SERION ELISA *agile*

SARS-CoV-2 IgA/IgG

CE

Instructions - English

(Version V a400AG-1)

virion\serion

Updates	
Current version No.:	**V a400AG-1**
Previous version:	**-**
Update in section:	**new**

SERION ELISA *agile* SARS-CoV-2 IgA/IgG

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Enzyme-immunoassay for determination of human antibodies

for *in vitro* diagnotic use

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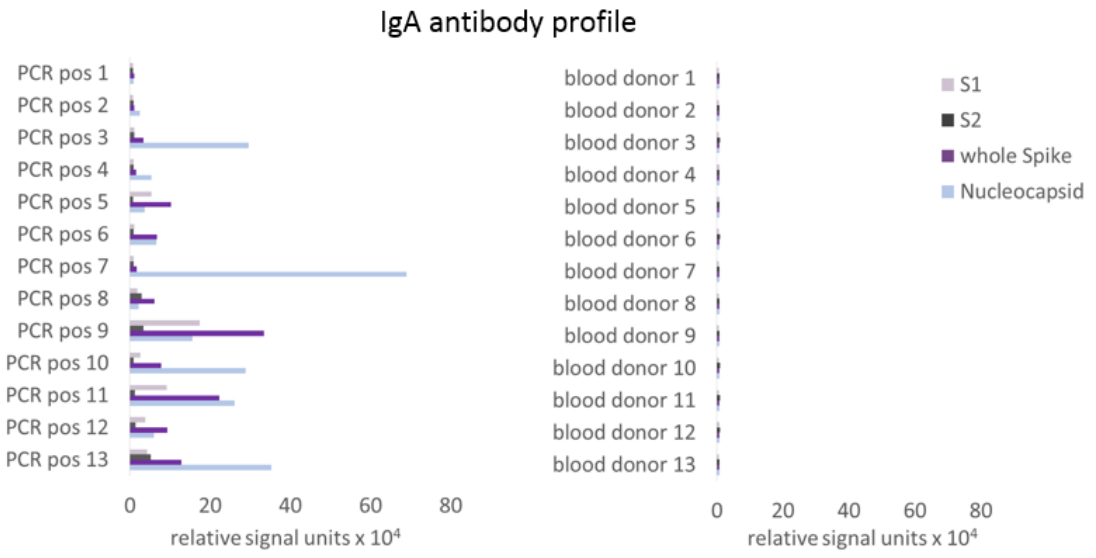
SERION ELISA *agile* SARS-CoV-2 IgG	Order No.:	ESR400G

1 INTENDED USE

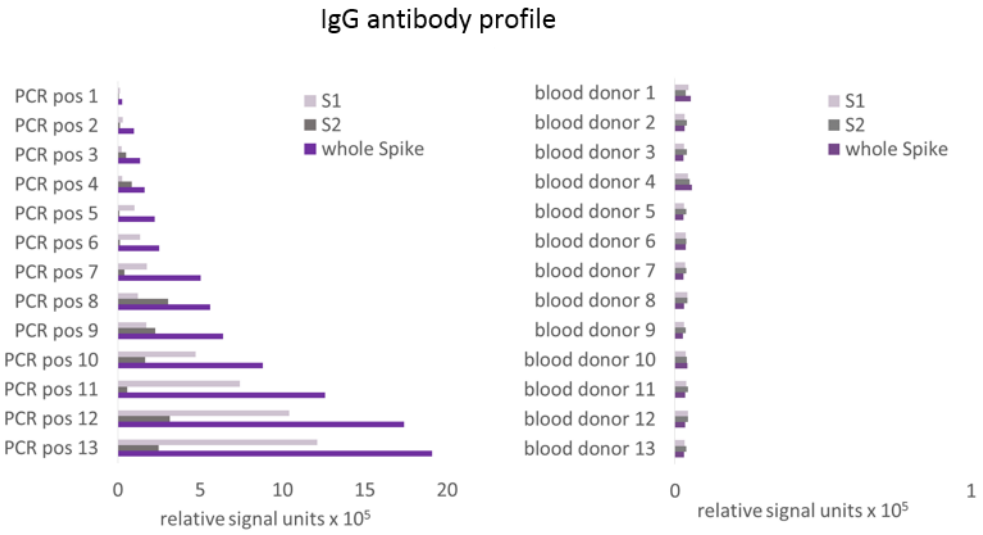
SERION ELISA *agile* SARS-CoV-2 IgA and IgG tests are qualitative and quantitative immunoassays for the detection of human antibodies in serum or plasma directed against SARS-CoV-2 and are recommended to support in the diagnosis of COVID-19 and as a complement to direct pathogen detection. SERION ELISA *agile* SARS-CoV-2 IgG can additionally be used for epidemiological studies.

