

# 1,5-Anhydroglucitol Assay Kit (1,5-AG)

**Method:** Enzymatic

Cat . No.	Size	Instrument
GB8122T	R1:3×20 ml R2:1×20 ml	For Hitachi 717 &ShimadzuCL7200/8000
GS8123T	R1:3×20 ml R2:1×20 ml	For Hitachi917 OlympusAU640/400/600

## INTENDED USE

The 1,5-Anhydroglucitol (1,5-AG) assay is used for the quantitation of 1,5-Anhydroglucitol in human serum or plasma.

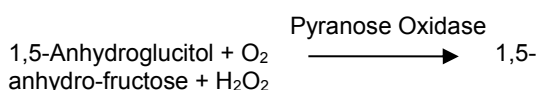
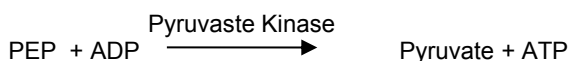
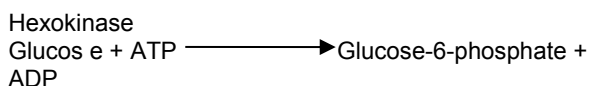
## CLINICAL SIGNIFICANCE

1,5-Anhydroglucitol (AG; popularly called 1-deoxyglucose) has a pyranoid structure, resulting from the deletion of an oxygen from glucose at the anomeric hydroxyl group. This compound is one of the main sugar alcohols in human cerebrospinal fluid and serum. In plasma, the concentration of AG is reduced specifically in diabetes mellitus, thus making it useful as a diagnostic marker for the disease.

Because 1,5-AG is similar structures with glucose, due to high blood glucose brings the glucose excrete (diabetes), competition with glucose 1,5 - AG, make urine reuptake 1,5-AG emissions increase of serum concentrations, reduced. At this time, the body 1,5-AG storage pool also reduces, reduce blood glucose after improvement, with normally accepted from food supply returned to normal. 1,5-AG can sensitive reaction, blood sugar control as a highly sensitive state-of-the-art of glucose in blood sugar, comprehensive index forecast changes, is determination can also mean days interval of meaningful change. Especially to grasp mild diabetics glucose change is very effective.

## ASSAY PRINCIPLES

Pyranose oxidase, Hexokinase and ATP regenerative system that can detect the serum 1,5 -AG concentration. The assay utilizes Hexokinase and ATP regenerative system converts glucose to Glucose-6-phosphate, a compound that does not react with Pyranose oxidase. The hydrogen peroxide produced in the oxidation of 1,5-AG by Pyranose oxidase is detected with a standard enzymatic color-developing system.



## REAGENT COMPOSITION

Contents	Concentration of Solutions
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Reagent 1 (R1)	
Mes	50mmol/L
Hexokinase	4KU/L
ATP	1mmol/L
PEP	4mmol/L
Pyruvate Kinase	3KU/L
4-aminoantipyrine	1.5mmol/L
Ascorbate oxidase	5KU/L
Mes	50mmol/L
Reagent 2 (R2)	
Hepes	200mmol/L
Pyranose Oxidase	80KU/L
Peroxidase	10KU/L
HTIB	4.5mmol/L

## SAMPLE COLLECTION AND PREPARATION

Serum or plasma samples.

Use fresh patient serum or plasma samples.

## STABILITY AND PREPARATION OF REAGENTS

All reagents are ready to use.

Stable up to the expiry date when stored at 2-8°C.

Once opened the reagent is stable for 1 month On-board the analyser at approximately 10°C.

## ASSAY PROCEDURE

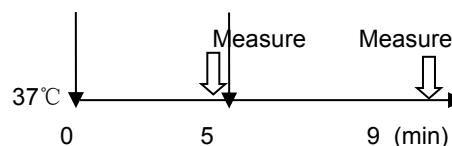
Test Procedure for Analyzers (HITACHI 917)

Assay Mode: Rate A 16-31

Wave Length (main/sub): 546 nm/ 700 nm

Sample: 6 µl

R1: 180 µl R2: 60 µl



- Mix 6µl sample with 180µl R1 and incubate at 37°C for 5 minutes.
- Read initial absorbance  $A_1$ .
- Add 60µl R2 into cuvette, mix and incubate at 37°C for 5 minutes.
- Read initial absorbance  $A_2$ .
- Calculate absorbance change ( $\Delta A = A_2 - A_1$ ).

## CALIBRATION

Recommend that this assay should be calibrated using Gcell Calibration.

## CALCULATION OF RESULTS

$$\text{Concentration} = \frac{\Delta A_{\text{sample}}}{\Delta A_{\text{calibrator}}} \times \text{calibrator value}$$

## QUALITY CONTROL

Gcell quality control, Level 1 and Level 2 are recommended for daily quality control. Two levels of

controls should be assayed at least once a day. Values obtained should fall within a specified range. If these values fall outside the range and repetition excludes error, the following steps should be taken:

1. Check instrument settings and light source.
2. Check reaction temperature.
3. Check expiration date of kit and contents.

#### NORMAL VALUE

Serum or plasma: > 14 µg/mL (85.26 µmol/L)

It is recommended that each laboratory establish its own reference range to reflect the age, sex, diet and geographical location of the population.

#### SPECIFIC PERFORMANCE CHARACTERISTICS

##### LINEARITY

The method is linear between AG concentrations of 10-600 µmol/L. If the concentration of the sample is above this concentration, please dilute it with 0.9% NaCl and repeat assay.

##### PRECISION

The CV of the test should be CV <10%

Intra assay precision		
N=20	level 1	level 2
Mean(µmol/L)	35.50	98.19
SD	0.47	0.95
CV(%)	1.33	0.96

Inter assay precision			
N=5	Batch 1	Batch 2	Batch 3
Mean(µmol/L)	96.19	93.81	96.80
$\bar{x}$	95.26		
$(X_{max}-X_{min})/\bar{x}$	$(96.80-93.81)/95.26*100=3.13\%$		

##### INTERFERENCE

The following analytes were tested up to the levels indicated and found not to interfere:

Hb	up to 200 mg/dL
Intralipid	up to 400 mg/dL
Ascorbic Acid:	up to 50 mg/dL
Glucose	up to 50 mmol/L

##### SAFETY PRECAUTIONS AND WARNINGS

1. For in vitro diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.
2. Reagent contains Sodium Azide. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water. In case of contact with eyes or if ingested, seek immediate medical attention.
3. Sodium Azide reacts with lead and copper plumbing, to form potentially explosive azides. When disposing of such reagents flush with large volumes of water to prevent azide from building up.










Exposed metal surfaces should be cleaned with 10% sodium hydroxide.

4. Specimens should be treated as potentially infectious (HIV, Hepatitis B virus, Hepatitis C virus, etc.) and handled with appropriate caution.
5. Reagents with different lot numbers should not be interchanged or mixed.

#### REFERENCES

1. Masahiko Yabuchi , etc. CLIN. CHEM 35/10,2039-2043(1989).
2. Kayhleen M , etc. DIABETES CARE.Vol 29, 1214-1219

#### INDEX OF SYMBOLS

	Manufacture
	Catalogue Number
	Lot number
	Date of manufacture
	Use by(Expiration date)
	For In-Vitro Diagnostic use only
	Stored at 2-8°C
	Attention:See instruction for use
	Authorized Representative in the European Company