Sialic Acid Assay Kit (SA)

Method: Enzymatic

Cat . No.	Size	Instrument
GS8621M	R1: 2×60 ml R2: 2×20 ml	For Hitachi 7060/7150& ShimadzuCL7200/8000
GB8620M	R1: 2×60 ml R2: 2×20 ml	For Hitachi 7060
GX8621M	R1: 2×60 ml R2: 2×20 ml	For Beckman CX/LX
GT8621M	R1: 2×48ml R2: 2×16ml	For Toshiba
GH8620M	R1: 2×48ml R2: 2×16ml	For Hitachi 7020
GD8621M	R1:24×3.8 ml R2:12×2.6 ml	For Dupont

INTENDED USE

For the quantitative determination of human Sialic acid in serum by enzymatic colorimetric assay. For in vitro diagnostic use only.

CLINICAL SIGNIFICANCE

Sialic acid is a generic term for the N- or O-substituted derivatives of neuraminic acid, a monosaccharide with a nine-carbon backbone.Increased SA concentrations have been observed in several diseases, e.g., tumors, myocardial infarction, diabetes, inflammatory disorders, and alcoholism.

ASSAY PRINCIPLE

Sialic in specimen is converted to N-Acetylneuraminic acid by neuraminidase;then N-Acetylneuraminic acid is converted to N-acetylmannosamine and Pyruvic acid by NANA-aldolase. The pyruvate formed reacts with NADH in the presence of LDH to form Lactate and NAD. The corresponding decrease in absorbance at 340nm is proportional to the sialic concentration.

Sialic acid $\xrightarrow{\text{neuraminidase}}$ N-Acetylneuraminic acid

N-Acetylneuraminic acid $\xrightarrow{\text{NANA-aldolase}}$ N-acetylmannosamine + Pyruvic acid

Pyruvic acid+NADH+H^{+} $\xrightarrow{\text{LDH}}$ Lactate+NAD^{+}

REAGENT COMPOSITION

Contents	Concentration of Solutions
Reagent 1 (R1)	
Glycine buffer	100mmol/L
Neuraminidase	0.2 KU/L
LDH	2.0 KU/L
Reagent 2 (R2)	
Tris/HCl buffer	100mmol/L
NADH	0.13mmol/L
NANA-aldolase	2.0 KU/L

SAMPLE COLLECTION AND PREPARATION

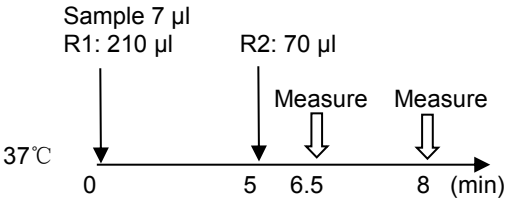
Use fresh patient serum samples.
Serum samples are stable for 6 days at 4℃.

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)
Assay Mode: 2 Point Rate 22-28
Wave length (main/sub): 340/405nm



1. Mix 7 µl sample with 210 µl R1 and incubate at 37℃ for 5 minutes.
2. Add 70 µl R2 into cuvette, mix and incubate for 1.5 minutes at 37℃.
3. Read initial absorbance A_1 and incubate for another 1.5 minutes, read final absorbance A_2.
4. Calculate the absorbance change $\Delta A=A_2-A_1$.

CALIBRATION

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

CALCULATION OF RESULTS

By constructing a standard curve from the absorbance of the standards, SA 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-SA 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

45.6-75.4 mg/dl

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

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

CE version 2014

PERFORMANCE CHARACTERISTICS

LINEARITY
In the range of 230mg/dl,the correlation of linearity is ≥0.990,and the deviation of linearity is in ± 10%.

PRECISION
the CV of the test should be ≤ 5%

Intar assay precision		
N=20	level 1	level 2
Mean(mg/dl)	60.26	149.47
SD	0.51	0.85
CV(%)	0.85	0.57

Inter assay precision			
N=5	Batch 1	Batch 2	Batch 3
Mean(mg/dl)	60.5	60.84	61.02
$\bar{x}$	60.79		
(Xmax-Xmin)/$\bar{x}$	(61.02-60.50)/60.79*100=0.86%		

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

Hemoglobin: up to 500 mg/dl
Bilirubin: up to 50mg/dl
Vitamin C: up to 100 mg/dl

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. Sugahara, K., et al., Enzymatic assay of serum sialic acid. Clin. Chim. Acta, 108, 493-498 (1980).
2. Hannu alho,et al,Serum sialic acid in a random sample of the general population.General Clinical Chemistry,45,No.10,1842-1849(1999).

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

Manufacture：Beijing Strong Biotechnology, Inc.
Address： No. 15, Yanqi North Second Street, Yanqi Economic Development Area, Huairou District, Beijing 101400, P. R. China
Tel：+86 10 61667168

EC REP :Lotus NL B.V.
Address： Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.
E-mail：peter@lotusnl.com
Tel：+31645171879(English), +31626669008（Dutch）