# GLUCOSE

5 x 100 mL, 1 x 1000 mL
51406001, 51406002

## Intended Use

This reagent is intended for *in vitro* quantitative determination of Glucose in serum, plasma & CSF.

- GOD-PAP methodology
- Linear upto 600 mg/dL

## Clinical Significance

Glucose is a major carbohydrate present in the blood & serves as a primary source of energy. It is usually obtained from ingested starch & sugar. The glucose concentration is normally maintained at a constant level. Excessive glucose is stored as inactive glycogen mainly in the liver & little in the muscles.

Elevated blood glucose levels are found in diabetes mellitus, hyperthyroidism, hyperadrenalism & certain liver diseases.

Decreased levels are found in Insulinoma, hypothyroidism, hypopituitarism.

## Principle

Enzymatic colorimetric determination of glucose according to the following reaction.

$$\text{Glucose} + O_2 + H_2O \xrightarrow{\text{Glucose Oxidase}} \text{Gluconic acid} + H_2O_2$$

$$2H_2O_2 + \text{phenol} + \text{4-Aminoantipyrine} \xrightarrow{\text{Peroxidase}} \text{Quinonimine} + 4H_2O$$

## Kit Components

| Reagent/ Component | Product Code 51406001 | Product Code 51406002 | Description |
|---|---|---|---|
| Glucose Reagent R1 | 5 x 100 mL | 1 x 1000 mL | Tris Buffer (pH 7.40) - 92 mmol/L<br>Phenol - 0.3 mmol/L<br>Glucose Oxidase - 15000 U/L<br>4- Aminophenazone - 2.6 mmol/L |
| Glucose Standard | 1 x 4 mL | 1 x 4 mL | Glucose standard concentration -100 mg/dL |

## Risk & Safety

Material Safety data sheets (MSDS) will be provided on request

## Reagent Preparation

Glucose Reagent & Standard are ready to use.

## Reagent Storage and Stability

The sealed reagents are stable up to the expiry date stated on the label, when stored at 2- 8°C and protected from light.

## Open Vial Stability

Once opened, the reagent is stable up to 4 weeks at 2-8°C,if contamination is avoided.

## Onboard Calibration Stability

On-board Calibration stability is 20 days

## Reagent Deterioration

Turbidity or precipitation in any kit component indicates deterioration and the component must be discarded. Values outside the recommended acceptable range for the Agappe Qualicheck Norm & Path control may also be an indication of reagent instability and associated results are invalid. Sample should be retested using a fresh vial of reagent.

## Precaution

To avoid contamination, use clean laboratory wares use clean, drydisposable pipette tips for dispensing. Close reagent bottles immediately after use.

Avoid direct exposure of reagent to light. Do not blow into the reagent bottles.

This reagent is only for IVD use and follow the normal precautions required for handling all laboratory reagents

## Waste Management

Reagents must be disposed off in accordance with local regulations

## Sample

Serum / plasma (free of hemolysis) / CSF

## Interferences

No interference for

| | |
|---|---|
| Bilirubin up to | 20 mg/dL |
| Haemoglobin up to | 1000 mg/dL |

## Materials Provided

Glucose reagent & Standard

## Materials required but not provided

- Pipettes & Tips
- Test Tubes & racks
- Timer
- Incubator
- Analyzer

## Test Procedure

| Semi Auto Analyser | |
|---|---|
| Mode of Reaction | End Point |
| Slope of reaction | Increasing |
| Wavelength | 505 (490-550 nm) |
| Temperature | 37°C |
| Standard Concentration | 100 mg/dL |
| Linearity | 600 mg/dL |
| Incubation Time | 10 Minutes |
| Blank | Reagent |
| Sample volume | 10 µL |
| Reagent volume | 1000 µL |
| Cuvette | 1 cm light path |

Application parameters for various instrument are available. Please contact customer support department for specific information.

## Unit Conversion

| Traditional Unit | SI Unit | Conversion from Traditional to SI |
|---|---|---|
| mg / dL | mmol/L | x 0.055 |

## Calibration

Agappe multicalibrator is recommended for Calibration of this assay in fully auto analyzers.

Provided standard is recommended for calibration of this assay on Semi auto analyzer.

## Procedure notes

| Laboratory procedure for Semi Auto Analyzer | | | |
|---|---|---|---|
| | Blank | Calibrator | Sample/control |
| Glucose Reagent | 1000 µL | 1000 µL | 1000 µL |
| Standard | - | 10 µL | - |
| Sample / control | - | - | 10 µL |
| Mix & incubate for 10 minutes at 37°C . Read the absorbance of standard and sample against reagent blank. | | | |

## Calculation

$$\text{Glucose Concentration (mg/dL)} = \frac{\text{Absorbance of sample}}{\text{Absorbance of standard}} \times \text{standard conc.}$$

**SYMBOLS USED ON THE LABELS**

SYMBOLS USED ON THE LABELS: IVD IN VITRO DIAGNOSTIC USE | SEE PACKAGE INSERT FOR PROCEDURE | LOT LOT NUMBER | MANUFACTURER'S ADDRESS | MANUFACTURING DATE | EXPIRY DATE | TEMPERATURE LIMIT

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CE ISO 9001 : 2008
ISO 13485 : 2003

## Quality Control

It is recommended to use Agappe Qualicheck Norm & Path (51601001) to verify the performance of the assay. Each laboratory has to establish its own internal quality control scheme and procedure for corrective action, if control do not recover within the acceptable range.

## Reference Range

It is recommended that each laboratory establish its own reference values.

The following value may be used as guide line.

Serum / Plasma : 70-105 mg/dL

CSF : 50 -70 mg/dL

Results obtained for patient samples are to be correlated with clinical findings of patient for interpretation and diagnosis.

## Performance

1. **Linearity**

This reagent is linear upto 600 mg/dL.

If the concentration is greater than linearity (600 mg/dL)dilute the sample with normal saline and repeat the assay. Multiply the result with dilution factor.

2. **Comparison**

A comparison study has been performed between Agappe reagent and another internationally available reagent yielded a correlation coefficient of $r^2$= 0.9989 and a regression equation of y = 1.0016x.

3. **Precision**

| Intra Run | | |
|---|---|---|
| | **Control Level 1** | **Control Level 2** |
| n | 20 | 20 |
| Mean (mg/dL) | 88.4 | 273.2 |
| SD | 2.56 | 8.77 |
| CV(%) | 2.89 | 3.21 |

| Inter Run | | |
|---|---|---|
| | **Control Level 1** | **Control Level 2** |
| n | 20 | 20 |
| Mean (mg/dL) | 87.20 | 269.43 |
| SD | 2.48 | 8.86 |
| CV(%) | 2.84 | 3.29 |

| Accuracy (mg/dL) | | |
|---|---|---|
| **Control** | **Expected Value** | **Measured Value** |
| Control Level 1 | 90 ± 19.60 | 89.7 |
| Control Level 2 | 289 ± 48 | 294.8 |
| Qualicheck Norm | 95 ± 10.60 | 97.3 |
| Qualicheck Path | 259 ± 27 | 264.4 |

## 4. Sensitivity

Lower detection Limit is 1.0 mg/dL

## Bibliography

1. Trinder, P.; Ann Clin Biochem. 6,24 (1969)
2. Dingeon, B.; Ann.Bio.Clin 33,3 (1975)
3. Lott, J. ; Clin.Chem. 21, 1754 (1975)



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