ALT/GPT

Cat. No. | Pack Name   | Packaging (Content)  
--------|-------------|----------------------
BLT00052 | ALT/GPT 250 | R1: 4 x 50 ml, R2: 1 x 50 ml  
BLT00053 | ALT/GPT 500 | R1: 4 x 100 ml, R2: 1 x 100 ml  

**INTENDED USE**
Diagnostic reagent for quantitative in vitro determination of ALT/GPT (Alanine Aminotransferase) in human serum and plasma.

**CLINICAL SIGNIFICANCE**
ALT/GPT is present in high concentration in liver and to a lesser extent in kidney, heart, skeletal muscle, pancreas, spleen and lung. Increased levels of ALT/GPT however is generally a result of liver disease associated with some degree of hepatic necrosis such as cirrhosis, viral or toxic hepatitis and obstructive jaundice. Characteristically ALT/GPT is generally higher than AST/GPT in acute viral or toxic hepatitis, whereas for most patients with chronic hepatic disease, ALT/GPT levels are generally lower than AST/GPT levels. Elevated ALT/GPT levels have also been found in extensive trauma and muscle disease, circulatory failure with shock, hypoxia, myocardial infarction and haemolytic disease.

**PRINCIPLE**
This ALT/GPT reagent is based on the recommendations of the IFCC without pyridoxal phosphate. The series of reactions involved in the assay system is as follows:

1. The amino group is enzymatically transferred by SGPT / ALAT present in the sample from alanine to the carbon atom of 2-oxoglutarate yielding pyruvate and L-glutamate.
2. Pyruvate is reduced to lactate by LDH present in the reagent with the simultaneous oxidation of NADH to NAD.
3. Sample pyruvate + NADH

By the reaction of LDH:

\[
\text{Pyruvate} + \text{NAD}^+ \rightarrow \text{L-Lactate} + \text{NAD}^+ \]

**STABILITY AND STORAGE**
The unopened reagents are stable till the expiry date stated on the bottle and kit label when stored at 2–8°C.

**SPECIMEN COLLECTION AND HANDLING**
Use unheamolytic serum or plasma (EDTA, heparin). It is recommended to follow NCCLS procedures (or similar standardized conditions).

**RESULT INTERPRETATION**

Two reagents method – substrate start

Reagents are ready to use. After the first opening the vials, reagents are stable for 30 days at 2–8°C in the dark.

Monoreagent method – sample start

Mix 4 portion of reagent R1 with 1 portion of reagent R2.

Stability: 5 days at 20–25°C in the dark

4 weeks at 2–8°C in the dark

**SPECIFIC PRECISION**

ALT/GPT (U/l) = \[ \Delta A_{405 \text{min}} \times C_{\text{cal}} \times f \]

Where:

\[ \Delta A_{405 \text{min}} \]

is the absorbance change exactly after 4 minutes at 405 nm,

\[ C_{\text{cal}} \]

is the calibrator concentration

\[ f \]

is the factor

**UNIT CONVERSION**

\[ \text{ALT} = \text{AST} \times 1.15 \]

**CALCULATION**

1. ALT/GPT (U/l) = \[ \Delta A_{405 \text{min}} \times C_{\text{cal}} \times f \]

2. Using factor:

\[ \text{ALT/GPT (U/l)} = \Delta A_{405 \text{min}} \times f \]

Factors:

<table>
<thead>
<tr>
<th>Substrate Start</th>
<th>25° or 30°C</th>
<th>37°C</th>
</tr>
</thead>
<tbody>
<tr>
<td>Factor at 340 nm</td>
<td>1151</td>
<td>2143</td>
</tr>
<tr>
<td>Factor at 334 nm</td>
<td>1173</td>
<td>2164</td>
</tr>
<tr>
<td>Factor at 365 nm</td>
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<td>3971</td>
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<tr>
<td>Factor at 340 nm</td>
<td>952</td>
<td>1745</td>
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<tr>
<td>Factor at 334 nm</td>
<td>971</td>
<td>1780</td>
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<tr>
<td>Factor at 365 nm</td>
<td>1765</td>
<td>3235</td>
</tr>
</tbody>
</table>

**APPLICATIONS FOR AUTOMATIC ANALYSERS**
Applications for automatic analysers are available on request.

**WARNING AND PRECAUTIONS**
For in vitro diagnostic use. To be handled by entitled and professionally educated person.

Reagents of the kit are not classified like dangerous but contain less than 0.1% sodium azide - classified as very toxic and dangerous substance for the environment.

**WASTE MANAGEMENT**
Please refer to local legal requirements.

**ASSAY PROCEDURE**

**Wavelength**

Hg 340 nm, Hg 334 nm, Hg 365 nm

**Cuvette**

1 cm

**Two reagents method – substrate start**

Reagent 1 (buffer) 1.000 ml

Sample 0.100 ml

Mix and incubate for 5 min. at 37°C. Then add:

Reagent 2 (substrate) 0.250 ml

Mix, incubate 1 min. at 37°C and then measure the initial absorbance of calibrator and sample against reagent blank. Measure the absorbance change exactly after 1, 2 and 3 min. Calculate 1 minute absorbance change (ΔA/min).

**Monoreagent method – sample start**

Working solution 1.000 ml

Sample 0.100 ml

Mix, incubate 1 min. at 37°C and then measure the initial absorbance of calibrator and sample against reagent blank. Measure the absorbance change exactly after 1, 2 and 3 min. Calculate 1 minute absorbance change (ΔA/min).

**INTERFERENCES**
Following substances do not interfere:

- Haemoglobin up to 2.5 g/l
- Bilirubin up to 30 mg/dl
- Triglycerides up to 2000 mg/dl

**COMPARISON**
A comparison between XL-Systems ALT/GPT (y) and a commercially available test (x) using 40 samples gave following results:

\[ y = 0.979 \times x + 1.8 \]

r = 0.996

**REFERENCES**

ALT/GPT (Alanine Aminotransferase) in human serum and plasma.

**ACKNOWLEDGMENTS**

*To be added by author*
ASSAY PARAMETERS FOR PHOTOMETERS

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
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<tbody>
<tr>
<td>Mode</td>
<td>Kinetic</td>
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<tr>
<td>Wavelength 1 (nm)</td>
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</tr>
<tr>
<td>Sample Volume (μl)</td>
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</tr>
<tr>
<td>Working Reagent Volume (μl)</td>
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<tr>
<td>Lag time (sec.)</td>
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<tr>
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<td>Reaction temperature (°C)</td>
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<td>Linearity Low (U/l)</td>
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<td>Linearity High (U/l)</td>
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<td>Blank with</td>
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<td>Absorbance limit (max.)</td>
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<tr>
<td>Units</td>
<td>U/l</td>
</tr>
</tbody>
</table>

REFERENCES

SYMBOLS USED ON LABELS

- REF: Catalogue Number
- Manufacturer
- See Instruction for Use
- LOT: Lot Number
- CE Mark - Device comply with the Directive 98/79/EC
- Storage Temperature
- Expiry Date
- IVD: In Vitro Diagnostics
- CONT: Content

QUALITY SYSTEM CERTIFIED
ISO 9001 ISO 13485

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