GLUCOSE HK

GHSL
GHSL-M490
R1 : 4 x 89 mL
R2 : 4 x 26 mL

CE

PIMAC-GHSL-EN-V1 (11/2020)

INTENDED USE

This *in vitro* diagnostic reagent is intended for the quantitative determination of glucose in human serum, plasma and urine samples on Selectra Mach Series analyzers.

This *in vitro* diagnostic reagent is for professional use only.

CLINICAL SIGNIFICANCE [1-3]

Glucose is the main source of energy for the human body. Glucose is converted either into glycogen or into triglycerides to be stored. Glucose blood level is mainly regulated by two antagonist hormones: insulin and glucagon.
Glycemia disorders appear mostly in type I or type II diabetes as well as in gestational diabetes. They can be also associated to various endocrinal, pancreatic or hepatic disorders, or linked to drugs.
In normal health condition, glucose is filtered then reabsorbed by kidneys and is therefore not present in urine. Elevated concentrations in urine are observed when the blood concentration is high or in case of impaired tubular reabsorption.
Glucose measurement in blood is indicated for diabetes, in screening, diagnosis or follow-up of patients. It is also indicated to monitor patients with symptoms of hyperglycemia or hypoglycemia.

LIMITATION OF USE

For diabetes assessment, the collection conditions and interpretation of serum glucose concentrations should follow local recommendations such as those published by WHO.[4]
The quantitative assay of glucose alone can not be used to diagnose a disease or a specific pathology.
The results must be interpreted in conjunction with other diagnostic test results, clinical findings and the patient's medical history.

METHOD & PRINCIPLE [5]

Hexokinase - End Point.

$$\text{Glucose + ATP} \xrightarrow{\textit{Hexokinase}} \text{Glucose-6-Phosphate+ ADP}$$

$$\text{Glucose-6-Phosphate + NAD}^{+} \xrightarrow{\textit{G-6-PDH}} \text{Gluconate-6-Phosphate + NADH + H}^{+}$$

G-6-PDH = Glucose-6-phosphate dehydrogenase

COMPOSITION

Reagent 1: R1
Good's buffer, pH 7.6

NAD		4.0	mmol/L
ATP		2.2	mmol/L
Sodium azide	<	0.1	% (w/w)

Reagent 2: R2

Hexokinase	≥	8 500	U/L
G-6-PDH	≥	8 500	U/L
Sodium azide	<	0.1	% (w/w)

Also contains magnesium salts for optimal performance.

MATERIALS REQUIRED BUT NOT PROVIDED

- CALI-0550 ELICAL 2
- CONT-0060 ELITROL I
- CONT-0160 ELITROL II
- Normal saline solution (NaCl 9 g/L)
- General Laboratory equipment (e.g. pipette).
- Selectra Mach analyzer and accessories.
- Do not use materials that are not required as indicated above.

WARNINGS AND PRECAUTIONS OF USE

- Take normal precautions and adhere to good laboratory practice.
- Use clean or single use laboratory equipment only to avoid contamination.
- The reagents contain sodium azide which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of these reagents always flush with copious amounts of water to prevent azide buildup.
- Consult Safety Data Sheet (SDS) for a proper handling.
- Do not interchange reagent vials from different kits.

STABILITY

Store at 2-8 °C and protect from light. Do not freeze.
Do not use after expiration date indicated on the vial labels.
On board stability : 8 weeks.

PREPARATION

The device is ready to use.

PRODUCT DETERIORATION

- The product should be clear. Cloudiness would indicate product deterioration.
- Do not use the product if there is visible evidence of contamination or damage (e.g. particle matter).
- Damage to the reagent container may impact on product performance. Do not use the reagent if there is physical evidence of deterioration (e.g. leakages or punctured container).

SAMPLES

Specimens required [1]
- Serum.
- Plasma (lithium heparin).
- Plasma (Sodium fluoride / potassium oxalate (glycolysis inhibitors)).
- Urine
- Using any other specimen type should be validated by the laboratory.

Warnings and precautions
- In samples collected without glycolysis inhibitors, blood cells must be removed rapidly to prevent the glucose loss (5% to 7% per hour in whole blood at room temperature). [1]
- 24h Urine should be collected in a dark vial, adding 5 mL of glacial acetic acid before sample collection [1]
- Samples should be collected in accordance with Good Laboratory Practice and appropriate guidelines that may be in place.

