# IMTEC-CIC IgG

## CIC IgG
## ELISA for the Quantitative Determination of C1q Binding Circulating Immune Complexes (IgG)

**Package Size**

| | | | |
|---|---|---|---|
| REF | ITC59031 | 96 Tests | Complete Testkit |
| IVD | | | |

**Please read the instructions carefully before testing.**

**Procedural precautions:**

**Do not use the reagents beyond the date of expiry.**

**WASH 20x WB05, SUB TMB ELISA and STOP STOP ELISA may be interchanged between lots and test kits that share the same reagent designation.**

**All other reagents are specific for the individual test kit lot and must not be interchanged with other lots and test kits**

**Store reagents at 2...8°C.**

**Intended Use**

IMTEC-CIC IgG is an enzyme immunoassay (ELISA) for the quantitative measurement of C1q-binding circulating immune complexes (IgG) in human serum. The assay is intended for in vitro diagnostic use only as an aid in the diagnosis and monitoring of immune dysfunctions.

The formation of immune complexes is a physiological defence mechanism for the rapid elimination of endogenous or exogenic antigens.

In autoimmune diseases, the detection of circulating immune complexes is an important criterion for the evaluation of the disease activity and the organic manifestation as well as for the indication of new therapy approaches.

**Principle**

The test is based on the covalent immobilisation of C1q to the solid phase of chemically activated microtiter strips and subsequent binding of the circulating immune complexes from patient serum. The bound immune complexes are detected afterwards with a peroxidase-labelled secondary antibody that is directed against human IgG. After addition of substrate solution, a colour appears which intensity is proportional to the concentration of the circulating immune complexes. Following the addition of stop solution, the colour switches from blue to yellow.

**Reagents and Contents**

| | | | |
|---|---|---|---|
| MTP | 12 | **Microtiter Strips** (in 1 strip holder)<br>8-well snap-off strips, ready for use<br>coated with C1q | |
| CAL | 1 – 4<br>4 x<br>3 vials | **Calibrators IgG**<br>aggregated IgG, lyophilised<br>Concentration: 25 µg/ml **(1)**, 50 µg/ml **(2)**,<br>100 µg/ml **(3)**, 400 µg/ml **(4)** | |
| PC | 3 x for<br>0.5 ml | **Control Solution**<br>aggregated IgG, lyophilised<br>Concentrations are stated on the labels. | |
| WASH 20x<br>WB05 | 50 ml | **Washing Buffer** (black cap)<br>Concentrate (20x) for 1 l<br>TRIS buffer | <br><br>pH 6.9 ± 0.2 |
| DIL<br>DB10G | 100 ml | **Dilution Buffer** (blue cap)<br>ready for use<br>Phosphate buffer | <br><br>pH 7.3 ± 0.2 |
| CON | 15 ml | **Conjugate Solution** (white cap)<br>anti-human-IgG HRP conjugate, ready for use | |
| SUB<br>TMB ELISA | 15 ml | **TMB solution** (black cap)<br>ready for use,<br>colourless to bluish<br>3,3', 5,5'-tetramethylbenzidin<br>Hydrogen peroxide | <br>pH 3.7 ± 0.2<br><br>1.2 mmol/l<br>3 mmol/l |
| STOP<br>STOP ELISA | 15 ml | **Stop Solution** (red cap)<br>Sulphuric acid, ready for use | <br>0.5 mol/l |
| | 1 | **Adhesive Strip** | |

**++++ Change of 🛈 ++++ Please read marked text carefully! ++++**

**Safety Notes**

Do not swallow the reagents. Avoid contact with eyes, skin and mucous membranes. All patient specimens and controls should be handled as potentially infectious. The human controls and calibrators were prepared from blood donations and have been checked on donor level for HCV and HIV-1/2 antibodies and HBsAg and found negative. Wear protective clothing and disposable gloves according to Good Laboratory Practices.

All materials contaminated with patient specimens or controls should be inactivated by validated procedures (autoclaving or chemical treatment) in accordance with applicable regulations.

**Stability**

The reagents are stable up to the stated expiry dates on the individual labels when stored at 2...8°C.

**Reagent Preparation**

**Allow the testkit and all its components to reach room temperature before use!** Used bottles should be closed carefully and stored at 2...8°C. Store SUB protected from light.

Do not use polystyrene vessels for handling of CON.

To avoid potential microbial and/or chemical contamination, unused reagents should never be transferred into the original vials.

