## SYMBOL KEYS

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | Temperature limitation | | Manufacturer | | This way up | SC | Smart card (RFID) |
| | Use by | | Consult Instructions for use | Σ | Contains sufficient for <n> tests | CT | Cuvettes |
| | Date of Manufacture | REF | Catalogue Number | EC REP | Authorised Representative in the European Community | R1 | Activation Buffer |
| LOT | Batch Number/ Lot Number | IVD | *In vitro* Diagnostic Medical Device | | | R2 | Anti-human C3 Reagent |


**TULIP DIAGNOSTICS (P) LTD.**

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EC REP

CMC Medical Devices & Drugs S.L., C/ Horacio Lengo No. 18, CP 29006, Malaga, Spain



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turbosmart™

# C3

## IMMUNOTURBIDIMETRIC ASSAY FOR DETERMINATION OF C3 IN HUMAN SERUM ON TURBOSMART™


## SUMMARY

Clinically complement determination helps to detect whether the complement system has been activated. A decrease in complement components due to activation of complement system or a hereditary deficiency and/or dysfunction of a complement component is of clinical significance.C3 is a central component of the complement system. C3 is the rate-limiting factor for both the alternate and the classical complement pathways. C3 is often decreased in active forms of SLE and membranoproliferative glomerulonephritis. C3 fixation on red cells and on tissue may result in autoimmune hemolytic disorder or severe tissue damage. Increased levels of C3 are observed in biliary obstruction, nephrotic syndrome and during corticosteroid therapy. Information regarding the concentration of C3 can be obtained by using **Turbosmart™ C3** reagents. **Turbosmart™ C3** is an immunoturbidimetric assay for the measurement of total C3 in human serum.


## PRESENTATION

| | |
|---|---|
| REF | 108800020 |
| Σ | 20 Tests |
| **R1** | 5.0 ml |
| **R2** | 1.0 ml |
| **SC** | 1 No. |
| **CT** | 20 Nos. |

## REAGENT

1. R1 **Turbosmart™ C3 Activation buffer (R1):** Ready to use.
2. R2 **Turbosmart™ C3 Anti-human C3 Reagent (R2)**: Ready to use.
3. SC **Turbosmart™ C3 RFID:** Card with C3 Master Calibration curve calibrated with a standard traceable to CRM 470.

Each batch of reagents undergoes rigorous quality control at various stages of manufacture for its specificity, sensitivity, and performance.

## REAGENT STORAGE AND STABILITY

1. Store the reagents at 2-8°C. DO NOT FREEZE.
2. The shelf life of the reagent and activation buffer is as per the expiry date mentioned on the respective vial labels.
3. Once opened the reagents are stable for 75 days when stored at 2-8°C provide the reagents are not contaminated.
4. Store the **Turbosmart™** RFID card at a clean dry place. The **Turbosmart™** RFID card data once transferred into **Turbosmart™** analyzer is valid upto the use of labelled number of tests within 75 days.

## PRINCIPLE

**Turbosmart™ C3** is a turbidimetric immunoassay for the estimation of C3 in human serum based on the principle of agglutination reaction. The test specimen is mixed with the Activation buffer (R1). Anti-human C3 reagent (R2) is then added and allowed to react. Presence of C3 in the test specimen results in the formation of an insoluble complex producing a turbidity, which is measured at wavelength 650 nm. The extent of turbidity corresponds to the concentration of C3 in the test specimen.

## NOTE

1. In vitro diagnostic reagent for laboratory and professional use only. Not for medicinal use.
2. All the reagents derived from human source have been tested for HBsAg and HIV antibodies and are found to be non-reactive. However handle the material as if infectious.
3. Reagent contains 0.09% Sodium Azide as preservative. Avoid contact with skin and mucosa. On disposal flush with large quantities of water.
4. The reagents can be damaged due to microbial contamination or on exposure to extreme temperatures.
5. Do not use vortex mixer for mixing reagents. Gently mix reagents and samples during test procedures.
6. **As the reagents and RFID card within lots have been matched, reagents or RFID cards from different lots must not be interchanged.**
7. It is recommended that the reagent performance and RFID card calibration must be validated periodically with known controls such as **Turbosmart™ C3** (REF: 108890005).
8. Do not use damaged or leaking reagents.
9. Use fresh clean disposable micropipette tips to aspirate the reagents for testing to prevent contamination.

