Product information

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COVID-19 (SARS-CoV-2) quantitative IgG ELISA

CE IVD

REF **DECOV1901Q**

Σ **96 wells**

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CONTENTS

1. INTENDED USE

The test is designed for the quantitative and qualitative detection of specific IgG-class antibodies to the spike protein of SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2) in human serum (venous, capillary) or plasma (citrate, heparin, EDTA). It is intended to aid in the diagnosis of patients suspected of having COVID-19 disease or asymptomatic infection with SARS-CoV-2, to monitor antibody levels during and after a COVID-19 disease, and to determine antibody levels before and after a COVID-19 vaccination.

2. PRINCIPLE OF THE ASSAY

The quantitative or qualitative immunoenzymatic determination of specific antibodies is based on the ELISA (Enzyme-linked Immunosorbent Assay) technique. Microtiterplates are coated with specific antigens to bind corresponding antibodies of the sample. After washing the wells to remove all unbound sample material a horseradish peroxidase (HRP) labelled conjugate is added. This conjugate binds to the captured antibodies. In a second washing step unbound conjugate is removed. The immune complex formed by the bound conjugate is visualized by adding Tetramethylbenzidine (TMB) substrate which gives a blue reaction product. The intensity of this product is proportional to the amount of specific antibodies in the sample. Acidic stopping solution is added to stop the reaction. This produces a yellow endpoint colour. Absorbance at 450/620 nm is read using an ELISA Microtiterplate reader.

3. MATERIALS

3.1. Reagents supplied

1. **SORB MT Microtiterplate:** 12 break apart 8-well snap-off strips coated with trimeric SARS-CoV-2 Spike antigen (derived from human cell culture); in resealable aluminium foil.
2. **SAM DIL Sample Dilution Buffer:** 2 bottles, each containing 50 mL phosphate buffer (10 mM) for sample dilution, with Tween 20; pH 7.2 ± 0.2; coloured blue; ready to use; blue cap; ≤ 0.0015 % (v/v) CMIT/MIT (3:1).
3. **STOP SOLN Stopping Solution:** 1 bottle containing 7.5 mL citric acid (1 M); < 1 % hydrochloric acid;< 2 % sulfuric acid; pH < 1.2; ready to use; red cap.
4. **WASH SOLN 20x Washing Buffer (20x conc.):** 1 bottle containing 50 mL of a 20-fold concentrated phosphate buffer (0.16 M); pH 7.0 – 7.5; for washing the wells; white cap; ≤ 0.0015 % (v/v) CMIT/MIT (3:1).
5. **ENZ CONJ Conjugate:** 1 bottle containing 13.5 mL of peroxidase labelled antibody to human IgG in buffer solution; with protein stabilizer; coloured green; ready to use; green cap; ≤ 0.0015 % (v/v) CMIT/MIT (3:1).
6. **SUB TMB TMB Substrate Solution:** 1 bottle containing 13.5 mL 3,3',5,5'-tetramethylbenzidine (TMB) solution; ready to use; black cap.
7. **CAL 1 – 5 Standards:** 5 vials, each containing 2 mL standard; ready to use.
   a. **CAL 1** light pink cap
   b. **CAL 2** light blue cap
   c. **CAL 3** blue cap
   d. **CAL 4** dark blue cap
   e. **CAL 5** red cap

   For the concentrations of **CAL 1 – 5** in AU/mL and their correlation to the ”First WHO International Standard for anti-SARS-CoV-2 immunoglobulin (human)” NIBSC code: 20/136, of the National Institute for Biological Standards and Control (NIBSC), Potters Bar, UK, please refer to the QC certificate. **CAL #** Lot-specific Standard for Cut-off calculation.
8. **CONTROL 2 Negative Control:** 1 vial containing 2 mL control; ready to use; light green cap. Concentration and target range are indicated on the QC certificate.
9. **CONTROL 1 Positive Control:** 1 vial containing 2 mL control; ready to use; green cap. Concentration and target range are indicated on the QC certificate.