2 DIAGNOSTIC RELEVANCE

The beta coronavirus SARS-CoV-2, which causes the disease COVID-19, has been responsible for a global pandemic since early 2020.
Common symptoms of COVID-19 are similar to those of a cold or flu, such as fever, cough, difficulty breathing or pneumonia in both lungs. In severe cases, the infection can lead to death [1-4].
During the first week after the onset of symptoms, qRT-PCR is used as a reliable method for detecting SARS-CoV-2 infection and as the infection progresses, the combination of qRT-PCR and antibody tests is optimal for accurate diagnosis [5-9]. The sole use of antibody detection is particularly important in the later stages of infection, when the virus has already been eliminated by the host's immune response [10]. In addition, antibody tests can also be used for epidemiological purposes to identify individuals who have developed immunity after infection that may protect against subsequent reinfection [11] or who may be potential plasma donors for therapeutic purposes. Furthermore, the extent of virus spread and population immunity can be defined and monitored at the social level.
The SERION ELISA *agile* SARS-CoV-2 IgA is based on a mixture of highly purified recombinant nucleocapsid and whole spike protein (S1/S2 ectodomain) of SARS-CoV-2, mapping the most important immunogenic proteins of SARS-CoV-2, thus allowing a very sensitive detection of anti-SARS-CoV-2 IgA antibodies. For the SERION ELISA *agile* SARS-CoV-2 IgG the whole spike protein is used exclusively to achieve a very specific detection and a high correlation with protective antibodies that are mainly produced against the spike protein [12].
Using a microparticle-based test system for the detection of SARS-CoV-2 IgA antibodies the antigens S1, S2, whole spike protein and nucleocapsid protein were coated and analyzed with a total of 337 sera (including PCR positive patient sera, sera from patients with suspected infection, blood donor sera and potentially cross-reactive sera).
The data reveal an increased sensitivity with very good specificity when nucleocapsid protein and whole spike protein are used in combination.



Using a microparticle-based test system for the detection of SARS-CoV-2 IgG antibodies the antigens S1, S2 and whole spike protein were coated and analyzed with a total of 337 sera (including PCR positive patient sera, sera from patients with suspected infection, blood donor sera and potentially cross-reactive sera).
The data reveal an increased sensitivity at the same specificity when using the whole spike protein.



3 TEST PRINCIPLE SERION ELISA *agile*

The test strips of the SERION ELISA *agile* microtiter plates are coated with specific antigens of the pathogen of interest. The diluted patient samples are incubated in the coated wells. The specific antibodies present in positive samples bind to the antigens and are detected with alkaline phosphatase-labelled secondary antibodies. This enzyme catalyzes the conversion of the colorless substrate p-nitrophenyl phosphate into the colored product p-nitrophenol. The signal intensity of the reaction product is proportional to the antibody concentration in the sample and is measured photometrically.

4 KIT COMPONENTS, STORAGE AND STABILITY

Test Components	Pieces / Volume	Storage	Stability
Break apart microtiter test strips each with eight antigen coated single wells, (altogether 96) MTP, 1 frame. The coating material is inactivated.	12 pieces	unopened after opening at 2 – 8 °C in closed aluminum bag with desiccant	see expiry date 6 months
Standard serum (ready-to-use) STD, Human serum in protein containing phosphate buffer; negative for anti-HIV Ab, HBs-Ag (Hepatitis B-Virus surface antigen) and anti-HCV Ab; preservative: < 0.1 % sodium azide; colouring: Amaranth O	2 x 1 ml	unopened after opening at 2 – 8 °C	see expiry date 6 months
Negative control serum (ready-to-use) NEG, Human serum in protein containing phosphate buffer; negative for anti-HIV Ab, HBs-Ag (Hepatitis B-Virus surface antigen) and anti-HCV Ab; preservative: < 0.1 % sodium azide; colouring: Lissamin Green V	1 ml	unopened after opening at 2 – 8 °C	see expiry date 6 months
Anti-human IgA or IgG conjugate (ready-to-use) Conjugate, Anti-human IgA or IgG polyclonal antibody, conjugated to alkaline phosphatase, stabilised with protein stabilisation solution; preservative: < 0.1 % methylisothiazolone, < 0.1 % bromnitrodioxane	14 ml	unopened after opening at 2 – 8 °C	see expiry date 6 months
Washing solution concentrate (sufficient for 1000 ml) WASH, Sodium chloride solution with Tween 20 and 30 mM Tris/HCl, pH 7.4; preservative: < 0.1 % sodium azide	33.3 ml	unopened / after opening at 2 – 8 °C working dilution at 2 – 8 °C working dilution at room temperature	see expiry date 2 weeks 1 week
Dilution buffer (ready-to-use) Diluent S5, Protein containing phosphate buffer with Tween 20; preservative: < 0.1 % sodium azide; colouring: 0.01 g/l Bromphenol blue	2 x 55 ml	unopened after opening at 2 – 8 °C	see expiry date 6 months
Stopping solution (ready-to-use) STOP, < 0.1 N sodium hydroxide, 40 mM EDTA	15 ml	unopened after opening at 2 – 8 °C	see expiry date 6 months
Substrate (ready-to-use) Substrate, Para-nitrophenylphosphate in solvent free buffer; preservative: < 0.1 % sodium azide	14 ml	unopened after opening at 2 – 8 °C	see expiry date 6 months
Quality control certificate with standard curve and evaluation table INFO, (quantification of antibodies in U/ml)	2 pages	n.a.	n.a.

