Gcell

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

Method: IFCC Method Without pyridoxal-phosphate

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 ninking 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

Pyranonse 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.

$$\text{Glucos e + ATP} \xrightarrow{\text{Hexokinase}} \text{Glucose-6-phosphate + ADP}$$

$$\text{PEP + ADP} \xrightarrow{\text{Pyruvaste Kinase}} \text{Pyruvate + ATP}$$

$$\text{1,5-Anhydroglucitol + } O_2 \xrightarrow{\text{Pyranose Oxidase}} \text{1,5-anhydro-fructose + } H_2O_2$$

$$H_2O_2 + \text{4-aminoantipyrine/HTIB} \xrightarrow{\text{POD}} H_2O + \text{Dye}$$

SAMPLE COLLECTION AND PREPARATION

Serum or plasma samples.
Use fresh patient serum or plasma samples.

REAGENT COMPOSITION

Contents	Concentration of Solutions
Reagent 1 (R1)	
Mes Buffer(pH=6.3)	50mmol/L
Hexokinase	4KU/L
ATP	1mmol/L
PEP	4mmol/L
Pyruvaste Kinase	3KU/L
4-aminoantipyrine	1.5mmol/L
Ascorbrate oxidase	5KU/L
preservative	0.1%
Reagent 2 (R2)	
Hepes Buffer (pH=8.0)	200mmol/L
Pyranose Oxidase	80KU/L
Peroxidase	10KU/L
HTIB	4.5mmol/L
preservative	0.1%
Calibration	
Control	

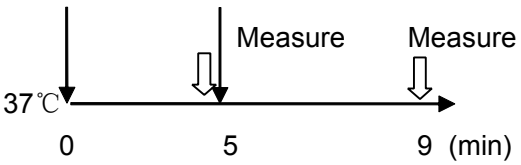
STABILITY AND PREPARATION OF REAGENTS

All reagents are ready to use.
Stable up to the expiry date when stored at 2-8℃.
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



1. Mix 6µl sample with 180µl R1 and incubate at 37℃ for 5 minutes.

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2. Read initial absorbance A_1.
3. Add 60μl R2 into cuvette, mix and incubate at 37℃ for 5 minute.
4. Read initial absorbance A_2.
5. Calculate absorbance change ($\Delta A=A_2-A_1$).

CALCULATION

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

CALIBRATION

Recommend that this assay should be calibrated using Gcell Calibration.

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 [1]

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.

LINEARITY

The method is linear between AG concentrations of 10- 300 μmol/L. If the Sample above this concentration should be diluted it with 0.9% NaCl and repeat assay.

SPECIFIC PERFORMANCE CHARACTERISTICS

INTERFERENCE

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

Hb	200 mg/dL
TG	500 mg/dL
Ascorbic Acid:	50 mg/dL
Glucose	20 mmol/L

SENSITIVITY

The minimum detectable concentration of AG with an acceptable level of precision was determined as 7.8 umol/L.

With serum sample 150umol/L test, as its every minute changes spectrophotometry between in 0.005 ~ 0.030.

PRECISION

The CV of the test should be CV <10%

Within run precision		
N=20	Level1	Level 2
Mean (U/L)	36.3	96.5
SD	0.50	1.80
CV	1.4%	1.9%
Between run precision		
N=3	Level1	Level 2
Mean (U/L)	35.9	96.4
SD	0.60	1.90
CV	1.7 %	2.0 %

CORRELATION

This method (Y) was compared with another commercially available method (X) and the following linear regression equation obtained:

Y=1.0969X-1.5974, and a correlation coefficient of 0.9995

130 patient samples were analyzed.

SAFETY PRECAUTIONS AND WARNINGS

1. For in vitro diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handing laboratory reagents.
2. The reagents 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 build up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.
4. All specimens used in this test should be considered potentially infectious. Universal Precautions, as they apply at your facility, should be used for handling and disposing of materials during and after testing.