For hazard and precautionary statements see 11.1

3.2. Materials supplied

- 3 Cover foils
- 1 Instructions for use (IFU)
- QC certificate with information on **CAL** **#** and concentrations and target values of **CAL** **1** **–** **5** and **CONTROL** **1** **&** **2**

3.3. Materials and Equipment needed

- ELISA Microtiterplate reader, equipped for the measurement of absorbance at 450/620 nm (reference wavelength 620 – 690 nm)
- Incubator 37 °C
- Cover for ELISA plates (as alternative to cover foil)
- Manual or automatic equipment for rinsing Microtiterplates
- Pipettes to deliver volumes between 10 and 1000 µL
- Vortex tube mixer
- Distilled water
- Disposable tubes
- Timer

4. STABILITY AND STORAGE

Store kit and all components at 2...8 °C when not in use.

- The shelf life of the unopened kit is stated on the kit box and on the QC certificate.
- The shelf life of the individual unopened components is indicated on the respective label.
- Store the **ENZ** **CONJ** and the **SUB** **TMB** in the dark.
- Withdraw only required volumes of reagents and do not return excess amounts to the respective container.

Component	After first opening	
	Storage	Shelf Life
SORB **MT**	2...8 °C (store in the supplied bag with desiccant)	3 months
CONTROL **1** **&** **2** **CAL** **1** **–** **5**	2...8 °C	
SAM **DIL**		
STOP **SOLN**		
ENZ **CONJ**	2...8 °C (protect from light)	
SUB **TMB**		
WASH **SOLN** **20x**	2...8 °C	3 months
	2...25 °C Final Dilution (ready to use)	4 weeks

5. REAGENT PREPARATION

It is very important to bring all reagents and samples to room temperature (20…25 °C) and mix them before starting the test run!

5.1. Microtiterplate

The break-apart snap-off strips are coated with trimeric SARS-CoV-2 Spike antigen. Immediately after removal of the strips, the remaining strips should be resealed in the aluminium foil along with the desiccant supplied and stored at 2...8 °C.

5.2. Washing Buffer (20x conc.)

Fill up **WASH** **SOLN** **20x** (50 mL) to 1 L with distilled water to the final dilution of 1:20 (1+19). If the concentrate crystallizes, bring it to room temperature (20…25 °C) before diluting and only then dilute it. Mix the ready to use Washing Solution thoroughly before use.

5.3. TMB Substrate Solution

The reagent is ready to use and has to be stored at 2...8 °C, away from the light. The solution should be colourless. If the substrate turns into blue, it may have become contaminated and should be discarded.

6. SAMPLE COLLECTION AND PREPARATION

Use human serum or plasma (citrate, heparin, EDTA) samples derived from venous blood (for further sample material refer to 6.1. Additional Sample Material) with this assay. If the assay is performed within 5 days after sample collection, the samples should be kept at 2...8 °C; otherwise they should be aliquoted and stored deep-frozen (-70…-20 °C). If samples are stored frozen, mix thawed samples well before testing. Avoid repeated freezing and thawing. Heat inactivation of samples is not recommended.

6.1. Additional Sample Material

Serum obtained from capillary blood e.g. from the fingertip, collected and processed using the Sarstedt Microvette® 100 Serum (product number 20.1308) device is also suitable as sample material.
Important: Do not use whole blood directly with the test!

6.2. Sample Dilution

Before assaying, all samples should be diluted 1+100 with **SAM** **DIL**. Dispense 10 µL sample and 1 mL **SAM** **DIL** into tubes to obtain a 1+100 dilution and thoroughly mix with a Vortex.

7. ASSAY PROCEDURE

Please read the instructions for use carefully **before** performing the assay. Result reliability depends on strict adherence to the instructions for use as described. The following test procedure is only validated for manual procedure. Pay attention to chapter 11. Prior to commencing the assay, a distribution and identification scheme for all samples and standards/controls (duplicates recommended) should be carefully established. Select the required number of microtiter strips or wells and insert them into the frame. Perform all assay steps in the order given and without any delays. A clean, disposable tip should be used for dispensing each standard/control and sample. Adjust the incubator to 37±1 °C.

