# GOT (AST, SGOT)

**IFCC**
**(Glutamate Oxaloacetate Transaminase)**

**Diagnostic reagent for determination of AST activity.**

Liquid. Dual Reagents. Store at 2°C - 8°C. For in Vitro Diagnostic Use. Do not freeze

| Ref No | Pack | Ref No | Pack | Ref No | Pack | Ref No | Pack |
|---|---|---|---|---|---|---|---|
| A2210 | 5 x 100 mL | DM2210 | 960 Tests | BY2210 | 7670 Tests | K2211 | 4000 Tests |
| A2211 | 5 x 50 mL | R2210 | 2885 Tests | BY2211 | 5114 Tests | M2210 | 2512 Tests |
| A2212 | 5 x 25 mL | R2211 | 962 Tests | N2210 | 800 Tests | M2211 | 1675 Tests |
| T2210 | 4000 Tests | S2210 | 3077 Tests | N2211 | 400 Tests | L2210 | 3750 Tests |
| T2211 | 2121 Tests | S2211 | 1477 Tests | K2210 | 6000 Tests | L2211 | 2000 Tests |

## INTENDED USE

The test is applied for the quantitative determination of AST activity in serum and plasma.

## TEST PRINCIPLE

The enzyme aspartate aminotransferase (EC 2.6.1.1; L-Aspartate: 2-Oxoglutarate Aminotransferase, AST or AspAT; Glutamate Oxaloacetate Transaminase, GOT) catalyzes the transaminase reaction between L-Aspartate and 2-Oxoglutarate. The 2-Oxalacetate formed, is reduced to malate in the presence of MDH. As the reactions proceed, NADH is oxidized to NAD. The disappearance of NADH per unit time is followed by measuring the decrease in absorbance at 340 nm. The present method has been made according to IFCC (2002).

## TEST PARAMETERS

| | |
|---|---|
| Method | : UV, Kinetic, Decreasing Reaction, mod. IFCC |
| Wavelength | : 340 nm |
| Temperature | : 37°C |
| Sample | : Serum, EDTA-Plasma, heparinized Plasma |
| Linearity | : - 440 U/L (340 nm, 37°C) |

## REAGENT COMPOSITION

| | |
|---|---|
| Tris buffer | ≤ 90 mM pH 7.65, |
| L-aspartate | ≤ 250 mM, |
| 2-Oxoglutarate | ≤ 14 mM, |
| NADH | ≤ 0.18 mM, |
| MDH | ≥ 600 U/L, |
| LDH | ≥ 900U/L. |

## REAGENT PREPARATION

Mix 4 parts of Reagent 1 (Buffer, Enzymes) with 1 part of Reagent 2 (Substrate). For example: 4 ml Reagent 1 and 1 ml Reagent 2.

Working reagents are stable at 2-8ºC in case of closed vials and avoiding contamination after preparation.

For manual working procedures; if working reagent will be used; shake the Reagent 2 vial gently before pouring its contents into the Reagent 1 bottle. It is advisable to wash the Reagent 2 vial with a small volume of the prepared mixture in order to completely rinse the vial and avoid any losses.

## REAGENT STABILITY AND STORAGE

Stability of working reagent is 30 days at 2-8°C, away from light sources. Protect from light. Note expiration date on the label.

Close immediately after use. Avoid contamination of the opened reagents.

Once opened vials are stable minimum 30 days at 2-8°C at optimum conditions. On board stability is strongly related to auto analyzers cooling specification and carry-over values.

## SAMPLE

Serum and plasma are collected by standard procedures.

GOT is stable for 4 days at 2-8ºC and 1 month at -20°C.

## TEST PROCEDURE

**Sample Start**
There have many ready application procedures dedicated to different kind of photometers and

ready manual working process can be supplied on request.

There have many ready application procedures dedicated to different kind of biochemistry auto analyzers can be supplied on request.

**Substrate Start**
There have many ready application procedures dedicated to different kind of biochemistry auto analyzers can be supplied on request.

## CALCULATION

Perform calculation in units per litre, multiplying the ΔA/min by the factor as it is indicated.
Calculation in U/L: ΔA/min x 1746
Activity in µkat/l: U/L x 0.0167 = µkat/L

## REFERENCE INTERVAL (NORMAL VALUES) (Based on CLSI C28-P Document)*

Men : < 35 U/L (< 0.58 µkat/L)
Women: < 31 U/L (< 0.52 µkat/L)

*It is recommended that each laboratory establish its own reference range.

## QUALITY CONTROL AND CALIBRATION

All control sera with GOT values determined by this method can be used. We recommend:

"ARCON N", Assayed Control Serum Normal
**Cat.No. A3910**

"ARCON P", Assayed Control Serum Abnormal
**Cat.No. A3920**

The use of a GOT Calibrator (for automated Systems) is optional. We recommend:
ARCAL AUTO Calibrator **Cat. No.** A39050

*Calibration Stability: It is strongly depend of application to auto analyzers and auto analyzers specification. Calibration stability is 30 days.

*Each laboratory should establish its own internal Quality Control scheme and procedures for corrective action if controls do not recover within the acceptable tolerances.