5 MATERIAL REQUIRED BUT NOT SUPPLIED

- Common laboratory equipment
- Photometer for microtiter plates with filter, wavelength 405 nm, recommended reference wavelength 620 nm - 690 nm (e.g. 650 nm)
- Microtiter plate washer
- Incubator 37 °C
- Moist chamber
- Distilled water
- Click-Clips (Order No. VT120.1)
- Optional: SERION ELISA *control*

6 TEST PROCEDURE SERION ELISA *agile*

6.1 General information and statements of warnings

The SERION ELISA *agile* is designed for use by qualified personnel who are familiar with good laboratory practice.

All kit reagents and human specimens should be handled carefully, using established good laboratory practice.

The test kit contains dilutions of human sera. Although all sera used have been tested and found negative for anti-HIV-ab, HBs-Ag (Hepatitis B Virus-surface Antigen) and anti-HCV-ab, they should be considered potentially infectious.

The instructions for use must be strictly followed.

Only use SERION ELISA *agile* reagents when using SERION ELISA *agile* immunoassays. They must not be exchanged with reagents of other manufacturers or components of the SERION ELISA *classic* line. Standard and control sera and conjugate of the SERION ELISA *agile* are lot specific. Washing solution, dilution buffer, substrate and stop solution can be used for all SERION ELISA *agile* independent of lot and kit.

The test reagents should be protected from strong light during storage and incubation.

The SERION ELISA *agile* is only valid if the lot-specific validation criteria on the quality control certificate are fulfilled

6.2 Sample Preparation and Storage

Lipaemic, hemolytic or icteric samples (serum or plasma) should only be tested with caution. Obviously contaminated samples should not be tested. Serum or plasma (EDTA, citrate, heparin) collected according to standard laboratory methods are suitable samples.

6.2.1 Dilution of Samples

Before running the test, patient samples (V_1) must be diluted in dilution buffer (V_2) as follows:

$V_1 + V_2 = 1+100$	e. g. add	5 µl	patient's sample
	each to	500 µl	dilution buffer

After dilution and before pipetting into the microtiter plate the samples must be mixed thoroughly to prepare a homogenous solution.

6.2.2 Sample Storage

The patient's samples should not be stored for more than 7 days at 2 – 8 °C. Extended storage is possible at ≤ -20 °C. Avoid repeated freezing and thawing of samples. Diluted samples can be stored at 2 – 8 °C for one week.

6.3 Preparation of Kit Reagents

Bring all reagents to room temperature before testing.

6.3.1 Microtiter Test Strips (ready-to-use)

The microtiter test strips labeled with abreviations for pathogen and immunoglobulin class are packed with a desiccant in an aluminum bag. To open the aluminum bag of the microtiter plate please cut off the top of the marked side only, in order to guarantee proper resealing. Take unrequired cavities out of the frame and put them back into the aluminum bag. Close bag carefully to ensure airtight conditions. Do not use the strips if the aluminum bag is damaged or if the bag with remaining strips and desiccant was not properly resealed.

6.3.2 Negative control Sera / Standard Sera (ready-to-use)

Negative control and standard sera are ready-to-use. For each test run - independent of the number of microtiter test strips to be used – negative control and standard sera must be included. Standard sera must be set up in duplicate.

6.3.3 Anti-human IgA or IgG Conjugate (ready-to-use)

6.3.4 Washing Solution (Concentrate)

Dilute washing buffer concentrate (V_1) 1:30 with aqua dest. to a final volume of V_2. Bottles used for the working dilution should be cleaned regularly. Discard cloudy solutions.

Example:

Buffer concentrate (V_1)	**Final volume (V_2)**
33.3 ml	1000 ml
1.0 ml	30 ml

6.3.5 Dilution Buffer for Samples (ready-to-use)

Discard cloudy solutions.

6.3.6 Substrate (ready-to-use)

Substrate in unopened bottle may have a slightly yellow coloring, which does not reduce the quality of the product! Avoid contamination.

6.3.7 Stopping Solution (ready-to-use)

6.4 Overview - Test Procedure

sample dilution
(patient´s samples)
1+100

Pipette diluted samples and ready-to-use negative control / standard sera into the microtest wells (100 µl)

⇩

INCUBATION 60 min./ 37 °C
moist chamber

⇩

WASH (4 x 300 µl DIL WASH) [1]

⇩

Pipette conjugate solution Conjugate (100 µl)

⇩

INCUBATION 30 min./ 37 °C
moist chamber

⇩

WASH (4 x 300 µl DIL WASH) [1]

⇩

Pipette substrate solution Substrate (100 µl)

⇩

INCUBATION 30 min./ 37 °C
moist chamber / dark incubation

⇩

Pipette stopping solution STOP (100 µl)

⇩

READ EXTINCTION at 405 nm

[1]For manual use:
tap plate at the end of the wash procedure on paper towel.

