentration. When using a logarithmic abscissa, the zero standard must be specified with a value less than 1 (e.g. 0.001).

2. Point-to-point calculation
   We recommend a linear ordinate for the optical density and a linear abscissa for the concentration.

3. Spline algorithm
   We recommend a linear ordinate for the optical density and a linear abscissa for the concentration.

The plausibility of the duplicate values should be examined before the automatic evaluation of the results. If this option is not available with the programme used, the duplicate values should be evaluated manually.

Stool samples
Multiply the obtained results by the dilution factor of 25 000 to get the real concentration.

Serum and plasma samples
For the calculation of the $\alpha_1$-antitrypsin concentration in serum and plasma samples, the result must be multiplied by 40000 or 250000 and additionally by a factor of 3 for each sample.

Clearance
Use the following formula to calculate the clearance:

$$\text{Clearance (ml/day)} = \frac{(V \times F)}{S}$$

$V$ = volume of faeces in ml/day, mean value from 3 days (1 ml stool=1g)
$F$ = mean faeces $\alpha_1$-antitrypsin concentration from 3 days, calculated from the standard curve and multiplied by the dilution factor ($\mu$g/l or mg/dl)
$S$ = mean serum $\alpha_1$-antitrypsin concentration from 3 days (mg/dl), calculated from the standard curve and multiplied by the dilution factor ($\mu$g/l or mg/dl)
9. LIMITATIONS
Samples with concentrations above the measurement range must be further diluted and re-assayed. Please consider this greater dilution when calculating the results.
Samples with concentrations lower than the measurement range cannot be clearly quantified.
The upper limit of the measurement range can be calculated as:
\[ \text{highest concentration of the standard curve} \times \text{sample dilution factor to be used} \]
The lower limit of the measurement range can be calculated as:
\[ \text{detection limit} \times \text{sample dilution factor to be used} \]

10. QUALITY CONTROL
Immundiagnostik recommends the use of external controls for internal quality control, if possible.
Control samples should be analysed with each run. Results, generated from the analysis of control samples, should be evaluated for acceptability using appropriate statistical methods. The results for the patient samples may not be valid if within the same assay one or more values of the quality control sample are outside the acceptable limits.

Reference range
Based on Immundiagnostik studies of stool samples of apparently healthy persons (n = 76) the following reference range was estimated

cut off value:  
\[ \alpha 1\text{-Antitrypsin-Clearance:} \quad < 27,5 \text{ ml/day} \]
\[ \alpha 1\text{-Antitrypsin concentration (serum and plasma):} \quad 90 - 180 \text{ mg/dl} \]

*L. Thomas 5. Auflage; Labor und Diagnose

We recommend each laboratory to establish its own reference range.
11. PERFORMANCE CHARACTERISTICS

**Precision and reproducibility**

**Intra-Assay (n = 20)**

The precision (intra-assay variation) of the Immundiagnostik α₁-antitrypsin ELISA test was calculated from 20 replicate determinations on each one of two samples.

<table>
<thead>
<tr>
<th>Sample</th>
<th>α₁-antitrypsin [mg/dl]</th>
<th>CV [%]</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>15.2</td>
<td>4.5</td>
</tr>
<tr>
<td>2</td>
<td>42.2</td>
<td>13.1</td>
</tr>
</tbody>
</table>

**Inter-Assay (n = 20)**

The total precision (inter-assay variation) of the Immundiagnostik α₁-antitrypsin ELISA test was calculated from data on 2 samples obtained in 20 different assays by three technicians on two different lots of reagents over a period of three months.

<table>
<thead>
<tr>
<th>Sample</th>
<th>α₁-antitrypsin [mg/dl]</th>
<th>CV [%]</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>16.15</td>
<td>9.8</td>
</tr>
<tr>
<td>2</td>
<td>54.46</td>
<td>14.8</td>
</tr>
</tbody>
</table>

**Spiking Recovery**

Two samples were spiked with different α₁-antitrypsin standard amounts and measured with the assay.