REFERENCES

1. Masahiko Yabuchi , etc. CLIN. CHEM 35/10,2039-2043(1989).

2. Kayhleen M , ete. DIABETES CARE.Vol 29, 1214-1219

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INDEX OF SYMBOLS

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

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INSTRUMENT SETTINGS FOR HITACHI 917

Hitachi 7170 Parameter Application **Gcell**

1, 5-AG

Cat. No: GB8122T/GS8123T

Analysis

Test / Type	1,5-AG							Ser/Pl	
Assay/Time/Point	2POINT END	A	10	A	16	34	0	0	
Wave (Sub/Main)	700	A	546	A					
S.Vol (Normal)	6	0.0	0						
S.Vol (Decrease)	0	0.0	0						
S.Vol (Increase)	0	0.0	0						
Diluent	Water		0						
Reagent (R1) T1	180	0	*	0					
Reagent (R2) T2	0	0	00000	0					
Reagent (R3) T3	60	0	*	0					
Reagent (R4) T4	0	0	00000	0					
Abs. Limit	32000	Increase		A					
Prozone Limit	0	34	Lower	A					
Cell Detergent	Detergent 1	A							

Range

Application Code	*	**Unit**	µmol/L	A			
Report Name	1,5-AG						
Data Mode	On Board	A					
Control Interval	0						
Instrument Factor (Y=aX+b)	**a=**	1.0	**b=**	0			
Technical Limit	0	300					
Expected Value							
					Qualitative		
(Male)	0	Y	A			Cancel	A
	100	Y	A		(1)	0	
					(2)	0	
(Female)	0	Y	A		(3)	0	
	100	Y	A		(4)	0	
					(5)	0	

Calibration

Calibration type	Linear	A		A
Point	2	**Span Point**	2	
Weight	0			
Auto calibration				
Time Out			**Change Over**	
Blank	0		Blank	A
Span	0		Blank	A
2Point	0			
Full	0			
SD Limit	999			
Duplicate limit	1000			
Sensitivity limit	0			
S1 Abs limit	-32000	32000		

STD Conc

<Standard>	(1)	(2)	(3)	(4)	(5)	(6)
Concentration	0	*	0	0	0	0
Position	Water	*	0	0	0	0
Volume	6	6	0	0	0	0
<Pre-Diluent>						
Volume	0	0	0	0	0	0
Diluent	0	0	0	0	0	0
Cal. Code	0	0	0	0	0	0

Attention: * entered by operator

K-factor = - 4180

INSTRUMENT SETTINGS FOR HITACHI 902

Hitachi 7020 Instrument Settings **Gcell**

1, 5-AG

Cat. No: GB8122T/GS8123T

No.	<Chemistry>	
1	Test Name	1,5-AG
2	Assay Code (Mthd)	2POINT END
3	Assay Code (2. Test)	0
4	Reaction Time	10
5	Assay Point 1	16
6	Assay Point 2	35
7	Assay Point 3	0
8	Assay Point 4	0
9	Wave Leng. (SUB)	700
10	Wave Leng. (MAIN)	546
11	Sample Volume	6
12	**R1** VOLUME	180
13	R1 Pos.	*
14	R1 Bottle Size	Large
15	**R2** VOLUME	0
16	R2 Pos.	0
17	R2 Bottle Size	Small
18	**R3** VOLUME	60
19	R3 Pos.	*
20	R3 Bottle Size	Small
21	Calib. Type (Type)	线性
22	Calib. Type (Wght)	0
23	Calib. Conc. 1	0.00
24	Calib. Pos. 1	99
25	Calib. Conc. 2	*
26	Calib. Pos. 2	*
27	Calib. Conc. 3	0
28	Calib. Pos. 3	0
29	Calib. Conc. 4	0
30	Calib. Pos. 4	0
31	Calib. Conc. 5	0
32	Calib. Pos. 5	0
33	Calib. Conc. 6	0
34	Calib. Pos. 6	0
35	S 1 ABS.	0
36	K Factor	10000
37	K 2 Factor	10000
38	K 3 Factor	10000
39	K 4 Factor	10000
40	K 5 Factor	10000
41	A Factor	0
42	B Factor	0
43	C Factor	0
44	SD Limit	999
45	Duplicate Limit	1000
46	Sens. Limit	0
47	S 1 ABS Limit (L)	-32000
48	S 1 ABS Limit (H)	32000
49	ABS Limit	32000
50	ABS Limit (D/I)	increase
51	Prz. Limit	0
52	Prz. Limit (U/D)	Lower
53	Prz. (End Point)	35
54	Expect. Value (L)	0
55	Expect. Value (H)	85.26
56	Instr. Fact. (a)	1
57	Instr. Fact. (b)	0
58	Key Setting	*

