COMPLEMENT C4

Diagnostic reagent for determination of C4 concentration.
Liquid. Dual reagents. Store at +2/+8°C. For in Vitro Diagnostic Use (IVD). Do not freeze.

Ref No	Pack
MH-422	75 mL
MH-423	50 mL
VH-422	75 mL
VH-423	50 mL

Changes made in the instructions for use are marked as grey.

INTENDED USE

The test is applied for the quantitative determination of C4 in serum and plasma.

TEST SUMMARY AND PROCEDURE [1, 2, 3, 4, 5]

Complements are part of a complex biological system that works with antibodies and other factors to protect the body against pathogen entry. When activated by the classical or alternative way, complements can act on biological membranes, leading to cell death.

C4 is a component of the complement system which is essential for activation of the classical pathway.

Plasma levels are modestly increased by the acute-phase response (inflammation, trauma or tissue necrosis).

A complete C4 genetic deficiency is associated with a very high prevalence of autoimmune or collagen vascular disease, particularly Systemic Lupus Erythematosus. Levels of C4 are also depressed because of consumption due to immuno complex formation.

In the presence of anti-human C3 antibodies, complement C3 in the sample precipitates. The light transmittance of the antigen-antibody complex is proportional to the C3 concentration and can be measured turbidimetrically.

Clinical diagnosis should not be made only with the findings of test results, integration of the laboratory data should be used in clinical diagnosis as well.

TEST PARAMETERS

Method : Turbidimetric
Wavelength : 340 nm
Linearity : 90 mg/dL

REAGENT COMPONENTS

Reagent 1:
Imidazole buffer ≤ 0.11 mol/L,
Goat anti-human C4 antibodies,
Sodium azide ≤ 1.2 g/L,
pH 7.5.

REAGENT PREPARATION

Reagent is ready for use.

REAGENT STABILITY AND STORAGE [6]

Reagents are stable at +2/+8°C till the expiration date stated on the label which is only for closed vials.

Once opened vials are stable for 30 days at +2/+8°C in optimum conditions. On board stability is strongly related to auto analyzers' cooling specification and carry-over values.

Reagent stability and storage data have been verified by using Clinical and Laboratory Standards Institute (CLSI) EP25-A protocol.

SAMPLE

Serum and plasma are collected according to the standard procedure. Use heparin or EDTA as anticoagulants. Lipemic samples are not suitable for testing.

Serum or plasma C4 is stable for 2 days at +2/+8ºC.

Unit Conversion:
mg/dL = 0.01 g/L

REFERENCE INTERVAL (NORMAL VALUES) [7]

Serum, adults : 10 - 40 mg/dL

It is recommended that each laboratory establish its own normal range.

Reference interval has been verified by using Clinical and Laboratory Standards Institute (CLSI) EP28-A3c protocol.

QUALITY CONTROL AND CALIBRATION

Commercially available control material with established values determined by this method may be used. We recommend:

Protein Control Serum I Lyophilized
Ref.No: VT-013

Protein Control Serum II Lyophilized
Ref.No: VT-014

The calibrator set contains 5 different levels of C4 concentration and should be used in order to prepare the calibration curve. The assay requires the use of a Protein Calibrator Lyophilized. We recommend:

Protein Calibrator Lyophilized
Ref.No: VT-012

Calibration Stability: It strongly depends on the application characteristics of in-use auto analyser and capacity of cooling. Calibration stability is 20 days.

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

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

PERFORMANCE CHARACTERISTICS

Limit of Detection (LoD): The limit of detection is18 mA dL/mg at 40 mg/dL.

Limit of Quantitation (LoQ) [LoQ values are based on Coefficient of Variation Percentage (CV) %≤ 20]:[8]1.0 mg/dL

LoD and LoQ values have been verified by using CLSI EP17-A protocol.

High Linearity: The method is linear up to 90 mg/dL.

For values above high linearity, dilute sample with 0.9% saline, repeat the test and multiply the result by the dilution factor.

Linearity may considerably vary depending on the instrument used.

Precision Studies:[9]

Repeatability (Within Run) (Intra-Assay):

Mean Concentration	CV%	n
21 mg/dL	2.20	40
50 mg/dL	1.70	40

Reproducibility (Run to Run) (Inter-Assay):

Mean Concentration	CV%	n
21 mg/dL	3.70	40
50 mg/dL	1.90	40

Precision Studies data have been verified by using CLSI EP05-A3 protocol.

Prozone Effect: No prozone effect has been observed up to 150 mg/dL value which is tested for C4.

Interference: [3, 4, 5, 12]
No significant interference was observed for hemoglobin, conjugated bilirubin, rheumatoid factors, lipemia up to the interferent concentration given.

Hemoglobin	: ≤ 2.5 g/L
Bilirubin	: ≤ 20 mg/dL
Rheumatoid Factors	: ≤ 300 IU/mL
Lipemia	: ≤ 3.0 g/L

The acceptable interference limit is set 10% below the highest interference concentration within ± 10% recovery of the target.

Interferences may affect the results due to medication or endogenous substances.

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

WARNINGS AND PRECAUTIONS

IVD: For in Vitro Diagnostic use only.
Do not use expired reagents.
Reagents with two different lot numbers should not be interchanged.
For professional use.
Follow Good Laboratory Practice (GLP) guidelines.
Contains sodium azide.
CAUTION: Human source samples are processed with this product. All human source samples must be treated as potentially infectious materials and must be handled in accordance with OSHA standards.

Danger

EUH032	:Releases a very toxic gas if contacts with acid.
H317	:May cause allergic skin reaction.

Precaution

P280	:Use protective gloves / clothes / glasses / mask.
P264	:Wash your hands properly after using.
P272	:Contaminated work clothes should not be allowed to be used outside of the workplace.

Intervention

P302+P352	:Wash with plenty of water and soap if it contacts with skin.
P333+P313	:Seek medical help if it irritates your skin or develops rash.
P362+P364	:Remove contaminated clothes and wash properly before using.

Disposal

P501	:Dispose the vials and contents according to the local regulations.

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SYMBOLS

IVD	In Vitro Diagnostic Medical Device
LOT	Lot Number
R1	Reagent 1
GTIN	Global Trade Item Number
REF	Reference Number
GLP	Good Laboratory Practice
FOR USE WITH	Identifies Products to Be Used Together
PRODUCT OF TURKEY	Product of Turkey
	Manufacturer
	Expiration Date
	Temperature Limits
	Consult Instructions for Use
	Caution
	Number of Tests