Storage and stability [1,6]
Serum / Plasma (lithium heparin)
- 8 hours at room temperature
- 3 days at 2-8°C

Plasma (sodium fluoride / potassium oxalate)
- 2 days at room temperature
- 7 days at 2-8°C

Urine
- Urine should be stored at 4°C during 24 hour-collection
- Analyze as soon as possible

REFERENCE VALUES [3]

Serum/plasma	mg/dL	mmol/L
Neonates	30 – 60	1.7 – 3.3
Children	60 – 100	3.3 – 5.6
Adults 18-60 y/o	74 – 106	4.1 – 5.9
Adults 60-90 y/o	82 – 115	4.6 – 6.4
Urine (24 h collection)	mg/dL	mmol/L
	1 - 15	0.1 - 0.8

Note : *The quoted range should serve as a guide only. It is recommended that each laboratory verifies this range or establishes a reference interval for the intended population.*

INSTALLATION AND USE

Consult Selectra Mach operator manual.
Programming of special washes : Use of special wash steps is mandatory when some combinations of tests are performed together on the analyzer. For more information on required special wash steps, please refer to instructions for use PIMAC-WASH

PROCEDURE

The application is included in the 2D barcode on this insert.

CALCULATION

Calculations and/or unit conversions are performed by the analyzer.

CALIBRATION

ELICAL 2 is traceable to ID-MS (Isotope Dilution - Mass Spectrometry) reference method.

Calibration frequency : 4 weeks.
Recalibrate when reagent lots change, when quality control results fall outside the established range and after a maintenance operation.

QUALITY CONTROL

It is recommended that quality control sera such as ELITROL I and ELITROL II be used to monitor the performance of the assay.
Controls have to be performed :
- prior to assaying patient samples,
- at least once per day,
- after every calibration,
- and/or in accordance with laboratory and regulatory requirements.

Results should be within the defined ranges. If values fall outside of the defined ranges, each laboratory should take necessary corrective measures.

WASTE MANAGEMENT

Disposal of all waste material should be in accordance with local, state and federal regulatory requirements (please refer to the Safety Data Sheet (SDS)).

PERFORMANCES

Performances were obtained on Selectra Mach5, following CLSI technical recommendations, under controlled environmental conditions.

- Measuring range

a) Serum/Plasma

20.0- 720.0 mg/dL (1.11-39.96 mmol/L)
Samples having greater concentrations will automatically be diluted 1:5 with NaCl 9 g/L solution and re-assayed. Results take the dilution into account. This procedure extends the measuring range up to 3600.0 mg/dL (199.82 mmol/L).
Do not report results outside this extended range.

b) Urine

10.0- 720.0 mg/dL (0.56 - 39.96 mmol/L)
Samples having greater concentrations will automatically be diluted 1:5 with NaCl 9 g/L solution and re-assayed. Results take the dilution into account. This procedure extends the measuring range up to 3600.0 mg/dL (199.82 mmol/L).
Do not report results outside this extended range.

- Limit of Detection (LoD) and Limit of Quantification (LoQ)

a) Serum/Plasma

LoD : 2.9 mg/dL (0.16 mmol/L)
LoQ : 5.0 mg/dL (0.28 mmol/L)

b) Urine

LoD : 2.3 mg/dL (0.13 mmol/L)
LoQ : 5.0 mg/dL (0.28 mmol/L)

- Precision

a) Serum/Plasma

Imprecision data has been obtained on 2 Selectra Mach5 analyzers over 20 days (2 runs per day, tests performed in duplicate).

Representative results are presented in the following table.

		Mean		Within-run	Total
	n	mg/dL	mmol/L	CV (%)	
Level 1	80	59.4	3.30	1.0	2.1
Level 2	80	132.1	7.33	0.8	2.1
Level 3	80	242.1	13.44	0.9	2.0
Level 4	80	504.3	27.99	0.7	1.8

b) Urine

Imprecision data has been obtained on 2 Selectra Mach5 analyzers over 20 days (2 runs per day, tests performed in duplicate).

Representative results are presented in the following table.

		Mean		Within-run	Total
	n	mg/dL	mmol/L	CV (%)	
Level 1	80	18.6	1.03	1.6	3.6
Level 2	80	193.3	10.73	0.8	2.5
Level 3	80	514.5	28.56	0.8	2.5

- Correlation

a) Serum/Plasma

A comparative study has been performed between GLUCOSE HK reagent on a Selectra Mach5 analyzer and a similar commercially available system on 100 human serum samples.
The sample concentrations ranged from 20.4 to 722.9 mg/dL (1.13 - 40.13 mmol/L).
The results are as follows :
Correlation coefficient : (r) = 1.000
Linear regression: y = 0.973x + 1.4 mg/dL (0.08 mmol/L).

b) Urine

A comparative study has been performed between GLUCOSE HK reagent on a Selectra Mach5 analyzer and a similar commercially available system on 55 human urine samples.
The sample concentrations ranged from 10.4 to 716.1 mg/dL (0.58 - 39.75 mmol/L).
The results are as follows :
Correlation coefficient : (r) = 0.999
Linear regression: y = 0.974x + 0.5 mg/dL (0.03 mmol/L).