For **quantitative** assay procedure, **CAL** **1 – 5** (in duplicate), **SAM** **DIL**, **CONTROL** **1** **&** **2** must be pipetted. Their target ranges are defined in the QC certificate.
For **qualitative** assay procedure, the **SAM** **DIL** , one standard **CAL** **#** (in duplicate), **CONTROL** **1** **&** **2** must be pipetted. Their target ranges are defined in the QC certificate.

Quantitative Assay Procedure	Qualitative Assay Procedure
1. Pipette 100 µL of the **SAM** **DIL** as the blank value (LW), **CAL** **1 – 5**, **CONTROL** **1** **&** **2** and diluted samples into their respective wells.	1. Pipette 100 µL of the **SAM** **DIL** as the blank value (LW), **CAL** **#**, **CONTROL** **1** **&** **2** and diluted samples into their respective wells.

2. Cover wells with the foil supplied in the kit.
3. **Incubate for 30 min at 37±1 °C.**
4. When incubation has been completed, remove the foil, aspirate the content of the wells and wash each well four times with 300-350 µL of ready to use washing solution. The interval between washing and aspiration should be > 5 sec. At the end carefully remove remaining fluid by tapping strips on tissue paper prior to the next step!
   Note: Washing is important! Insufficient washing results in poor precision and false results.
5. Dispense 100 µL **ENZ** **CONJ** into all wells.
6. Cover wells with the foil supplied in the kit.
7. **Incubate for 30 min at 37±1 °C.** Do not expose to direct sunlight.
8. Repeat step 4.
9. Dispense 100 µL of the **SUB** **TMB** into all wells.
10. Cover wells with the foil supplied in the kit.
11. **Incubate for 30 min at 37 °C in the dark.** A blue colour occurs due to an enzymatic reaction.
12. Dispense 50 µL **STOP** **SOLN** into all wells in the same order and at the same rate as for the **SUB** **TMB**, thereby a colour change from blue to yellow occurs. Shake plate gently and carefully until liquid is completely mixed and a uniform yellow color is visible.
13. Measure the absorbance at 450/620 nm (reference wavelength 620-690 nm) within 1 h after addition of the **STOP** **SOLN**.

7.1. Measurement

Measure the absorbance of all wells at **450 nm**.
Bichromatic measurement using a reference wavelength of 620-690 nm is recommended.
Where applicable calculate the mean absorbance values of all duplicates.

8. RESULTS

8.1. Run Validation Criteria

The OD values of the blank (LW), **CONTROL 1 & 2**, and **CAL 1 – 5** must meet the specifications stated in the QC certificate.
The value of the calculated units of the **CONTROL 1 & 2** must be within the range specified in the QC certificate. If any of the above requirements for OD values or unit values are not met, the test must be repeated.

8.2. Calculation of Results

8.2.1. Qualitative Results

Calculation of Cut-off

Correction Factor (CF): To differentiate between positive and negative samples a Cut-off value has been defined. This Cut-off value is correlated with the specific standard **CAL #** by a lot-specific Correction Factor (refer to QC certificate).
The Cut-off OD value is the mean absorbance value of the **CAL #** determinations x Correction Factor (CF):

$$\text{OD Cut-off } (\triangleq \textbf{10 AU}) = \frac{\textbf{CAL \#}\ \text{OD1} + \textbf{CAL \#}\ \text{OD2}}{2} \times \text{CF}$$

Results in Arbitrary Units

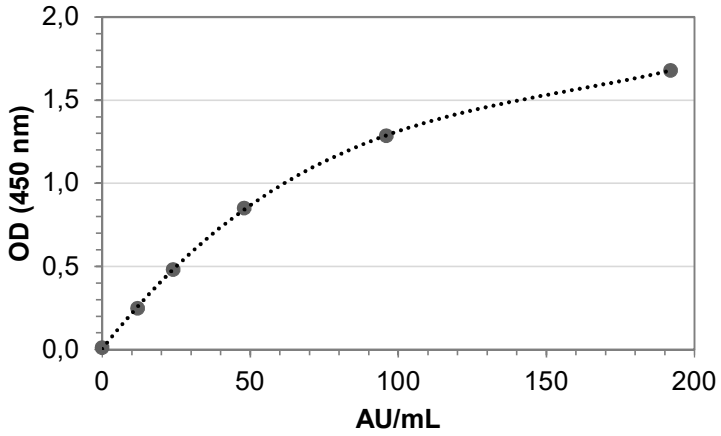
$$\frac{\text{Sample (mean) absorbance value x 10}}{\text{Cut-off}} = \text{AU (Arbitrary Units)}$$