6.5 Manual Test Procedure

1. Place the required number of **cavities in the frame** and prepare a protocol sheet.
2. Add each **100 µl of diluted sample or ready-to-use negative control/standard sera** into the appropriate wells of microtiter test strips. Spare one well for substrate blank, e.g.:

Well	ELISA
A1	substrate blank
B1	negative control serum
C1	standard serum
D1	standard serum
E1	patient 1 ...
F1	patient 2 ...

3. **Sample incubation** for 60 minutes (+/- 5 min.) at 37 °C (+/- 1°C) in moist chamber
4. After incubation **wash** all wells with washing solution (by automated washer or manually):
   - aspirate or shake out the incubation solution
   - fill each well with 300 µl washing solution
   - aspirate or shake out the washing buffer
   - repeat the washing procedure 3 times (altogether 4 times!)
   - dry by tapping the microtiter plate on a paper towel
5. **Addition of conjugate**
   Add 100 µl of the ready-to-use IgA/IgG conjugate to the appropriate wells (except substrate blank)
6. **Conjugate incubation** for 30 minutes (+/- 1 min.) at 37 °C (+/- 1 °C) in moist chamber.
7. After incubation **wash** all wells with washing solution (see above).
8. **Addition of substrate**
   Add 100 µl of ready-to-use substrate solution to each well (including well for substrate blank!)
9. **Substrate incubation** for 30 minutes (+/- 1 min.) at 37 °C (+/- 1 °C) in moist chamber. Ensure dark incubation.
10. **Stopping of the reaction**
    Add 100 µl stopping solution to each well, shake microtiter plate gently to mix.
11. **Read extinction**
    Read optical density (OD) within 60 minutes at 405 nm against substrate blank, reference wave length between 620 nm and 690 nm (e.g. 650 nm).

6.6 Automated Test Procedure

SERION ELISA *agile* are validated for use with Immunomat (using the following consumables: VT124, VT111, VT112) and suited for processing on similar analyzers. For processing on the Immunomat the current software version including reagent check has to be used. Please note, that under special working-conditions internal laboratory adaptations of the substrate incubation times may be necessary.

6.7 SERION ELISA *controls* (external Positive Control / Accuracy Control)

For the periodic verification of the test method, in order to fulfil the requirements of laboratory internal quality management systems, we recommend using SERION ELISA *controls* to determine precision and accuracy of SERION ELISA *agile* test runs. SERION ELISA *controls* are separately available and the usage is described in specific instruction manuals. SERION ELISA *controls* are not available in all countries and the customer should consult the local distributor.

7 TEST EVALUATION

7.1 Qualitative Evaluation

For the SERION ELISA *agile* test evaluation a lot-specific quality control certificate with standard curve and an evaluation table is included in the test kit so that the obtained OD values may be assigned to the corresponding antibody activities. The substrate blank must be subtracted from all OD values prior to evaluation. Mean OD value of the standard serum (STD), tested in duplicate, has to be used.

Method 1:
In the first line of the table, several ranges of OD values for the standard serum are depicted covering the whole standard validity range. According to the measured mean OD value of the standard serum, the corresponding column can be chosen. This column contains the information of upper and lower cut-off OD values to allow evaluation of the patient sample. OD values below the lower cut-off are evaluated negative and values above the upper cut-off are evaluated positive. Implementation of the correction factor F is not necessary in the context of the evaluation table.

Method 2:
To fix the cut-off ranges multiply the mean value of the measured standard OD with the numerical data of the quality control certificate (see special case formulas), e.g.:

OD = 0.502 x MW(STD) with upper cut-off

OD = 0.352 x MW(STD) with lower cut-off

7.2 Quantitative Evaluation

The mathematical curve fitting for antibody quantification with SERION ELISA *agile* immunoassays is based on the 4-parameter logistic (4 PL) function.

$$Activity\ (U/ml) = e^{C-\frac{1}{B}\ln\left(\frac{D-A}{OD(Patient)*F-A}-1\right)}$$

The 4 parameters A, B, C, and D are representative for the exact shape of the standard curve and are indicated on the quality control certificate of each individual SERION ELISA *agile* test.

The correction factor F is calculated by dividing the standard reference OD value indicated on the quality control certificate with the measured, test run-specific, standard OD value.

$$F = \frac{STD\ reference\ OD\ value}{measured\ STD\ OD\ value}$$

7.3 Automated Evaluation / Software

Institut Virion\Serion GmbH recommends the use of the SERION *easy*ANALYZE software for the automated evaluation of optical measurement signals.