<table>
<thead>
<tr>
<th>Sample</th>
<th>Unspiked Sample [µg/l]</th>
<th>Spike [µg/l]</th>
<th>α₁-antitrypsin expected [µg/l]</th>
<th>α₁-antitrypsin measured [µg/l]</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>6.3</td>
<td>1.65</td>
<td>7.95</td>
<td>7.2</td>
</tr>
<tr>
<td></td>
<td></td>
<td>5.0</td>
<td>11.3</td>
<td>11.4</td>
</tr>
<tr>
<td></td>
<td></td>
<td>15.0</td>
<td>21.3</td>
<td>20.9</td>
</tr>
<tr>
<td></td>
<td></td>
<td>45.0</td>
<td>51.3</td>
<td>46.7</td>
</tr>
</tbody>
</table>
Dilution recovery

Two patient serum samples were diluted with wash buffer. The results are shown below (n = 2):

<table>
<thead>
<tr>
<th>Sample</th>
<th>Dilution</th>
<th>α₁-antitrypsin expected [mg/dl]</th>
<th>α₁-antitrypsin measured [mg/dl]</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>1:12500</td>
<td>48.0</td>
<td>48.88</td>
</tr>
<tr>
<td></td>
<td>1:25000</td>
<td>24.5</td>
<td>23.25</td>
</tr>
<tr>
<td></td>
<td>1:50000</td>
<td>12.3</td>
<td>11.9</td>
</tr>
<tr>
<td></td>
<td>1:100000</td>
<td>6.1</td>
<td>6.0</td>
</tr>
<tr>
<td>B</td>
<td>1:12500</td>
<td>158.4</td>
<td>158.4</td>
</tr>
<tr>
<td></td>
<td>1:25000</td>
<td>79.3</td>
<td>99.0</td>
</tr>
<tr>
<td></td>
<td>1:50000</td>
<td>39.6</td>
<td>33.0</td>
</tr>
<tr>
<td></td>
<td>1:100000</td>
<td>19.8</td>
<td>22.1</td>
</tr>
</tbody>
</table>

Analytical Sensitivity

The Zero-standard was measured 20 times. The detection limit was set as \( B_0 + 2 \text{ SD} \) and estimated to be 1.8 mg/dl.

Specificity

No cross reactivity with other plasma proteins in stool was observed.
No cross reactivity with alpha-1-antitrypsin in mouse serum was observed.
12. PRECAUTIONS

- All reagents in the kit package are for *in vitro* diagnostic use only.

- Human materials used in kit components were tested and found to be negative for HIV, Hepatitis B and Hepatitis C. However, for safety reasons, all kit components should be treated as potentially infectious.

- Kit reagents contain sodium azide or ProClin as bactericides. Sodium azide and ProClin are toxic. Substrates for the enzymatic color reactions are toxic and carcinogenic. Avoid contact with skin or mucous membranes.

- The stop solution consists of diluted sulphuric acid, a strong acid. Although diluted, it still must be handled with care. It can cause burns and should be handled with gloves, eye protection, and appropriate protective clothing. Any spill should be wiped up immediately with copious quantities of water. Do not breath vapour and avoid inhalation.

13. TECHNICAL HINTS

- Do not interchange different lot numbers of any kit component within the same assay. Furthermore we recommend not assembling wells of different microtiter plates for analysis, even if they are of the same batch.

- Control samples should be analyzed with each run.

- Reagents should not be used beyond the expiration date stated on kit label.

- Substrate solution should remain colourless until use.

- To ensure accurate results, proper adhesion of plate sealers during incubation steps is necessary.

- Avoid foaming when mixing reagents.

- Do not mix plugs and caps from different reagents.

- The assay should always be performed according the enclosed manual.

14. GENERAL NOTES ON THE TEST AND TEST PROCEDURE

- This assay was produced and distributed according to the IVD guidelines of 98/79/EC.

- The guidelines for medical laboratories should be followed.
• Incubation time, incubation temperature and pipetting volumes of the components are defined by the producer. Any variation of the test procedure, which is not coordinated with the producer, may influence the results of the test. Immundiagnostik AG can therefore not be held responsible for any damage resulting from incorrect use.

• Warranty claims and complaints regarding deficiencies must be logged within 14 days after receipt of the product. The product should be send to Immundiagnostik AG along with a written complaint.

15. REFERENCES


Integrative Biology, 7(1), pp.45–52.

