Complement C3 Assay Kit (C3)

Method: Immunoturbidimetric

Cat . No.	Size	Instrument
GB670M	R1: 2×50 ml R2: 2×10 ml	For Hitachi 7060/7150 &ShimadzuCL7200/8000
GS671M	R1: 2×50 ml R2: 2×10 ml	For Hitachi7170/7080 &OlympusAU640/400/600
GT681M	R1: 2×50 ml R2: 2×10 ml	For Toshiba only

INTENDED USE
The Complement C3 (C3) assay kit is used for the quantitation of complement C3 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 [1, 2, 3]
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 C3 in the sample.

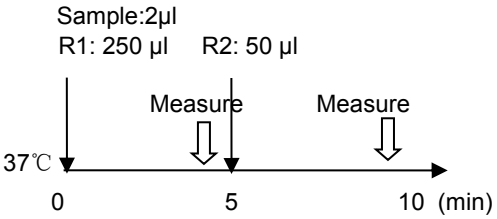
REAGENT COMPOSITION

Contents	Concentration of Solutions
Reagent 1 (R1)	
Tris Buffer(pH=7.60)	18.16mmol/L
Sodium Chloride	123.20mmol/L
Reagent 2 (R2)	
Tris Buffer(pH=7.60)	18.16mmol/L
Anti C3 antibody	1.90%

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: 2P END
Wave Length (sub/main): None/340nm



CALIBRATION
Using recommended Calibrator(Cat.No.GC-C3), calibrate the assay:
1. When using a new reagent kit or changing lot number.
2. Following preventive maintenance or replacement of a critical part of the photometer used.
3. When Quality Control results are out of range.

CALCULATION OF RESULTS
Determine the corresponding concentration from the calibration curve.

QUALITY CONTROL
Using recommended Controls:RANDOX,Liquid assayed specific protein control PS2682,PS2683,PS2684.
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: 82-180 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 C3 concentrations of 7-510 mg/dl. If the concentration in sample is above this concentration,please dilute it with 0.9% NaCl and assay it again.

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

Intar assay precision			
N=20	level 1	level 2	level 3
Mean(mg/dl)	68.7	126.7	181.4
SD	0.32	0.84	1.15
CV(%)	0.46	0.66	0.64

Inter assay precision			
N=5	Batch 1	Batch 2	Batch 3
Mean(mg/dl)	61.9	62.4	62.3
$\bar{x}$	62.2		
(Xmax-Xmin)/$\bar{x}$	(62.4-61.9)/62.2*100=0.80%		

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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

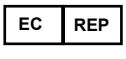
SAFETY PRECAUTIONS AND WARNINGS

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

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