Quality control is recommended every morning. Calibration is not recommended if QC control values are acceptable. Reagent should be calibrated after lot changes.

## PERFORMANCE CHARACTERISTICS

**Low linearity:**

**High Linearity:** The method is linear up to 440 U/L.

If a ΔA/min of 0.200 is exceeded, it is suggested to dilute sample 1+9 with saline and to repeat the test, multiplying the result by 10.

Linearity may considerably vary depending on the instrument used.

**Precision Studies (Based on CLSI EP5 Doc.):**

**Repeatibility (within run) (Intra-assay)**

| Mean conc. | SD | CV | n |
|---|---|---|---|
| 38.88 U/L | 0.56 | 1.40% | 10 |
| 132.50 U/L | 0.96 | 0.70% | 10 |

**Reproducibility (run to run) (Inter-assay)**

| Mean conc. | SD | CV | n |
|---|---|---|---|
| 37.87 U/L | 0.46 | 1.20% | 20 |
| 134.48 U/L | 1.48 | 1.10% | 20 |

**Sensitivity (LOD) (Based on CLSI EP17 document):** The limit of detection is 0.47 U/L.

**Trueness:** Results obtained with this reagent did not show systematic differences when compared with reference reagents. Details of the comparison experiments are available on request.

**Interferences:** No interference was observed by the presence of:

| | |
|---|---|
| Hemoglobin | ≤ 400 mg/dL |
| Bilirubin | ≤ 25 mg/dL |
| Lipids | ≤ 500 mg/dL |

**Methods comparison:** A comparison between Archem and a commercially available product gave the following results:

GOT Archem = x
GOT competitor = y
n = 112
y = 0.986x + 1.636 U/l r2 = 0.997

These performance characteristics have been obtained using an analyzer. Results may vary if a different instrument or a manual procedure is used.

## NOTES

1. For in vitro diagnostic use only. Do not pipette by mouth. Avoid contact with skin and mucous membranes.
2. All the calibrators, controls and some reagents must be considered as human & animal sample, so potentially infectious; all the protection actions must be applied to avoid any potential biological risk.
3. Material safety data sheet will be supplied on request.
4. Exercise the normal precautions required for handling laboratory reagents.
5. After measurements are taken, reagent bottles should cap and kept at 2-8°C. Caps of the reagents bottles cannot be used between two different kind of reagent and between R1 & R2.
6. Reagents with different lot numbers should not be interchanged or mixed.
7. The linearity limit depends on the sample to reagent ratio.

## PRECAUTIONS AND WASTE DISPOSAL

This product is made to be used in professional laboratories and by professional operators. Perform the test according to the general "Good Laboratory Practice" (GLP) guidelines.
R36/38 : Irritating to eyes and skin.
S20/21 : When using, do not eat, drink or smoke.
S26 : In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S28 : After contact with skin wash immediately with plenty of water.
S36/37/39: Wear suitable protective clothing, gloves and eye/face protection.
S45 : In case of accident or if you feel unwell, seek medical advice immediately.
S56 : Dispose of this material and its container at hazardous or special waste collection point.
S57 : Use appropriate container to avoid environmental contamination.
S61 : Avoid release in environment. Refer to special instructions/safety data sheets.
Please consult local regulations for a correct waste disposal.

## ABBREVIATIONS

AST : Aspartate Amino Transferase
CLSI : Clinical and Laboratory Standards Institute
CV% : Coefficient of Variation Percentage
EP : Evaluation Protocols
GLP : Good Laboratory Practice
GOT : Glutamate Oxaloacetate Transaminase
IU : International Unit
mA : miliabsorbance
mL : mililiter
NCCLS : National Committee for Clinical Laboratory Standards
QC : Quality Control

## REFERENCES


1. Young, DS. Effect of Drugs on Clinical Laboratory Tests, AACC Press, 3rd Edition, Washington, (1990).
2. Tietz Textbook of Clinical Chemistry, Second Edition, Burtis- Ashwood (1994).
3. CCLM 2002; 40(7):725-733, Schumann et al. - IFCC reference procedure for aspartate aminotransferase.
4. J. Clin.Chem.Clin.Biochem 8 (1970) 658; 10 (1972) 182
5. Clinical and Laboratory Standards Institute (formerly NCCLS). Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline - Second Edition. Wayne, PA: Clinical and Laboratory Standards Institute; 2004. NCCLS Document EP05-A2.
6. International Federation of Clinical Chemistry, Committee on Reference Systems for Enzymes, Chem Clin Lab Med 2002; 40 (7): 725-733.
7. HU Bergmeyer - Methods of enzymatic analysis, (1987).


## SYMBOLS

| | |
|---|---|
| IVD | Only for invitro diagnostic use |
| LOT | Lot of manufacturing |
| R1 | Reagent 1 |
| R2 | Reagent 2 |
| CONC | Concentration |
| INGRED | Reagent Ingredients |
| REF | Reference Number (Catalog No) |
| SN | Serial Number |
|  | Expiration date |
|  | Storage temperature interval |
|  | Read the directions |
|  | Biological risk |

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