## SPECIMEN COLLECTION AND PREPARATION

No special preparation of the patient is required prior to specimen collection by approved techniques. Only serum should be used for testing. Should delay in testing occur, store the sample at 2-8°C, provided they are not contaminated.

## ADDITIONAL MATERIAL REQUIRED

**Turbosmart™ analyser,** test-tubes, normal saline, Stopwatch, well calibrated micropipettes, disposable tips and incubator.

## TEST PROCEDURE

1. Bring reagent and sample to room temperature before use.
2. Select the C3 test from the Measure Menu of Instrument.
3. Load the **Turbosmart™ C3** test data from the RFID card (Provided with the kit) to the analyser as described in the Instrument User Manual. The Instrument is ready to perform the C3 test.
4. The instrument will indicate to place cuvette with R1 + sample in the reading chamber.
5. Take a disposable cuvette (provided in the kit) and add 250µl R1 to the cuvette using fresh clean disposable micropipette tips.
6. Then add 20µl sample and incubate the cuvette for 5 minutes.
7. Place the cuvette with R1 + sample in the **Turbosmart™** reading chamber.
8. Long Press "Test"key. The instrument will mix the sample and then indicate to add R2.
9. Long press **Turbosmart™** electronic Pipette to dispense 50µl R2 reagent to the cuvette with R1+sample.
10. The reaction will start and the counter will start in the display. Results will be displayed on completion of reaction.

## SPECIFIC PERFORMANCE CHARACTERISTICS

### Measuring Range

The **Measuring Range** of **Turbosmart™ C3** reagent has been designed to measure C3 concentrations in the range 10 - 360 mg/dl under the described assay conditions.

### Detection limit / Analytical Sensitivity

Detection limit: 10 mg/dl.

The detection limit represents the lowest measurable C3 concentrations that can be distinguished from zero.

### Precision

| Intra-assay precision | n | Mean mg/dl | SD | CV (%) |
|---|---|---|---|---|
| Sample 1 | 10 | 45.043 | 1.12 | 2.49 |
| Sample 2 | 10 | 105.79 | 1.51 | 1.42 |
| Sample 3 | 10 | 255 | 1.35 | 0.53 |

| Inter-assay precision | n | Mean mg/dl | SD | CV (%) |
|---|---|---|---|---|
| Sample 1 | 10 | 45.336 | 0.7 | 1.6 |
| Sample 2 | 10 | 106.349 | 0.97 | 1.0 |
| Sample 3 | 10 | 256.3 | 0.7 | 0.3 |

### Interference

No interference was observed by Glucose upto 500 mg/dl, Albumin upto 10 g/dl, Bilirubin upto 50 mg/dl, Haemoglobin upto 500 mg/dl and Triglycerides upto 1000 mg/dl.

## REFERENCE VALUES

The interim reference values for C3 in normal populations are 90 - 180 mg/dl. When fresh serum samples (less than 8 hours old) are used, lower values than those mentioned above can be expected.

The reference values are related to age, geographical and methodological differences and vary widely. Each laboratory should define its own reference range for the relevant population.

## REMARKS

1. Usage of well-calibrated pipettes and procedures is critical for achieving correct results.
2. Markedly lipemic, hemolysed, and contaminated serum samples could produce non-specific values.
3. Use of plasma rather than serum can lead to erroneous values.
4. It is recommended that results of the tests should be correlated with clinical findings to arrive at the final diagnosis.
5. The measuring range of the assay is as indicated in the pack insert. Values outside the measuring range are extrapolated values and should not be considered as accurate.

## WARRANTY

This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

## BIBLIOGRAPHY


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2. Tietz textbook of Clinical Chemistry Edited by Carl A Burtis, 2nd Ed., Pg. 688-691.
3. Dati et al., Interim reference ranges for 14 serum proteins based on standardization with CRM 470, Eur. J. Clin. Chem.Clin. Biochem. 1996; 34: 517-520.
4. Data on file: Tulip Diagnostics (P) Ltd.