**Calibrators CAL 1-4 / Control PC**

Dissolve the lyophilisate of one bottle CAL 1-4 or PC with exactly 0.5 ml dist. or deionised water. Shake gently for 20 min., avoid foaming. **DO NOT VORTEX.**

For further usage, aliquot reconstituted CAL or PC and store at -20°C. **Do not use reconstituted CAL or PC repeatedly thawed and frozen, only thaw up once.**

**Washing Buffer Solution WASH**

Any crystallised salt inside the bottle must be resolved before use. Dilute 1 part WASH 20x with 19 parts distilled water. WASH is stable for 6 weeks stored at 2...8°C.

**Specimen**

Patient sera

Use samples freshly collected or freeze samples at –20°C**. Freeze and thaw once only.** Do not use serum samples inactivated by heat treatment at 56°C.

Allow the samples to reach room temperature (30 min.).

Dilute sera 1:101 with DIL (add 10 µl serum to 1 ml DIL).

**Procedure**

- Pipette **100 µl** of **diluted patient serum,** CAL and PC into MTP, for blank use DIL instead of sample dilution, seal MTP with adhesive strip.
- Incubate for **1 hour** at RT.
- **Discard** the solution from MTP. **Wash** MTP **3 times** using 300 µl WASH per well.
- **Discard** WASH **and knock out residues** on an absorbent paper or cloth.
- **Pipette 100 µl** CON and seal MTP with adhesive strip.
- Incubate for **30 min**. at RT.
- **Discard** the solution from MTP. **Wash** MTP **3 times** using 300 µl WASH per well.
- **Discard** WASH **and knock out residues** on an absorbent paper or cloth.
- **Pipette 100 µl** SUB and incubate for **10 min**. At room temperatures above 25°C the substrate incubation could be shortened, but should never fall short of 5 min..
- **Add 100 µl** STOP per well.
- **Read absorbance at 450 nm** within the next 10 min. after stopping. Bichromatic measurement with a reference wavelength at 620 – 690 nm is recommended.

**Automation**

The IMTEC-CIC IgG ELISA may be processed with suitable automated ELISA analyzers. Applications have to be validated prior to diagnostic use.

**Validation of the Test**

The test results are valid provided the following criteria are met for the obtained results:

- PC is within the indicated range (see label).
- CAL 4 does not fall below an absorbance value of 0.6.
- The absorbances of CAL 1-4 keep raising.

In order to improve accuracy of the test results we recommend to run CAL 1-4, PC and patient samples in duplicate.

**Interpretation of Results**

Plot the measured absorbances against concentrations of CAL 1-4 (0 µg/ml **(blank),** 25 (**1**), 50 (**2**), 100 (**3**), 400 (**4**) µg/ml) in semi-log.

By interpolating the plotted measuring points, a calibration curve is obtained, from which the concentrations of circulating immune complexes as equivalent to aggregated IgG of the examined sera can be determined.

Results above 55 µg/ml are considered positive; concentrations between 45-55 µg/ml are considered equivocal and the test should be repeated.

Values exceeding CAL 4 are to be reported as > 400 µg/ml. Retesting at higher dilutions is not recommended, because the dilution behaviour of circulation immunocomplexes is nonlinear.

**Limitations**

A positive result must be used in association with clinical evaluation and diagnostic procedures. The values obtained from this assay are intended to be an aid for diagnosis only.

The performance characteristics for this assay have not been established for plasma samples.

**Performance Characteristics**

Typical performance data can be found in the Verification Report, accessible via:

www.human.de/data/gb/vr/el-59031.pdf or

www.human-de.com/data/gb/vr/el-59031.pdf

If the performance data are not accessible via internet, they can be obtained free of charge from your local distributor.

**Safety Notes**

STOP **Warning**

**· Hazard statements**

H315 Causes skin irritation.

H319 Causes serious eye irritation.

SUB **Danger**

**· Hazard statements**

H360D May damage the unborn child.

**· Precautionary statements**

CAL NC PC WASH 20x DIL CON SUB STOP

P234 Keep only in original container.

P260 Do not breathe dust/fume/gas/mist/vapours/spray.

P262 Do not get in eyes, on skin, or on clothing.

P281 Use personal protective equipment as required.

P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P337+P313 If eye irritation persists: Get medical advice/attention.

P401 Store in accordance with local/regional/national/international regulations.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

**References**


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3. Lambert P.H. *et al.*, J. Clin. Lab. Immunol. **1**, 1-15 (1978)
4. Theofilopoulos A.N., Progress in Clin. Immunol. **4**, 63-106 (1980)



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Human Gesellschaft für Biochemica und Diagnostica mbH
Max-Planck-Ring 21 · 65205 Wiesbaden · Germany
Telefon +49 6122-9988-0 · Telefax +49 6122-9988-100 · e-Mail human@human.de