Example: $OD_{Sample} = 1.591$; $OD_{Cut\text{-}off} = 0.43 \quad \Rightarrow \quad \frac{1.591 \times 10}{0.43} = 37$ AU

8.2.2. Quantitative Results

In order to obtain **quantitative results in AU/mL** or **IU/mL** plot the (mean) absorbance values of **CAL 1 – 5** and the blank (LW) on the y-axis against their corresponding concentrations (refer to the QC certificate) on the x-axis and draw the best-fit curve through the plotted points. Read results from this calibration curve employing the (mean) absorbance values of each sample and control.

Typical Calibration Curve



Reporting of Results in International Units (IU/mL)

The COVID-19 (SARS-CoV-2) quantitative IgG has been calibrated against the “First WHO International Standard for anti-SARS-CoV-2 immunoglobulin (human)”, NIBSC code: 20/136. The WHO assigned an arbitrary unitage of 1000 IU/mL for neutralising activity and 1000 IU/mL for binding activity.
Please refer to the QC certificate for the lot specific assignment of International Standard Units (IU/mL) for **CAL 1 – 5**. Perform calculation for the patient specimens as described above using IU/mL for the standards instead of AU/mL.

8.3. Interpretation of Results

qualitative	quantitatiev	Interpretation
< 9 AU	< 9 AU/mL	No significant level of antibodies to SARS-CoV-2 in patient sample. Result does however not exclude infection with SARS-CoV-2. Serological evidence is best obtained by testing of paired acute and convalescent-phase samples obtained several weeks apart.
9 – 11 AU	9 – 11 AU/mL	Equivocal results should only be interpreted as initial evidence for detection of antibodies to SARS-CoV-2. Additional testing is recommended for equivocal test results. Serological evidence is best obtained by testing of paired acute- and convalescent-phase samples obtained 2 to 4 weeks apart.
> 11 AU	> 11 AU/mL	Antibodies to SARS-CoV-2 presumptively detected in patient sample. Contact with the antigen (pathogen resp. vaccine) can be assumed.
Diagnosis of an infectious disease should not be established on the basis of a single test result. A precise diagnosis should take into consideration clinical history, symptomatology as well as serological data. In immunocompromised patients and newborns serological data only have restricted value.		

The COVID-19 (SARS-CoV-2) quantitative IgG has been calibrated against the "First WHO International Standard for anti-SARS-CoV-2 immunoglobulin (human)", NIBSC code: 20/136. Quantitative results in IU/mL provide information about the level of IgG antibodies present.
Important: no reliable data are yet available regarding the correlation of an IgG titer and the presence or duration of immune protection after infection or vaccination.

9. SPECIFIC PERFORMANCE CHARACTERISTICS

The results refer to the groups of samples investigated; these are not guaranteed specifications.

9.1. Precision

A precision sample panel consisting of a negative, a low positive, a moderate positive and a high positive sample were tested in a total of 11 independent runs over a period of 6 days. Tests were performed individually by three different persons. Within each run, each sample was tested in duplicate. Repeatability (Intra-Assay-Coefficient of variation) & Reproducibility (Inter-Assay-Coefficient of variation) were calculated.

