Glycated albumin Assay Kit (GA)

Method: Peroxidase

Cat . No.	Size	Instrument
GS8129T	GA: R1:1×60 ml R2:1×15 ml ALB: R:2×38 ml	For Hitachi 7170/7180 &Olympus AU400
GB8128T	GA: R1:1×60 ml R2:1×15 ml ALB: R:2×38 ml	For Hitachi 7060/ 7150& Shimadzu CL7200/8000
GX8129T	GA: R1:1×60 ml R2:1×15 ml ALB: R:2×38 ml	For Beckman CX/LX
GT8129T	GA: R1:1×40 ml R2:1×10 ml ALB: R:1×50 ml	For Toshiba
GH8129T	GA: R1:1×40 ml R2:1×10 ml ALB: R:1×50 ml	For Hitachi 7020
GD8129T	GA: R1:12×3.8ml R2:3×3.8 ml ALB:R:15×3.8 ml	For Dupont

INTENDED USE

For the quantitative ratio determination of human glycated albumin(GA) and albumin(ALB) in serum or plasma. For in vitro diagnostic use only.

CLINICAL SIGNIFICANCE

Glycation is the result of a sugar molecule,such as gluctose or fructose,binding to a protein or lipid molecule without the controlling action of an enzyme.It is a haphazard process that inpairs the function of biomecules.The high levels of glucose present in diabetes mellitus results in increased glycation of all protein, including albumin.So the glycated albumin assay may be used as a market of glycemic control in diabetes and reflects glycemic control over the previous 2 to 4weeks.

ASSAY PRINCIPLE

1. Measurement of GA
   Add protease which is specific to albumin into sample to decopose glycated albumin,producing glycated animo acid. Then glycated amino acid is translated into glucosone,animo acid,H_2O_2 by the function of glycated amino acid oxidase.By the function of POD,H_2O_2 reacts with 4AAP and HTIB,
   producing red material.So calculate the concentration of GA in sample by assaying the absorbance of the red material.
2. Measurement of Albumin
   Albumin reacts with BCG at pH4.2,producing blue-green material.Calculate the ALB concentration by assaying the absorbance.
3. Ratio calcution(%)

$$\text{Ratio}(\%) = \frac{\text{Concentration of GA}}{\text{Concentration of ALB}} \times 0.95 + 1.9\%$$

REAGENT COMPOSITION

	Contents	Concentration of Solutions
GA	**Reagent 1 (R1)**	
	Protease	500KU/L
	HTIB	10mmol/L
	POD	50KU/L
	Reagent 2 (R2)	
	Glycated amino acid	200KU/L
	4-AAP	10mmol/L
ALB	Bromocresol green	0.15mmol/L

SAMPLE COLLECTION AND PREPARATION

Use fresh patient serum or plasma (EDTA, heprin)samples.
Serum samples are stable for 6 days at 4℃,4 weeks at -20℃.

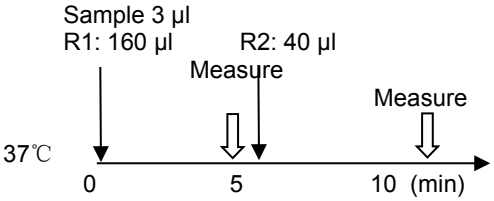
STABILITY AND PREPARATION OF REAGENTS

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

ASSAY PROCEDURE

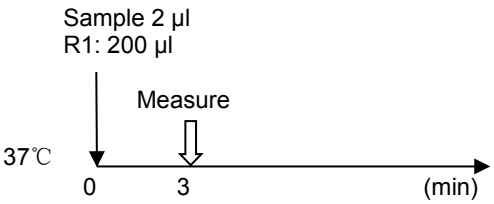
Test Procedure for Analyzers (Hitachi 7180)

1. Assay procedure of GA
   Assay Mode: 2 Point End 16-34
   Wave length (main/sub): 546/700nm



1) Mix 3 µl sample with 160 µl R1 and incubate at 37℃ for 5 minutes, then read initial absorbance A1 at 546nm.
2) Add 40 µl R2 into cuvette, mix and incubate for 5 minutes at 37℃.
3) Calculate the absorbance change $\Delta A=A_2-A_1$.