7.4 Borderline Ranges

The borderline ranges are specified on the quality control certificates and indicate the range of borderline test results. Values below this range indicate a negative test result; values above the borderline range are interpreted positive.

7.5 Limits of Quantification

The limits of quantification are specified on the quality control certificate. In case a patient sample shows a test result above the upper limit of quantification, the sample may be tested at a higher dilution. The resulting antibody activity must then be multiplied by the additional dilution factor.

7.6 Criteria of Validity

The substrate blank must be < 0.25 OD.

The negative control must be negative.

The mean OD value (after subtraction of the substrate blank!) of the standard serum must be within the validity range, which is given on the lot specific quality control certificate.

The variation of OD values of the standard serum must not be higher than 20 %.

If these criteria are not met, the test is not valid and must be repeated.

7.7 Interpretation of Results

A positive test result confirms the presence of specific antibodies. A negative result indicates that no clinically relevant antibodies against the pathogen are present in the patient´s sample, but does not exclude the possibility of an acute infection. In case of a borderline result a reliable evaluation is not possible. A definitive diagnosis can only be achieved by testing paired serum samples, taken at one to two weeks intervals, in parallel.

7.8 **Reference Range of Healthy Individuals**

Testing of random blood donor sera, collected in the region of southern Germany, with SERION ELISA *agile* SARS-CoV-2 IgA/IgG resulted in the following distribution:

SERION ELISA *agile*	Number	negative	borderline	positive
SARS-CoV-2 IgA	138	138 (100 %)	0 (0 %)	0 (0 %)
SARS-CoV-2 IgG	136	135 (99.3 %)	0 (0 %)	1 (0.7 %)

8 PERFORMANCE CHARACTERISTICS

8.1 Sensitivity and Specificity

To calculate the performance characteristics of the SERION ELISA *agile* SARS CoV-2 IgA and IgG, 285 resp. 283 serum samples from healthy blood donors, patients with suspected infection and external quality assessment services were examined in comparison to anti-SARS-CoV-2 IgA and IgG ELISA test systems from another manufacturer. Analyses have been performed according to the corresponding instructions for use. Borderline results were not included in the calculation of sensitivity and specificity.

	Sensitivity	Specificity
SERION ELISA *agile* SARS-CoV-2 IgA	96,3 %	> 99 %
SERION ELISA *agile* SARS-CoV-2 IgG	96,2 %	99,2 %

8.2 Reproducibility

SERION ELISA *agile* SARS-CoV-2 IgA:

Sample	**Mean Value (OD)**	**Intraassay CV (%)**	**Mean Value (OD)**	**Interassay CV (%)**
Serum 1	0.234	2.7	0.238	4.7
Serum 2	0.441	3.2	0.418	7.6
Serum 3	1.052	2.3	0.758	13.4

SERION ELISA *agile* SARS-CoV-2 IgG:

Sample	Mean Value (OD)	Intraassay CV (%)	Mean Value (OD)	Interassay CV (%)
Serum 1	0.185	4.1	0.180	3.6
Serum 2	0.787	2.3	0.755	3.5
Serum 3	1.931	1.7	1.840	1.2

8.3 Cross-reactivities

SERION ELISA *agile* SARS-CoV-2 IgA
To determine detection of cross-reactive antibodies directed against different parameters sera were analyzed with SERION ELISA *agile* SARS-CoV-2 IgA and a commercially available anti-SARS-CoV-2 IgA ELISA. Positive sera (9 or 10 sera each) for Epstein-Barr Virus VCA IgM, Adenovirus IgA, Influenza A Virus IgA and other coronaviruses have been tested as well as sera positive for rheumatoid factor (RF) and anti-nuclear antibodies (ANA). Within this internal evaluation no potential cross-reactivities have been observed. Other cross-reactivities cannot be ruled out in general.

SERION ELISA *agile* SARS-CoV-2 IgG
To determine detection of cross-reactive antibodies directed against different parameters sera were analyzed with SERION ELISA *agile* SARS-CoV-2 IgG and a commercially available anti-SARS-CoV-2 IgG ELISA. Positive sera (9 or 10 sera each) for Epstein-Barr Virus VCA IgG, Adenovirus IgG, Influenza A Virus IgG, Epstein-Barr Virus EA IgG and other coronaviruses have been tested as well as sera positive for rheumatoid factor (RF) and anti-nuclear antibodies (ANA). Within this internal evaluation no potential cross-reactivities have been observed. Other cross-reactivities cannot be ruled out in general.

8.4 Interfering substances

SERION ELISA *agile* SARS-CoV-2 IgA/IgG
To determine the influence of interfering substances, sera with different reactivities were analyzed with SERION ELISA *agile* SARS-CoV-2 IgA/IgG. No interferences have been detected for sera with concentrations up to 2.00 g/L hemoglobin, 11.50 g/L lipemia/triglyceride, 0.201 g/L bilirubin (conjugated and unconjugated), 1.6 mg/ml EDTA, 16 IU/ml heparin or 0.106 mol/l citrate.

