Cat. No 4-514

# DIAGNOSTIC KIT FOR DETERMINATION OF ASPARTATE AMINOTRANSFERASE ACTIVITY

## HC – ASAT

### INTRODUCTION

Aspartate aminotransferase (ASAT, AST, GOT) is an enzyme participated in amino acids metabolism. ASAT is found in all tissues but particularly high level of ASAT is observed in heart muscle, skeletal muscle, liver and kidney. This is why elevated ASAT serum level is marker of myocardial infarction and kidney, liver or skeletal muscle injury.

### METHOD PRINCIPLE

Optimized, modified method according to International Federation of Clinical Chemistry (IFCC), without pyridoxal phosphate.

$$\text{L-aspartate} + \text{2-oxoglutarate} \xleftrightarrow{\text{ASAT}} \text{oxalacetate} + \text{L-glutamate}$$

$$\text{oxalacetate} + \text{NADH} + H^+ \xleftrightarrow{\text{MDH}} \text{malate} + NAD^+$$

The rate of absorbance changing at $\lambda$=340 nm is directly proportional to aspartate aminotransferase activity.

### REAGENTS

**Package**

| | |
|---|---|
| 1-Reagent | 6 x 76 ml |
| 2-Reagent | 6 x 19.5 ml |

The reagents when stored at 2-8°C are stable up to expiry date printed on the package. The reagents are stable for 12 weeks on board the analyser at 2-10°C. Protect from light and avoid contamination!

**Concentrations in the test**

| | |
|---|---|
| Tris (pH 7.8) | 80 mmol/l |
| L-aspartate | 240 mmol/l |
| MDH | > 10 µkat/l |
| LDH | > 20 µkat/l |
| 2-oxoglutarate | 15 mmol/l |
| NADH | 0.18 mmol/l |
| sodium hydroxide | < 1 % |

**Warnings and notes**

- Product for in vitro diagnostic use only.
- The reagents contain < 0.1% sodium azide as a preservative. Avoid contact with skin and mucous membranes.
- 1-Reagent is classified as an irritant!

**Ingredients:** Contains sodium hydroxide.

**Xi** – Irritating.
**R 36/38**: Irritating to eyes and skin.
**S 26-28-45:** In case of contact with eyes, rinse immediately with plenty of water and see medical advice. After contact with skin, wash immediately with plenty of water. In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

### SPECIMEN

Serum, heparinized or EDTA plasma free from hemolysis.
Do not use heparine ammonium salt!
Hemolysis should be avoided, since ASAT activity in erythrocytes is 10 times higher than in normal serum.
Do not freeze the samples. ASAT activity remains stable in specimen up to 1 day at 15-25ºC or up to 4 days at 2-8ºC.
Nevertheless it is recommended to perform the assay with freshly collected samples!

### PROCEDURE

The reagents are ready to use.
These reagents may be used in automatic analyser Hitachi 911/912.
Application should be entered using handheld barcode scanner and attached barcodes sheet, according to procedure described below:

1. Delete previous version of application and calibrators assigned to it and restart the analyser.
2. Enter codes of calibrators according to the attached list.
3. Enter barcoded application and assign proper values to calibrators.
4. To activate entered application go to the tab UTILITY | APPLICATION | RANGE and change value of field DATA MODE from INACTIVE to ON BOARD. Confirm the change using UPDATE button.
5. Put reagents on board the analyser – they will be assigned to relevant tests automatically. Perform also measurement of level of reagents inside the bottles.
6. After calibration analyser is ready to use.

### REFERENCE VALUES [6]

| serum / plasma | 37ºC | |
|---|---|---|
| female | up to 31 U/l | up to 0.518 µkat/l |
| male | up to 37 U/l | up to 0.618 µkat/l |

It is recommended for each laboratory to establish its own reference ranges for local population.

### QUALITY CONTROL

For internal quality control it is recommended to use the CORMAY SERUM HN (Cat. No 5-172) and CORMAY SERUM HP (Cat. No 5-173) with each batch of samples.
For the calibration of automatic analysers systems the CORMAY MULTICALIBRATOR LEVEL 1 (Cat. No 5-174; 5-176) is recommended. **Calibrator and 0.9% NaCl** should be used for calibration.
The calibration curve should be prepared every 12 weeks, with change of reagent lot number or as required e.g. quality control findings outside the specified range.

### PERFORMANCE CHARACTERISTICS

These metrological characteristics have been obtained using the automatic analyser Hitachi 912. Results may vary if a different instrument or a manual procedure is used.

- **Sensitivity:** 6.19 U/l (0.103 µkat/l).
- **Linearity:** up to 620 U/l (10.4 µkat/l).
- **Specificity / Interferences**

Haemoglobin up to 0.16 g/dl, ascorbate up to 62 mg/l, bilirubin up to 20 mg/dl and triglycerides up to 1000 mg/dl do not interfere with the test.

- **Precision**

| Repeatability (run to run) n = 20 | Mean [U/l] | SD [U/l] | CV [%] |
|---|---|---|---|
| level 1 | 39.23 | 0.69 | 1.76 |
| level 2 | 198.48 | 1.03 | 0.52 |

| Reproducibility (day to day) n = 80 | Mean [U/l] | SD [U/l] | CV [%] |
|---|---|---|---|
| level 1 | 40.02 | 1.06 | 2.64 |
| level 2 | 200.36 | 4.36 | 2.18 |

- **Method comparison**

A comparison between ASAT values determined at Hitachi 912 (y) and at Cobas Integra 400 PLUS (x) using 110 samples gave following results:
y = 0.9108 x + 2.7265 U/l;
R = 0.9984 (R – correlation coefficient)

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

**LITERATURE**

1. Clin. Chem. Acta 105, 147-172 (1980).
2. Wallhofer H., Schmidt E., Schmidt U.F.W.: Synopsis Der Leberkrankheiten. G. Thieme Verlag, Stuttgart (1974).
3. Thefeld W. et al: Dtsch. Med. Wschr. 99, 343 (1974).
4. Bergmeyer H.U., Horder M., Rej R.: J. Clin. Chem. Clin. Biochem. 24, 497 (1986).
5. Tietz N.W., ed. Clinical Guide to Laboratory Tests, 3rd ed. Philadelphia, PA: W.B. Saunders, 76 (1995).
6. Dembińska-Kieć A., Naskalski J.W.: Diagnostyka laboratoryjna z elementami biochemii klinicznej, Volumed, 777, (1998).


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