- Limitations/Analytical interferences

a) Serum/Plasma

- Studies have been performed to determine the level of interference from different compounds.
The following glucose levels were tested: 50.0 mg/dL and 120.0 mg/dL.
A no significant interference is defined by a recovery ≤±10% of the initial value.

Unconjugated bilirubin : No significant interference up to 30.0 mg/dL (513 µmol/L)
Conjugated bilirubin : No significant interference up to 29.5 mg/dL (505 µmol/L) .
Hemoglobin : No significant interference up to 500 mg/dL.
Triglycerides : No significant interference up to 500 mg/dL (5.6 mmol/L).
Methyl dopa : No significant interference up to 2.0 mg/dL.
Acetaminophen : No significant interference up to 30 mg/dL.
Acetylsalicylic acid : No significant interference up to 200 mg/dL.
Uric acid : No significant interference up to 20.0 mg/dL (1190 µmol/L).
Ascorbic acid : No significant interference up to 20.0 mg/dL.
L-Dopa : No significant interference up to 30 mg/dL.
Tolazamide : No significant interference up to 50 mg/dL.

- In very rare cases, monoclonal gammopathies (multiple myeloma), in particular IgM type (Waldenstrom's macroglobulinemia) can cause unreliable results.[7]

- Many other substances and drugs may interfere. Some of them are listed in reviews plublished by Young.[8-9]

b) Urine

- Studies have been performed to determine the level of interference from different compounds.
The following glucose levels were tested: 18.0 mg/dL and 200.0 mg/dL.
A no significant interference is defined by a recovery ≤±10% of the initial value.

Conjugated bilirubin : No significant interference up to 29.5 mg/dL (505 µmol/L) .
Hemoglobin : No significant interference up to 500 mg/dL.
Uric acid : No significant interference up to 100.0 mg/dL (5.9 mmol/L).
Urea : No significant interference up to 5000 mg/dL (833 mmol/L).
pH: No significant interference between 2.5 and 12.

- Many other substances and drugs may interfere. Some of them are listed in reviews plublished by Young.[8-9]

DECLARATION OF SERIOUS INCIDENT

Please notify the manufacturer (through your distributor) and competent authority of the Member State of the european union in which the user and/or the patient is established, of any serious incident that has occurred in relation to the device. For other jurisdictions, the declaration of serious incident should be in accordance with local, state and federal regulatory requirements.
By reporting a serious incident, you provide information that can contribute to the safety of *in vitro* medical devices.

BIBLIOGRAPHY

1. Sacks, D.B., *Carbohydrates*. Tietz Fundamentals of Clinical Chemistry, 6th Ed., Burtis, C.A, Ashwood, E.R., Bruns, D.E. (W.B. Saunders eds.), (2008), 373.
2. Dods, R.F., *Diabetes Mellitus*. Clinical Chemistry : Theory, Analysis, Correlation, 5th Ed., Kaplan, L.A, Pesce, A.J., (Mosby Inc. eds.), (2010), 729 and appendix
3. Wu, A. H. B., Clinical guide to laboratory tests, 4th Ed., (W.B. Saunders eds.), (2006), 444.
4. World Health Organization (WHO), *Definition and Diagnosis of Diabetes Mellitus and Intermediate Hyperglycemia*, (2006).
5. Neeley, W.E., Clin. Chem., (1972), **18**, 509.
6. Guder, W.G., *et al., Use of anticoagulants in diagnostic laboratory investigations and stability of blood, plasma and serum samples*. (2002). WHO/DIL/LAB/99.1 Rev.2.
7. Berth, M. & Delanghe, J., *Protein precipitation as a possible important pitfall in the clinical chemistry analysis of blood samples containing monoclonal immunoglobulins: 2 case reports and a review of literature*, Acta Clin Belg., (2004), **59**, 263.
8. Young, D.S., Effects of preanalytical variables on clinical laboratory tests, 2nd Ed., AACC Press, (1997).
9. Young, D.S., Effects of drugs on clinical laboratory tests, 4th Ed., AACC Press, (1995).

SYMBOLS

Symbols used are defined in ISO 15223-1 standard, except those presented bellow :

CONT	Content
R1	Reagent 1
R2	Reagent 2
	Modification from previous version
CE	European Conformity

TECHNICAL ASSISTANCE:

Contact your local distributor or ELITech Clinical Systems SAS (CCsupport@elitechgroup.com).

GHSL

Place pour le code barres 2D

ELITech Clinical Systems SAS
Zone Industrielle - 61500 SEES FRANCE
www.elitechgroup.com