	Mean (AU/mL)	Within-Run (Repeatability)		Between-Run (Reproducibility)	
		SD	%CV	SD	%CV
#1	6.22	0.38	5.93	0.88	14.11
#2	14.40	0.88	6.37	1.65	11.44
#3	21.13	0.78	3.78	1.77	8.37
#4	32.03	1.62	5.00	1.77	5.52

9.2. Diagnostic Specificity

The diagnostic specificity is defined as the probability of the assay of scoring negative in the absence of the specific analyte. SARS-CoV-2 infections emerged in December 2019 in Wuhan, China. The expected prevalence values for blood donors from before December 2019 therefore amount to 0 %.
The diagnostic specificity was determined by testing 392 specimens from asymptomatic individuals without a history of SARS-CoV-2 infection either confirmed by a negative PCR result or based on the time of sampling before emergence of SARS-CoV-2.

Sample Panel	Number of samples (n)	Positive	Equivocal	Negative	Specificity (Eqv excluded)	95 % CI
Blood donors (Germany)	258	0	1	257	100 %	
Blood donors (US)	134	2	0	132	98.51 %	
Total	392	2	1	389	99.49 %	98.16 - 99.94 %

9.3. Diagnostic Sensitivity

The diagnostic sensitivity is defined as the probability of the assay of scoring positive in the presence of the specific analyte. A total of 146 samples from patients tested positive for SARS-CoV-2 RNA by RT-PCR were analyzed on the COVID-19 (SARS-CoV-2) quantitative IgG ELISA. Of these, 66 samples were from 48 symptomatic patients and 80 samples were from asymptomatic patients.
To determine the diagnostic sensitivity, the samples were sorted by the timing post symptom onset.

Days post symptom onset	Number of samples (n)	Positive	Equivocal	Negative	Sensitivity (Eqv excluded)
0-7	12	2	0	10	16.67 %
8-14	20	15	1	4	78.95 %
≥ 15	34	33	1	0	100 %
asymptomatic	80	73	4	3	96.05 %

Only with increasing duration of infection the antibody production starts to rise to a detectable level. Individually, this can vary from a few days up to 2 weeks. At the beginning of an infection a negative test result is therefore not a criterion for exclusion of an acute SARS-CoV-2 infection.

9.4. Limit of Blank (LoB), Limit of Detection (LoD), Limit of Quantitation (LoQ)

The LoB, LoD and LoQ were determined according to the approved guideline "CLSI. *Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline-Second Edition*. CLSI document EP17-A2. Wayne, PA: Clinical and Laboratory Standards Institute; 2012".
LoB: 2.4 AU/mL
LoD: 3.6 AU/mL
LoQ: 12.3 AU/mL

9.5. Linearity

Evaluation of assay linearity was performed according to the recommendations in "CLSI. Evaluation of Linearity of Quantitative Measurement Procedures. 2nd ed." CLSI guideline EP06. Clinical and Laboratory Standards Institute; 2020. The COVID-19 (SARS-CoV-2) quantitative IgG shows linearity from **CAL 5** to **CAL 1** with deviation from linearity within ± 15 %.

9.6. Method Comparison

		CLIA (Spike)			
		Positive	Equivocal	Negative	Total
COVID-19 (SARS CoV-2) quantitative IgG	Positive	33	0	1	34
	Equivocal	2	0	0	2
	Negative	2	0	34	36
	Total	37	0	35	72

Positive Percent Agreement (PPA): 94.29 %
Negative Percent Agreement (NPA): 97.14 %
Overall Percent Agreement (OPA): 95.71 %
(Equivocal samples on both assays excluded from calculation)

		ELISA (Spike)			
		Positive	Equivocal	Negative	Total
COVID-19 (SARS CoV-2) quantitative IgG	Positive	30	1	3	34
	Equivocal	1	0	1	2
	Negative	0	1	35	36
	Total	31	2	39	72

Positive Percent Agreement (PPA): 100 %
Negative Percent Agreement (NPA): 92.11 %
Overall Percent Agreement (OPA): 95.59 %
(Equivocal samples on both assays excluded from calculation)

9.7. Interferences

The COVID-19 (SARS-CoV-2) quantitative IgG ELISA was evaluated for interferences according to guideline EP07-A3 (“Interference Testing in Clinical Chemistry” from the Clinical and Laboratory Standards Institute). Four samples, two equivocal, a moderate positive and a high positive sample were spiked with high levels of interferents and were tested along with the unspiked sample. The following table shows the tested substances added to patient samples at the indicated concentrations. These correspond to the recommendations in the CLSI guideline to represent pathological elevated concentrations in patient samples.