*** Data entry by the user**

本参数设置仅供参考。应当结合试剂说明书和分析仪器操作手册使用，请在检测之前，参读这些文档以获取更详细信息。任何问题您可以直接拨打免费咨询电话，800 810 1373。

INSTRUMENT SETTINGS FOR OLYMPUS 400/640/2700

Olympus AU640/400/2700 Instrument Settings **Gcell**

1, 5-AG

Cat. No: GB8122T-GS8123T

Specific Test Parameters General

Test Name:	AG			**Type:**	Serum	**Operation:**	Yes
Sample: Volume	6	**Dilution**	0	**Pre-Dilution Rate:**			
Reagents: R1 Volume	180	**Dilution**	0	**Min OD**		**Max OD**	
R2 Volume	60	**Dilution**	0	**L**	-2.0000	**H**	2.5000
				Reagent OD Limit:			
Wavelength: Pri.	540	**Sec.**	700	**First L**	-2.0000	**First H**	2.5000
Method:	END			**Last L**	-2.0000	**Last H**	2.5000
Reaction Slope:	+			**Dynamic Range:**			
Measuring Point 1: First	10	**Last**	27	**L**	1	**H**	300
Measuring Point 2: First		**Last**		**Correlation Factor:**			
Linearity:	30%			**A**	1.0	**B**	0.0
No-Lag-Time:	YES			**Onboard Stability Period:**			

Specific Test Parameters Range

Unit: umol/L **Decimal places:** 2

Calibration Specific

Test No.:		**Name:**	AG	**Type:**	SER
Cal. Type:	AB			**Counts:**	2
Formula:	Y = AX + B			**Process:**	CONC
Calibration Selection:					

	Cal. No.	OD	Conc.	Factor/OD-L	Factor/OD-H
Point 1	*		*	-.9999999	9999999
Point 2					
Point 3					
Point 4					
Point 5					
Point 6					
Point 7					
1-Point Cal..Point:					
MB Type Factor:					
Cali. Stability Period:					

Attention: * Entered By Operator

INSTRUMENT SETTINGS FOR BECKMAN CX4/5/7/9

Synchron CX-4/5/7/9 User-defined Chemistries **Gcell**

1, 5-AG

Cat. No: GB8122T/GS8123T

USER ID:
Chemistry Name: 1,5-AG
Test Name: 1,5-AG

Calculate Factor:

Reaction Type: Endpoint 1
Reaction Direction: POSITIVE
Units: µmol/L

Math Model: Linear
Cal Time Limit: 336 **Hrs**
No. Of Calibrators: 1

Decimal Precision: X.XX

Primary Wavelength: 560 **nm**

Secondary Wavelength: 700 **nm**

Sample Volume: 6 **µl**
Primary Inject Rgt:
A: 180 **µl**
None: **µl**
Secondary Inject Rgt:
B: 60 **µl**
Add Time: 624 **sec**

CALIBRATORS
#1: *
#2:
#3:
#4:
#5:

MULTIPOINT SPAN

1 - 2	0.000
2 - 3	0.000
3 - 4	0.000
4 - 5	0.000
5 - 1	0.000

REAGENT BLANK
Start Read: 576 **sec**
End Read: 608 **sec**
Low ABS Limit: -1.500
High ABS Limit: 1.500

REACTION
Start Read: 592 **sec**
End Read: 624 **sec**
Low ABS Limit: -1.500
High ABS Limit: 1.500

USABLE RANGE
Lower Limit: 0
Upper Limit: 300

SUBSTRATE DEPLETION
Initial Rate: 99.999
Delta ABS: 1.5

RECOVERY/SENSITIVITY
Std Dev (conc): *
CV (%): *
Std Dev (mA): *
Threshold: *

Attention: * Entered By Operator

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