2. Assay procedure of ALB
   Assay Mode: 1 Point 9
   Wave length (main/sub): 600/700nm



1) Mix 2 µl sample with 200 µl R1 and incubate at 37℃ for 3 minutes.
2) Read initial absorbance A_1
3) Calculate the concentration in sample.

CALIBRATION

Recommend that this assay should be calibrated using Gcell calibrator (Cat .No. GC-GA).

Beijing Strong Biotechnologies, Inc.
Add: 5/F Kuang Yi Building, No. 15 Hua Yuan Dong Lu, Haidian District, Beijing 100191 P. R. China
Tel: +86 10 8201 2486 Fax: +86 10 8201 2812

Web: www.bsbe.com.cn Email: jq.tech@bsbe.com.cn

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CALCULATION OF RESULTS

By constructing a standard curve from the absorbance of the standards, GA and ALB concentration of sample can be determined. Do not attempt to extrapolate above or below the range of the calibrators.

QUALITY CONTROL

For quality control, use GQ-GA/1 and GQ-GA/2 as daily quality control and can be purchased separately. Values should fall within a specific 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/plasma:10.8-17.1%

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

PERFORMANCE CHARACTERISTICS

LINEARITY

In the range of 9.0%-69.0%,the correlation of linearity is ≥0.990. Between 9.0% and 20.0%,the absolute deviation is in the range ± 2.0%.Between 20.0% and 69.0%,the relative deviation is in the range ± 10%.

PRECISION

the CV of the test should be ≤ 5%.

1. GA

Intar assay precision		
N=20	level 1	level 2
Mean(g/dl)	0.563	1.591
SD	0.01	0.01
CV(%)	1.00	0.89

Inter assay precision			
N=5	Batch 1	Batch 2	Batch 3
Mean(g/dl)	0.567	0.563	0.562
$\bar{x}$	0.564		
(Xmax-Xmin)/$\bar{x}$	(0.567-0.562)/0.564*100=0.74%		

2. ALB

Intar assay precision		
N=20	level 1	level 2
Mean(g/dl)	4.116	4.003
SD	0.03	0.04
CV(%)	0.84	0.98

Inter assay precision			
N=5	Batch 1	Batch 2	Batch 3
Mean(g/dl)	4.086	4.119	4.105
$\bar{x}$	4.103		
(Xmax-Xmin)/$\bar{x}$	(4.119-4.086)/4.103*100=0.81%		

INTERFERENCE

The following analytes concentrations were not found to affect the assay:

Hemoglobin:	up to 200 mg/dl
Bilirubin:	up to 20mg/dl
Vitamin C:	up to 50 mg/dl
Intralipid:	up to 600 mg/dl
Glucose:	up to 2400 mg/dl

SAFETY PRECAUTIONS AND WARNINGS

1. For *in vitro* diagnostic use.
2. Avoid ingesting and contact with skin and eyes.
3. Do not use after expiration date printed on label.
4. Both reagents contains sodium azide. Disposal of this reagent into sinks with copper or lead plumbing should be followed with copious amounts of water to prevent formation of potentially explosive metallic azides.
5. 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. Santiago Rodriguez-Segade et al. Progression of nephropathy in type 2 diabe -tes: The glycation gap is a significant predictor after adjustment for glycohemoglobin (HbA1c). Clinical Chemistry, 2011, 57(2): 264-271
2. M. Koga, et al. Glycated albumin and glycated hemoglobin are infuenced differently by endogenous insulin secretion in patients with type 2 diabetes. Diabetes care, 2010, 33(2): 270 - 272
3. T. Kouzuma, et al. An enzymatic method for the measurement of glycated albumin in biological samples. Clinica Chimica Acta, 2002, 324(1-2): 61-71

INDEX OF SYMBOLS

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

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Web: www.bsbe.com.cn Email: jq.tech@bsbe.com.cn

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