CORMAY COMPLEMENT C4

DIAGNOSTIC KIT FOR DETERMINATION OF COMPLEMENT C4 CONCENTRATION

Kit name	Kit size	Cat. No
CORMAY COMPLEMENT C4	1 x 76 ml	4-586

INTRODUCTION

Complement is a group of 20 immunologically distinct proteins present in blood and tissues. They are able to interact with antigen-antibody complexes, with each other and with cell membranes, in a complex way intended at destroying viruses and bacteria. They are synthesised in liver and are present in serum as functionally inactive molecules. They are activated by antigen-antibody complexes. C4 complement is a α-glycoprotein of 3 subunits. It is an acute phase reactant whose levels are increased during the acute phase. Low levels are found in immune complex diseases and in inherited angioedema, while C3 complement levels are normal.

METHOD PRINCIPLE

The complement C4 present in a sample form with the specific antibody an immunological complex. The increase of turbidity after the addition of antiserum measured at λ=340 nm is proportional to complement C4 concentration in the sample.

REAGENTS

Package

1-Reagent	1 x 63 ml
2-Reagent	1 x 13 ml

The reagents are stable up to the expiry date printed on the package when stored at 2-8°C. The reagents are stable for 4 weeks on board the analyser at 2-10°C. Do not freeze the reagents. Protect from light and contamination!

Concentrations in the test

Imidazole buffer (pH 7.0); PEG; sodium chloride; anti human complement C4 antiserum; HEPES buffer (pH 7.4); stabilizers.

Warnings and notes

- Products for in vitro diagnostic use only.
- The reagents must be used only for the intended purpose, by suitably qualified laboratory personnel, under appropriate laboratory conditions.
- Do not use after expiry date.
- Do not interchange caps.
- Products from human source have been tested for HBsAg and antibodies to HIV and HCV and found to be non-reactive. However this material should be handled as thought capable of transmitting infectious disease.
- Products contain sodium azide (< 0.1%) as a preservative. Avoid contact with skin and mucous membranes.

ADDITIONAL EQUIPMENT

- automated clinical chemistry analyser capable of accommodating two-reagent assays;
- general laboratory equipment;

SPECIMEN

Serum or plasma.

Serum should be separated from red blood cells as soon as possible after blood collection. If the test can not be done immediately, the sample should be stored at -70°C.

Nevertheless it is recommended to perform the assay with freshly collected samples!

PROCEDURE

The reagents are ready to use.

These reagents may be used in automatic analysers according to their user manual. Applications for analysers are available on request.

These reagents may be used directly in Hitachi 911/912 analysers.

Application should be entered using handheld barcode scanner and attached barcodes sheet, according to procedure described below:

1. Delete previous version of application and calibrators assigned to it and restart the analyser.
2. Enter codes of calibrators according to the attached list.
3. Enter barcoded application and assign proper values to calibrators.
4. To activate entered application go to the tab UTILITY | APPLICATION | RANGE and change value of field DATA MODE from INACTIVE to ON BOARD. Confirm the change using UPDATE button.
5. Put reagents on board the analyser – they will be assigned to relevant tests automatically. Perform also measurement of level of reagents inside the bottles.
6. After calibration analyser is ready to use.

REFERENCE VALUES [2]

adults	0.1 – 0.4 g/l

It is recommended for each laboratory to establish its own reference ranges for local population.

QUALITY CONTROL

For internal quality control it is recommended to use the CORMAY IMMUNO-CONTROL III (Cat. No 4-291) with each batch of samples.

For the calibration of automatic analysers systems the CORMAY IMMUNO-MULTICAL (Cat. No 4-287) is recommended. **Calibrators and 0.9% NaCl** should be used for calibration.

The calibration curve should be prepared every 4 weeks, with change of reagent lot number or as required e.g. quality control findings outside the specified range.

PERFORMANCE CHARACTERISTICS

These metrological characteristics have been obtained using an automatic analyser Cobas Mira. Results may vary if a different instrument is used.

- **Analytical range:** 0.0004 g/l – 1.0 g/l.

- **Specificity / Interferences**

Hemoglobin up to 0.32 g/dl, bilirubin up to 29.5 mg/dl triglycerides up to 1000 mg/dl, heparin up to 0.5 g/l, sodium fluoride up to 4 g/l, EDTA up to 5 g/l, sodium citrate up to 5 g/l do not interfere with the test.

- **Precision**

Repeatability (run to run) n = 10	Mean [mg/dl]	SD [mg/dl]	CV [%]
level 1	13.1	0.5	3.7
level 2	26.5	0.5	1.7

Reproducibility (day to day) n = 10	Mean [mg/dl]	SD [mg/dl]	CV [%]
level 1	13.9	0.6	4.2
level 2	26.3	0.5	1.9

- **Method comparison**

A comparison between CORMAY reagent (y) and commercially available assay (x) using 22 samples gave following results:
y = 1.2 x + 1.2 mg/dl;
R = 0.9503 (R – correlation coefficient)

WASTE MANAGEMENT
Please refer to local legal requirements.

LITERATURE

1. Tietz Textbook of Clinical Chemistry, W.B. Saunders, Philadelphia, (1994).
2. Burtis C.A., Ashwood E.R., ed. Tietz Textbook of Clinical Chemistry and Molecular Diagnostics 4th ed., PA: WB Saunders, 2262, 2006

Date of issue: 04. 2016.

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04/16/04/16