Interferent	Concentration tested
Albumin	60 mg/mL
Bilirubin	0.4 mg/mL
Cholesterol	4 mg/mL
Hemoglobin	10 mg/mL
Triglycerides	15 mg/mL

No clinically significant interference effect was found for all tested substances in the COVID-19 (SARS-CoV-2) quantitative IgG ELISA.

9.8. Cross Reactivity

65 samples with antibody activities to potentially cross reacting parameters (including antibodies to several members of the Coronaviridae family) were tested to evaluate the cross reactivity of the assay.

Samples positive for antibodies to	Number of samples (n)	Positive	Equivocal	Negative
human coronavirus 229E (HCoV-229E)	5	0	1	4
human coronavirus NL63 (HCoV-NL63)	5	0	1	4
human coronavirus HKU1 (HCoV-HKU1)	5	0	0	5
human coronavirus OC43 (HCoV-OC43)	5	0	0	5
ANA	5	0	0	5
Haemophilus influenzae	5	1	1	3
hepatitis B virus (HBV)	5	0	0	5
hepatitis C virus (HCV)	5	0	0	5
HIV	10	0	0	10
Influenza A virus	5	0	0	5
Influenza B virus	5	0	0	5
Respiratory syncytial virus (RSV)	5	0	0	5

Cross reactions with antibodies to Haemophilus influenzae cannot be excluded. Cross reactivity with other human coronaviruses should be considered for result interpretation.

10. LIMITATIONS OF THE PROCEDURE

Bacterial contamination or repeated freeze-thaw cycles of the sample may affect the absorbance values.

11. PRECAUTIONS AND WARNINGS

- The test procedure, the information, the precautions and warnings in the instructions for use have to be strictly followed. The use of the testkits with analyzers and similar equipment has to be validated. Any change in design, composition and test procedure as well as for any use in combination with other products not approved by the manufacturer is not authorized; the user himself is responsible for such changes. The manufacturer is not liable for false results and incidents for these reasons. The manufacturer is not liable for any results by visual analysis of the patient samples.
- Only for in-vitro diagnostic use.
- All materials of human or animal origin should be regarded and handled as potentially infectious.
- All components of human origin used for the production of these reagents have been tested for anti-HIV antibodies, anti-HCV antibodies and HBsAg and have been found to be non-reactive.
- Do not interchange reagents or Microtiterplates of different production lots.
- No reagents of other manufacturers should be used along with reagents of this test kit.
- Do not use reagents after expiry date stated on the label.
- Use only clean pipette tips, dispensers, and lab ware.
- Do not interchange screw caps of reagent vials to avoid cross-contamination.
- Close reagent vials tightly immediately after use to avoid evaporation and microbial contamination.
- After first opening and subsequent storage check conjugate and standard/control vials for microbial contamination prior to further use.
- To avoid cross-contamination and falsely elevated results pipette patient samples and dispense reagents without splashing accurately into the wells.
- The ELISA is only designed for qualified personnel following the standards of good laboratory practice (GLP).
- For further internal quality control each laboratory should additionally use known samples

11.1. Safety note for reagents containing hazardous substances

Reagents may contain CMIT/MIT (3:1) or acidic substances (refer to 4.1).
Therefore, the following hazard and precautionary statements apply.

WASH SOLN 20x ENZ CONJ SAM DIL		
Warning	H317	May cause an allergic skin reaction.
	P261	Avoid breathing spray, vapours, mist, fume.
	P280	Wear protective clothing, eye protection, face protection, protective gloves.
	P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
	P362+P364	Take off contaminated clothing and wash it before reuse.

