Complement C4 Assay Kit (C4)

Method: immunoturbidimetric

Cat . No.	Size	Instrument
GB680M	R1: 2×50 ml R2: 2×10 ml	For Hitachi 7060/7150 &ShimadzuCL7200/8000
GS681M	R1: 2×50 ml R2: 2×10 ml	For Hitachi7170/7080 &OlympusAU640/400/600
GT681M	R1: 2×50 ml R2: 2×10 ml	ForToshiba only

INTENDED USE

The Complement C4 (C4) assay kit is used for the quantitation of complement C4 in human serum or plasma.

CLINICAL SIGNIFICANCE

Complement components are synthesised primarily in the liver. C3 and C4 are the components most frequently measured. C3 and C4 are increased in a number after an Acute Phase Response but they are weak and late reacting. Acute Phase Protein C3 and C4 are also elevated in biliary obstruction.

ASSAY PRINCIPLES

This assay is based on the reaction between antigen and antibody. This reaction forms an insoluble complex producing a turbidity, which is measured spectrophotometrically. The amount of complex formed is directly proportional to the amount of C4 in the sample.

C4 Antigen + Anti-C4 Antibodies ⟶ Antigen/Antibody complex

REAGENT COMPOSITION

Contents	Concentration of Solutions
Reagent1 (R1)	
Tris Buffer (pH=7.60)	18.16mmol/L
Sodium Chloride	123.20mmol/L
Preservatives	--
Reagent2 (R2)	
Tris Buffer (pH=7.60)	18.16mmol/L
Anti C4 antibody	--
Preservatives	--

SAMPLE COLLECTION AND PREPARATION

Serum or plasma samples.

Use fresh patient serum or EDTA treated plasma samples.

STABILITY AND PREPARATION OF REAGENTS

All reagents are ready to use.

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

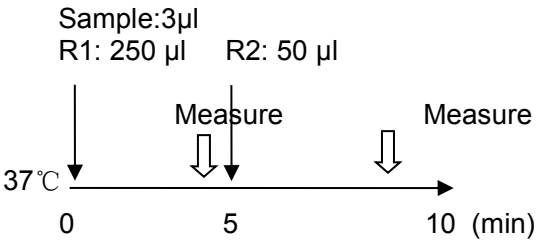
Avoid contamination once opened.

ASSAY PROCEDURE

Test Procedure for Analyzers (Hitachi 7080)

Assay Mode: 2Point END

Wave Length (main): 340nm



CALCULATION

Using recommended Calibrator(Cat.No.GC-C4),

CALCULATION OF RESULTS

Plot calibrator concentrations against the corresponding ΔA values using graph paper. The concentration of C4 in the sample is obtained by reading of a value from the calibration curve. Do not attempt to extrapolate above or below the range of the calibrators.

QUALITY CONTROL

Using recommended Controls are RANDOX,Liquid assayed specific protein control ,Cat.No.PS2682,PS2683,PS2684,

Controls should be assayed:

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

NORMAL VALUE

Serum or plasma: 10-40 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.

MAIN PERFORMANCE CHARACTERISTICS

LINEARITY

The method is linear between C4 concentrations of 1.0-125 mg/dl. If the sample above this concentration should be diluted it with 0.9% NaCl and repeat assay.

PRECISION

The CV of the test should be CV <10%.

Beijing Strong Biotechnologies, Inc.
Add: 5/F,KuangYi 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

Intar assay precision			
N=20	level 1	level 2	level 3
Mean(mg/dl)	16.4	34.8	51.8
SD	0.24	0.74	0.71
CV(%)	1.47	2.13	1.38

Inter assay precision			
N=5	Batch 1	Batch 2	Batch 3
Mean(mg/dl)	30.2	30.2	29.8
$\bar{x}$	30.1		
(Xmax-Xmin)/$\bar{x}$	(30.2-29.8)/30.1*100=1.45%		

INTERFERENCE

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

Hemoglobin up to 500mg/dl
Intralipid up to 500mg/dl
Direct bilirubin up to 35mg/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. Karl J, Engel WD. Determination of Apolipoprotein A1 and B without sample dilution. Poster presented at the 57th meeting of the European Atherosclerosis Society, Lisbon and the IX European Congress of Clinical Chemistry, Cracow 1991.
2. Burtis CA, Ashwood ER. Tietz Fund. Of Clin. Chem. 5th ed. 30-54, 335-336, 462-494 and 972-973.
3. Consensus values of the Deutsche Gesellschaft fur Laboratoriums-medizin, the Deutsche Gesellschaft fur Klinische Chemie and the Verband der Diagnostica-Industrie.V. (VDGH). DG Klinische Chemie Mitteilungen 1995; 26:119-122.

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℃
	Attention:See instruction for use
	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）