8.5 Disposal

Please observe the relevant statutory requirements!

8.6 Limitation of the test

Please note that diagnosis should never be solely based on serological data. Rather, serological results have to be interpreted in the context of the clinical picture and other diagnostic findings.

9 LITERATUR / REFERENCES / RÉFÉRENCES / BIBLIOGRAFIA / BIBLIOGRAFÍA / REFERÊNCIAS / ΑΝΑΦΟΡΕΣ / ODKAZY / BIBLIOGRAFIA / ЛИТЕРАТУРА / REFERENCER / REFERENSER / REFERENCIE / REFERENCE / REFERANSER / REFERENCIÁK

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SERION ELISA *agile*

Symbole auf den Etiketten/ symbols on labels/ symboles et étiquettes/ simboli sulle etichette/ символы на этикетках/símbolos sobre las etiquetas/ σύμβολα στις ετικέτες/ símbolos nos rótulos / Symboly na štítcích / symboler på etiketter/ symboler på etiketterna/ Symbole na etykietach/ symboly na označení/ Simboli na oznakah/ symbol på etiketter

Hersteller/ Manufacturer/ Fabricant/ Produttore/Производитель/ Fabricante/ Κατασκευαστής/ Fabricante/ Výrobce/ Fremstiller/ Tillverkare/ Producent/ Výrobca/ Izdelovalec/ Produsent

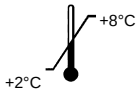
Ausreichend für 96 Tests/ sufficient for 96 tests/ suffisant pour 96 tests/ sufficiente per 96 test/ достаточно для 96 тестов / suficiente para 96 pruebas/ επαρεκεί για 96 δοκιμασίες/ suficiente para 96 ensaios/ stačí na 96 testů/ nok til 96 test/ tillräckligt för 96 tester/ Wystarcza na 96 testów/ postačuje na 96 testov/ Zadostuje za 96 testov/ Tilstrekkelig til 96 tester

LOT

Charge/ lot/ lot / lotto/ lote/ παρτίδα/ lote/ šarže/ lot/ lot/ seria/ šarža/ serija/ lot /lot

REF

Referenz oder Bestellnummer/ reference or order number/ numéro de référence ou de commande/ numero di riferimento o ordinazione/ ссылка или номер для заказа / referencia o número de pedido/ Αριθμός αναφοράς ή παραγγελίας/ referência ou número para encomenda/ reference nebo číslo objednávky/ reference eller bestillingsnummer/ referens eller beställningsnummer/ Numer referencyjny lub numer zamówienia/ referenčné číslo alebo číslo objednávky/ referenčna ali kataloška številka/ Referanse eller ordrenummer



Lagern zwischen 2 und 8 Grad Celsius/ store between 2 and 8 degree celsius/ entre 2 et 8 degré celsius/ conservare a temperatura compresa tra 2 e 8 gradi centigradi/ хранить при температуре от 2 до 8 градусов цельсия / conservar entre 2 y 8 grados celsius/ Φύλαξη μεταξύ 2 και 8 βαθμούς Κελσίου/ Armazenar entre 2º e 8º Celsius/ uchovávejte při teplotě 2 až 8 °C/ opbevares mellem 2 og 8 grader celsius/ förvara vid 2 till 8 grader Celsius/ Przechowywać w temp. pomiędzy 2 a 8 stopni Celsjusza/ skladovať pri teplote 2 až 8 stupňov Celzia/ Shranjujte pri temperaturi od 2 do 8 C/ Oppbevares mellom 2 og 8 grader Celsiu

CE

CE-Markierung bei Erfüllung der IVD Richtlinie 98/79 EG/ CE marking according to IVD guideline 98/79 EC/ Étiquetage CE selon les directives DIV/ marcatura CE in conformità alla direttiva IVD 98/79 EC/ маркировка CE согласно директивам IVD 98/79 /marca CE según la directiva IVD 98/79 CE/ Σήμανση CE σύμφωνα με την οδηγία IVD 98/79 ΕΕ/ Marcação CE de acordo com a Directiva 98/79/ značení CE podle směrnice IVD 98/79/ES/ CE-mærkning iht. IVD-retningslinje 98/79/EF/ CE-märkning enligt riktlinjerna för IVD i direktiv 98/79/EC/ Oznakowanie CE zgodne z wytycznymi dot. diagnostyki in vitro 98/79 EC/ označenie CE podľa smernice IVD 98/79/ES/ oznaka CE, skladna s smernico IVD 98/79/ES/ CE-merking i henhold til IVD-retningslinjer 98/79/EØF