STOP SOLN		
Warning	H290	May be corrosive to metals.
	H315	Causes skin irritation.
	H319	Causes serious eye irritation.
	H335	May cause respiratory irritation.
	P261	Avoid breathing spray, vapours, mist.
	P280	Wear protective clothing, eye protection, face protection, protective gloves.
	P312	Call a POISON CENTER, doctor if you feel unwell.
	P337+P313	If eye irritation persists: Get medical advice/attention.
	P390	Absorb spillage to prevent material damage.

Further information can be found in the safety data sheet

11.2. Disposal Considerations

Residues of chemicals and preparations are generally considered as hazardous waste. The disposal of this kind of waste is regulated through national and regional laws and regulations. Contact your local authorities or waste management companies which will give advice on how to dispose hazardous waste.

ABBREVIATIONS

CMIT	5-chloro-2-methyl-4-isothiazolin-3-one
MIT	2-methyl-2H-isothiazol-3-one

SUMMARY OF TEST PROCEDURE

SCHEME OF THE ASSAY
COVID-19 (SARS-CoV-2) quantitative IgG

Test Preparation

Prepare reagents and samples as described.
Establish the distribution and identification plan for all samples and standards/controls.
Select the required number of microtiter strips or wells and insert them into the holder.

Assay Procedure

	SAM DIL	CAL 1 – 5	CAL #	CONTROL 1	CONTROL 2	Sample (diluted 1+100)
Quantitative Procedure	100 µL	100 µL	-	100 µL	100 µL	100 µL
Qualitative Procedure	100 µL	-	100 µL	100 µL	100 µL	100 µL

Cover wells with foil supplied in the kit **Incubate for 30 min at 37±1 °C**
Wash each well four times with 300-350 µL of Washing Buffer
Add 100 µL **ENZ CONJ** to all wells Cover wells with foil supplied in the kit **Incubate for 30 min at 37±1 °C** Do not expose to direct sunlight
Wash each well four times with 300-350 µL of Washing Buffer
Add 100 µL **SUB TMB** to all wells Cover wells with foil supplied in the kit **Incubate for 30 min at 37±1 °C in the dark**
Add 50 µL **STOP SOLN**
Photometric measurement at 450/620 nm (reference wavelength: 620-690 nm)

SYMBOLS USED WITH DEMEDITEC ASSAYS

Symbol	English	Deutsch	Française	Espanol	Italiano
CE	European Conformity	CE-Konformitäts-kennzeichnung	Conforme aux normes européennes	Conformidad europea	Conformità europea
	Consult instructions for use	Gebrauchsanweisung beachten	Consulter les instructions d'utilisation	Consulte las Instrucciones	Consultare le istruzioni per l'uso
IVD	In vitro diagnostic device	In-vitro-Diagnostikum	utilisation Diagnostic in vitro	Diagnóstico in vitro	Per uso Diagnostica in vitro
RUO	For research use only	Nur für Forschungszwecke	Seulement dans le cadre de recherches	Sólo para uso en investigación	Solo a scopo di ricerca
REF	Catalogue number	Katalog-Nr.	Référence	Número de catálogo	No. di catalogo
LOT	Lot. No. / Batch code	Chargen-Nr.	No. de lot	Número de lote	Lotto no
	Contains sufficient for <n> tests/	Ausreichend für "n" Ansätze	Contenu suffisant pour "n" tests	Contenido suficiente para <n> ensayos	Contenuto sufficiente per "n" saggi
	Note warnings and precautions	Warnhinweise und Vorsichtsmaßnahmen beachten	Avertissements et mesures de précaution font attention	Tiene en cuenta advertencias y precauciones	Annoti avvisi e le precauzioni
	Storage Temperature	Lagerungstemperatur	Température de conservation	Temperatura de conservacion	Temperatura di conservazione
	Expiration Date	Mindesthaltbarkeitsdatum	Date limite d'utilisation	Fecha de caducidad	Data di scadenza
	Legal Manufacturer	Hersteller	Fabricant	Fabricante	Fabbricante
Distributed by	Distributed by	Vertrieb durch	Distribution par	Distribución por	Distribuzione da parte di
V<x>	Version	Version	Version	Versión	Versione
	Single-use	Einmalverwendung	À usage unique	Uso único	Uso una volta