SARS-CoV-2 (RBD) IgG Ab ELISA

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

INTENDED USE

The test is applied for the quantitative determination of IgG/IgM/IgA antibodies to SARS-CoV-2 in serum or plasma.

TEST SUMMARY AND PROCEDURE

The DRG SARS-CoV-2 (RBD) IgG ELISA is used for detecting individuals who have adaptive immunity. Previous or recent infection can be found by response to SARS-CoV-2. Anti-SARS-CoV-2 RBD can also help monitoring neutralization progress as well as quantification of IgG antibodies.

The response to SARS-CoV-2 infection can be observed as early as 3 days after the onset of symptoms and can reach to the peak over time. IgG and IgM seroconversion occur simultaneously or consecutively after 14 to 21 days. It is possible to observe an increase of 40%-100% in the number of sensitivity serological tests from the first week to 15 days after the symptoms are observed. After infection, it is also observed that the antititers decrease over time.

Diluted patient samples, Standards and Controls are pipetted into the wells. During incubation, SARS-CoV-2 specific antibodies of the standards/controls and positive samples bind to the immobilized RBD antigen. Dispensing of enzyme conjugate into the wells is necessary to remove unbound sample and control material. During a second incubation, binding of the anti-IgG conjugate to the IgG antibody occurs for immune complex formation.

Incubation of the solid phase after washing is necessary to remove unbound substances. The colorimetric reaction is stopped with the stop solution and the optical density (OD) of the resulting yellow color is measured. The intensity of the color is proportional to the concentration of the analyte in the sample.

TEST PARAMETERS

Wavelength : 450 nm
Linearity : 70.0 DU/mL

REAGENT PREPARATION

Reagents are ready for use.

REAGENT STABILITY AND STORAGE

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.

SAMPLE

Serum and plasma are collected according to the standard procedures.

Samples are stable for:
7 days at +2/+8ºC,
6 months at -20°C.

ASSAY PROCEDURE

1. **Add** 100 µL of specimen into the wells and **incubate** at +25 ºC for 30 minutes.
2. **Rinse** the wells for 5 times with diluted Wash Solution. The rinse process must be handled thoroughly as the assay is highly influenced by it.
3. **Add** 100 µL of enzyme conjugate into the wells and **incubate** for 30 minutes.
4. **Add** 100 µL of TMB and **incubate** for 15 minutes at Dark Room Temperature.
5. **Add** 100 µL of Stop Solution. The colour stability is 15 minutes after this.
6. **Reading:**
   Main wavelength: 430 or 450 nm
   Side wavelength: 620 or 630 nm
7. **Total liquid in the well** is 300 µL (The capacity of one well is usually 350-400 µL).

REFERENCE INTERVAL (NORMAL VALUES)

Negative : < 4.86 DU/mL
Equivocal : 4.86 - 5.94 DU/mL
Positive : > 5.94 DU/mL

For those whose results are equivocal, the test should be repeated with a fresh sample after 2 weeks. If the result is in the same interval again, it considered to be negative.

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

QUALITY CONTROL AND CALIBRATION

Use the specific calibrator and control included in the reagent package.

If controls are not within acceptable limits, calibration is required and each laboratory should establish its own Quality Control diagrams and corrective and preventive action procedures.

Quality control is recommended every morning. Calibration is not recommended if quality control values are acceptable.

PERFORMANCE CHARACTERISTICS

Limit of Detection (LoD): The limit of detection is 0.046 DU/mL.

High Linearity: The method is linear up to 70.0 DU/mL.

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:

Repeatibility (Within Run) (Intra-Assay)

Mean Concentration	CV%	n
3.6 DU/mL	7.40	20
13.9 DU/mL	5.70	20
23.2 DU/mL	5.40	20
40.7 DU/mL	5.60	20

Repeatibility (Day to Day) (Inter-Assay)

Mean Concentration	CV%	n
3.9 DU/mL	13.4	20
13.6 DU/mL	7.40	20
24.0 DU/mL	7.00	20
42.2 DU/mL	11.2	20

Interference:

No significant interference was observed up to the interferent concentration given.

Hemoglobin	: ≤ 4 mg/mL
Bilirubin	: ≤ 0.5 mg/mL
Triglyceride	: ≤ 7.5 mg/mL

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

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.

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
R2	Reagent 2
GTIN	Global Trade Item Number
REF	Reference Number
GLP	Good Laboratory Practices
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