INTENDED USE
MEDICON C3 is a set of immunoturbidimetric reagents for the quantitative determination of C3 in human serum and plasma, with BECKMAN COULTER AU400/60/600/IVD/640/2700/5400 and other discrete analyzers. For in vitro diagnostic use only.

CLINICAL SIGNIFICANCE
Increased levels of C3 are observed in many inflammatory conditions (bacteremias), biliary obstruction, amyloidosis (mainly during the recovery period), acute myoccardial arrest, high rheumatic fever, ulcerative colitis, cancer. Deficiencies of C3 are notable in autoimmune diseases, glomerulonephritis, Sjögren system, hepatitis, anemia.

METHOD PRINCIPLE
The method applied is immunoturbidimetry. When the sample is mixed with the appropriate buffer (R1) and antiserum solution (R2), C3 reacts with anti-human C3 leading to formation of insoluble aggregates. The absorbance of these aggregates (380 nm) is proportional to C3 concentration in the sample.

METHOD LIMITATIONS
Refer to the book "Effects of Preanalytical Variables on Clinical Laboratory Tests" for possible interference of other pharmaceutical agents in this particular test. Interference of other agents is described in the "Clinical Guide to Laboratory Tests". The reagent is designed for in vitro diagnostic use only. In vitro diagnostic reagents can be hazardous. They should be handled according to good laboratory practices and techniques. Avoid inhalation and contact with eyes and skin.

REAGENT COMPOSITION
Reagent 1 (R1)
Polyethylene glycol in Tris buffer
Non-reactant components and preservatives
Reagent 2 (R2)
Goat anti-human C3 protein antibodies
Non-reactant components and preservatives

WARNINGS – PRECAUTIONS
- This reagent is designed for in vitro diagnostic use. In vitro diagnostic reagents can be hazardous. They should be handled according to good laboratory techniques. Avoid inhalation and contact with eyes and skin.
- Samples should be considered as potentially infectious. Handle according to the universal precautions and good laboratory practices.
- Antisera are raised in clinically healthy animals in monitored facilities under constant surveillance.
- The reagent contains sodium azide (NaN₃). Avoid swallowing and contact of the reagent with skin and mucous membrane.
- Dispose all waste according to national laws.
- MSDS is available by MEDICON upon request.

PREPARATION
Reagent 1 and 2 are ready to use. Vials bear barcode for recognition by BECKMAN COULTER AU Series analyzers.

REAGENT DESTRUCTION
The reagent should not be used:
- When it does not exhibit the specified linearity or recovery of control values lies outside the acceptable range after recalibration.
- When prolonged exposure to sunlight or high temperature.
- When the solution appears cloudy.

SHELF LIFE
Unopened, reagents are stable up to the stated expiry date when stored at 2 – 8°C. Once opened, they can be stored refrigerated on the instrument for 2 months.

SAMPLE
Use serum or EDTA-plasma as specimen. No fasting or special preparation of the patient needed. Separate sample from and test immediately. Sample is stored at 20°C.

CALIBRATION
MEDICON Protein Standard Set (1578-1190) traceable to CRM 470 from IRMM or BECKMAN COULTER CDR 3201 (MEDICON code: 4478-0754) can be used for calibration. Calibrate the assay every 1 month. Recalibrate following preventive maintenance or replacement of a critical part of the analyser, when using a new reagent kit or a new reagent kit number, or when Quality Control results are out of range.

QUALITY CONTROL
MEDICON provides the following products for quality control: Immunology Control levels 1,2,3 (1578-1195-04, 1578-1196-04, 1578-1197-04) or BECKMAN COULTER ODC0114 IGA Control Serum 1, ODC0115 IGA Control Serum 2, ODC0018 IGA Control Serum 3 (MEDICON code: 4478-1190, 4478-1191, 4478-1192).

Control target values and limits should fall within acceptable intervals adjusted to the requirements of each laboratory. Target values for C3 should be verified with the corresponding working protocol. Results outside the specified values even after recalibration could be due to degradation, unsuitable storage conditions or control deterioration, instrument malfunction, or error during test procedure.

MATERIALS REQUIRED BUT NOT PROVIDED WITH THE KIT
C3 calibrator
Quality control material
Automated biochemistry analyzer

REFERENCE INTERVALS
Serum: 60 – 170 mg/dL
Each laboratory should determine its own expected values as dictated by good laboratory practice.

WASTE DISPOSAL
This product contains sodium azide (NaN₃), which forms sensitive explosive compounds with copper or lead. Flush waste pipes with water after the disposal of uniluted reagent in order to avoid azide build up in the drain pipes.

SPECIFIC PERFORMANCE CHARACTERISTICS
Linearity
The assay is linear within measuring range 6 – 450 mg/dL. When values exceed this range samples should be diluted accordingly.

Prozone Tolerance
No hook effect is observed up to 3750 mg/dL

Sensitivity
The lowest detectable level of C3 is estimated at 2 mg/dL.

Sample range: 55 – 237 mg/dL

Precision
Mean (mg/L) Within run CV% Total CV%
73 3.05 3.58
132 1.33 2.85

Precision is estimated on two concentration levels of analytic according to NCLLS protocol EP-5T (20 consecutive days, 2 runs per day, 2 repeats per run).

Interference
Lipemic: insignificant up to 1000 mg/dL, intralipid<sup>Ο</sup>
Hemoglobin: insignificant up to 500 mg/dL
Non Conj. Bilirubin: insignificant up to 20 mg/dL
Conj. Bilirubin: insignificant up to 20 mg/dL
Ascorbic acid: insignificant up to 3 mg/dL

Refer to Young<sup>9</sup> for further information on interfering substances.

Method Comparison
A comparison was performed between this reagent and another commercially available product. The results were as follows:

Y = 0.995X – 3.918
R² = 0.9896
N = 50
Sample range: 55 – 237 mg/dL

BIBLIOGRAPHY

SYMBOLS
θ = Temperature limits (2°C-8°C)
(ISO 15223/rev. EN980.ISO7000)
NDH SHEDL
BS Code (ISO 15223/rev. EN980)
Batch Code (ISO 15223/rev. EN980)
Catalog Number (ISO 15223/rev. EN980)
Date of Expiry (ISO 15223/rev. EN980)
Manufacturer (ISO 15223/rev. EN980)
Content enough for (rev. EN980/ISO/7000).
Production Date (ISO 15223/rev. EN980/ISO/7000).
For in vitro use (ISO 15223/rev. EN980).

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