CE 0197

CE-Markierung bei Erfüllung der IVD Richtlinie 98/79 EG gemäß Anhang II, Liste B/ CE marking according to IVD guideline 98/79 EC according to annex II, list B/ Étiquetage CE selon les directives DIV 98/79 CE selon l'annexe II, liste B/ marcatura CE in conformità alla direttiva IVD 98/79 EC secondo l'allegato II, elenco B/ маркировка CE согласно директивам IVD 98/79, приложение II, список B / marca CE según la directiva IVD 98/79 CE de acuerdo con el anexo II, lista B/ Σήμανση CE σύμφωνα με την οδηγία IVD 98/79 ΕΕ, σύμφωνα με το παράρτημα II, κατάλογο B/ Marcação CE de acordo com a Directiva 98/79/ CE relativo aos dispositivos médicos de diagnóstico *in vitro*, segundo a lista B do anexo II/ značení CE podle směrnice IVD 98/79/ ES podle příloh II, seznamu B/ CE-mærkning iht. IVD-retningslinje 98/79 /EF iflg. anneks II, liste B/ CE-märkning enligt riktlinjerna för IVD i direktiv 98/79/EC, bilaga II, lista B/ Oznakowanie CE zgodne z wytycznymi dot. diagnostyki in vitro 98/79 EC, zgodnie z aneksem II, lista B/ označenie CE podľa smernice IVD 98/79 ES v znení dodatku II, zoznam B/ oznaka CE, skladna s smernico IVD 98/79/ES in seznamom B v Dodatku II/ CE-merking i henhold til IVD-retningslinjer 98/79/EØF, tillegg II, liste B

Verfallsdatum/ expiry date/ date d'expiration/ data di scadenza/ срок годности до /fecha de caducidad/ ημερομηνία λήξης/ data de validade/ datum exspirace/ udløbsdato/ förfallodatum/ data upływu ważności/ dátum exspirácie/ datum izteka roka uporabnosti/ utløpsdatp

MTP

Mikrotiterplatte (brechbare Streifen)/ microtiter plate (breakable strips)/ plaque de microtitration (bandelettes détachables)/ piastra per microtitolazione (strisce separabili)/ микротитровальная панель (отрывные стрипы) /placa de microtitulación (tiras rompibles)/ Πλάκα μικροτιτλοποίησης (αποσπωμενες ταινίες)/ placa de microtitulação (tiras quebráveis)/ mikrotitrační deska (rozlomitelné proužky)/ mikrotiterplade (afbrækkelige strimler)/ mikrotiterplatta (brytbara strips)/ Płytka mikrotitracyjna (paski do odrywania)/ mikrotitračná platnička (rozlomiteľné prúžky)/ vsebnik za mikrotitriranje (z razdelki, ki jih je mogoče odlomiti)/ Mikrotiterplate (avbrytbare strips)

STD

Standardserum/ standard serum/ Sérum standard/ siero standard/ стандартная сыворотка /suero patrón/ πρότυπος ορός/ soro padrão/ standardní sérum/ standardserum/ standardserum/ Surowica standardowa/ štandardné sérum/ standardni serum/ Standardserum

NEG

Negativkontrolle/ negative control/ Contrôle négatif/ controllo negativo/ отрицательные контроли /control negativo/ αρνητικός έλεγχος/ controlo negativo/ negativní kontrola/ negativ kontrol/ negativ kontroll/ Kontrola negatywna/ negatívna kontrola/ negativna kontrola/ Negativ kontroll

Conjugate

Alkalisches Phosphatase Konjugat antihuman/ alkaline phosphatase conjugate anti-human/ conjugué phosphatase alcaline anti-humain/ coniugato con fosfatasi alcalina anti-umano/ античеловеческий щелочной конъюгат фосфатазы / conjugado anti humano de fosfatasa alcalina/ Σύζευξη αλκαλικής φωσφατάσης/ conjugado anti-humano com fosfatase alcalina/ konjugát alkalické fosfatázy anti-humánní/ alkalisk phosphatase konjugat antihumant/ antihumant alkaliskt fosfatas-konjugat/ Anty-ludzki koniugat fosfatazy alkalicznej/ konjugát antihumánnej alkalickej fosfatázy/ konjugat alkalne fosfataze, antihumani/ Alkalisk fosfatase-konjugat, anti-humant

Diluent S5

Verdünnungspuffer für Serum/ dilution buffer for sera/ sérum pour le tampon de dilution/ tampone di diluizione per sieri / разбавляющий буфер для сыворотки / solución amortiguadora para los sueros/ ρυθμιστικό διάλυμα αραίωσης για ορούς/ tampão de diluição para soro/ ředicí pufr pro séra/ fortyndingsbuffer til sera/ spädningsbuffert för serum/ bufor rozcieńczający do surowic / pufor na riedenie sér/ pufer za redčenje seruma/ Fortynningsbuffer til serum

