COMPLEMENT COMPONENT C3

Diagnostic reagent for determination of C3 concentration.

Liquid. Mono Reagent. Store at 2°C - 8°C. For in Vitro Diagnostic Use. Do not freeze

Ref No	Pack	Ref No	Pack	Ref No	Pack	Ref No	Pack
TA170	5 x 25 mL	DMT170	990 Tests	SAB171	545 Tests	KAB170	2439 Tests
TA171	5 x 10 mL	RAB170	370 Tests	BY171	3535 Tests	MAB170	1364 Tests
TAB170	1167 Tests	RAB171	185 Tests	NAB170	848 Tests	MAB171	682 Tests
LAB170	2667 Tests						

INTENDED USE

The test is applied for the quantitative determination of complement component C3 in serum and plasma.

C3 is a component of the complement system which is involved in both the classical and the alternative pathways of activation.

C3 is often increased as a result of an acute-phase response (inflammation, trauma or tissue necrosis), biliary obstruction and focal glomerulosclerosis.

Plasma C3 levels are decreased in genetic or acquired deficiencies, which are associated with a significantly increased risk for infection, particularly with encapsulated bacteria.

Clinical diagnosis should not be made on the findings of a single test result, but should integrate both clinical and laboratory data.

TEST PRINCIPLE

Complement component C3 in the sample precipitates in the presence of anti-human C3 antibodies. The light scattering of the antigen-antibody complexes is proportional to the C3 concentration and can be measured by turbidimetry.

TEST PARAMETERS

Method : Turbidimetric,
Wavelength : 340 nm
Temperature : 37°C
Sample : Serum / Plasma
Linearity : 3.7 mg/ dL - 400 mg/dL

REAGENT COMPOSITION

Reagent 1:
Imidazole buffer ≤ 0.12mol/L,
goat anti-human C3 antibodies,
sodium azide ≤ 0.95 g/L,

pH 7.5.

REAGENT PREPARATION

Reagents are provided ready to use.

REAGENT STABILITY AND STORAGE

Once opened vials (reagent 1) are stable minimum 30 days at 2-8°C at optimum conditions. On board stability is strongly related to auto analyzers cooling specification and carry-over values.

SAMPLE

Serum or plasma collected by standard procedures. Use heparin or EDTA as anticoagulants. Lipemic samples are not suitable for testing.

C3 in serum or plasma is stable for 2 days at 2-8°C and 8 days at -20°C.

TEST PROCEDURE

Sample Start
There have many ready application procedures dedicated to different kind of photometers and ready manual working process can be supplied on request.

There have many ready application procedures dedicated to different kind of biochemistry auto analyzers can be supplied on request.

CALCULATION

Calibration curve: Plot the absorbance difference values of each calibrator against its C3 concentration. Use the Blank as the calibrator of 0 concentration. C3 concentration in the sample is calculated by interpolation of its absorbance difference on the calibration curve.

Unit Conversion
mg/dL = 0.01 g/L

REFERENCE INTERVAL (NORMAL VALUES)*

Serum, adults: 90 - 180 mg/dL

*It is recommended that each laboratory establish its own reference range.

QUALITY CONTROL AND CALIBRATION

It is recommended to use the Protein Control Serum level I (PCN01) and II (PCN05) to verify the performance of the measurement procedure.

*Calibration Stability: It is strongly depend of application to auto analyzers and auto analyzers specification. Calibration stability is 30 days.

*Each laboratory should establish its own internal Quality Control scheme and procedures for corrective action if controls do not recover within the acceptable tolerances.

Quality control is recommended every morning. Calibration is not recommended if QC control values are acceptable. Reagent should be calibrated after lot changes.

PERFORMANCE CHARACTERISTICS

Low linearity: 3.7 mg/dL C3

High Linearity: The test is linear up to 400 mg/dL. For higher values, dilute sample 1/5 with distilled water, repeat measurement and multiply results by dilution factor.

Linearity may considerably vary depending on the instrument used.

Precision Studies:

Repeatibility (within run) (Intra-assay)

Mean concentration	CV	n
97 mg/dL	2.9 %	25
227 mg/dL	2.3 %	25

Reproducibility (run to run) (Inter-assay)

Mean concentration	CV	n
97 mg/dL	5.0 %	25
227 mg/dL	2.8 %	25

Sensitivity (LOD): Limit of detection is 3.17 mA dL/mg at 180 mg/dL.

Trueness: Results obtained with this reagent did not show systematic differences when compared with reference reagents. Details of the comparison experiments are available on request.

Prozone effect: Falsely low values are obtained when C3 is present in the sample at a concentration higher than 600 mg/dL.

Interferences: Bilirubin (20 mg/dL) and rheumatoid factors (300 IU/mL) do not interfere. Lipemia (triglycerides 4.5 g/L) and hemoglobin (2.5 g/L) may affect the results.Other drugs and substances may interfere.

These performance characteristics have been obtained using an analyzer. Results may vary if a different instrument or a manual procedure is used.

NOTES

1. For in vitro diagnostic use only. Do not pipette by mouth. Avoid contact with skin and mucous membranes.
2. All the calibrators, controls and some reagents must be considered as human & animal sample, so potentially infectious; all the protection actions must be applied to avoid any potential biological risk.
3. Material safety data sheet will be supplied on request.
4. Exercise the normal precautions required for handling laboratory reagents.
5. After measurements are taken, reagent bottles should cap and kept at 2-8°C. Caps of the reagents bottles cannot be used between two different kind of reagent and between R1 & R2.
6. Reagents with different lot numbers should not be interchanged or mixed.
7. The reagents contain sodium azide (< 0.1%) as a preservative.
8. The linearity limit depends on the sample to reagent ratio.

PRECAUTIONS AND WASTE DISPOSAL

This product is made to be used in professional laboratories and by professional operators. Perform the test according to the general “Good Laboratory Practice” (GLP) guidelines.
R36/38 : Irritating to eyes and skin.
S20/21 : When using, do not eat, drink or smoke.
S26 : In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S28 : After contact with skin wash immediately with plenty of water.
S36/37/39: Wear suitable protective clothing, gloves and eye/face protection.
S45 : In case of accident or if you feel unwell, seek medical advice immediately.
S56 : Dispose of this material and its container at hazardous or special waste collection point.
S57 : Use appropriate container to avoid environmental contamination.
S61 : Avoid release in environment. Refer to special instructions/safety data sheets.
Please consult local regulations for a correct waste disposal.

ABBREVIATIONS

CV% : Coefficient of Variation Percentage
GLP : Good Laboratory Practice
IU : International Unit
mA : miliabsorbance
mL : mililiter
NCCLS : National Committee for Clinical Laboratory Standards
QC : Quality Control

REFERENCES

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4. Friedman and Young. Effects of disease on clinical laboratory tests, 3th ed. AACC Press, 1997.
5. Clinical and Laboratory Standards Institute (formerly NCCLS). Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline – Second Edition. Wayne, PA: Clinical and Laboratory Standards Institute; 2004. NCCLS Document EP05-A2.
6. Dati F et al. Consensus of a group of professional societies and diagnostic companies on guidelines for interim reference range for 14 proteins in serum based on the standarization against the IFCC/CAP reference material (CRM 470). Eur J Clin Chem Clin Biochem 1996; 34: 517-520.
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SYMBOLS

IVD	Only for invitro diagnostic use
LOT	Lot of manufacturing
R1	Reagent 1
CONC	Concentration
INGRED	Reagent Ingredients
REF	Reference Number (Catalog No)
SN	Serial Number
	Expiration date
	Storage temperature interval
	Read the directions
	Biological risk

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