WASH

Waschlösungskonzentrat/ washing solution concentrate/ concentré de solution de lavage / soluzione di lavaggio concentrata / промывочный концентрат /concentrado de solución de lavado/ συμπύκνωμα έκπλυσης/ concentrado de solução de lavagem/ koncentrát promývacího roztoku/ vaskeopløsningskoncentrat/ tvättlösningskoncentrat/ Stężony roztwór do płukania/ koncentrát premývacieho roztoku/ koncentrat za raztopino za izpiranje/ Vaskeløsningskonsentrat

Substrate

pNPP Substrat/ pNPP substrate/ substrat Pnpp/ substrato pNPP/ pNPP субстрат / sustrato pNPP/ Υπόστρωμα pNPP/ substrato pNPP/ pNPP substrát/ pNPP-substrat/ pNPP-substrat/ Substrat pNPP/ substrát pNPP/ substrat pNPP/ pNPP-substrat

STOP

Stopplösung/ stopping solution/ solution d'arrêt/ soluzione di arresto/стоп-раствор/ solución de parada/ διάλυμα διακοπής/ solução de paragem/ zastavovací roztok/ stopopløsning/ stopplösning/ roztwór zatrzymujący reakcję/ ukončovací roztok/ raztopina za ustavitev reakcije/ stoppeløsning

INFO

Gebrauchsanweisung, Zertifikat (Standardkurve und Auswertetabelle), CD/ instructions, certificate (standard curve and evaluation table), CD/ instructions, certificat (courbe de référence et tableau d'évaluation), CD/ istruzioni per l'uso, certificato (curva standard e tabella interpretativa), CD/ Инструкция по применению, сертификат (стандартная кривая и таблица для оценки), компактный диск /instrucciones, certificado (curva patrón y tabla de evaluación), CD/ Οδηγίες χρήσης, Πιστοποιητικό (πρότυπη καμπύλη και

πίνακας υπολογισμού), CD/ instruções, certificado (curva padrão e tabela de avaliação), CD/ (standardní křivka a vyhodnocovací tabulka), CD/ brugsanvisning, certifikat (standardkurve og evalueringstabel), CD/ instruktioner, certifikat (standardkurva och utvärderingstabell), CD/ Instrukcje, certyfikat (krzywa standardowa i tabela do określania wyników/ CD/ pokyny, certifikát (štandardná krivka a hodnotiaca tabuľka), disk CD/ navodila, certifikat (standardna krivulja in ocenjevalna tabela), CD/ Instruksjoner, sertifikat (standardkurve og evalueringstabell), CD

RTU — gebrauchsfertig/ ready-to-use/ prêt à l'emploi/ pronto per l'uso/ готовый к использованию /listo para usar/ έτοιμο προς χρήση/ pronto a utilizar/ připravený k použití/ klar til brug/ bruksfärdig/ gotowy do użycia/ pripravené na použitie/ pripravljen za uporabo/ klar til bruk

CONC — Konzentrat/ concentrate/ concentré/ concentrato/ концентрат / concentrado/ Συμπύκνωμα/ concentrado/ koncentrát/ koncentrat/ koncentrat/ Koncentrat/ koncentrát/ koncentrat/ Konsentrat

DIL — verdünnen oder lösen in/ dilute or disolve in/ diluez ou dissoudre dans/ diluire o sciogliere in/ разбавить или растворить в /diluir o disolver en/ αραίωση ή διάλυση σε/ diluir ou dissolver em/ nařeďte nebo rozpusťte v/ fortynd eller opløs i/ späd eller lös i/ Rozcieńczyć lub rozpuścić w/ rozriediť alebo rozpustiť v/ razredčite ali raztopite v/ Fortynnes eller løses opp i

AQUA — destilliertes Wasser/ aqua detillata/ eau distillée/ acqua distillata/ дистиллированная вода /agua destilada/ αποσταγμένο νερό/ água destilada/ destilovaná voda/ destilleret vand/ destillerat vatten/ woda destylowana/ destilovaná voda/ destilirana voda/ Destillert vann

IVD — In-vitro Diagnostik Anwendung/ in-vitro diagnostic use/ utilisation en diagnostic in-vitro/ uso diagnostico in vitro/ использование в диагностике ин-витро /uso diagnóstico in-vitro/ Διάγνωση, χρήση in-vitro/ para diagnóstico *in vitro*/ diagnostické použití in-vitro/ til in-vitro diagnostik/ *in vitro*-diagnostisk användning/ do diagnostyki in vitro/ diagnostické použitie in-vitro/ uporaba pri diagnostiki *in vitro*/ In vitro-diagnostisk bruk

 — Gebrauchsanweisung beachten/ consult instructions for use/ se référer à la notice d'instruction/ consultare le istruzioni per l’uso/ ознакомьтесь с инструкцией по использованию/ consúltense las instrucciones de uso/ συμβουλευτείτε τις οδηγίες χρήσης/ consultar as instruções de utilização/ čtěte návod k použití/ se brugsanvisningen/ se bruksanvisningen/ zapoznaj się z instrukcją stosowania/ dodržuj návod na použitie/ glejte navodila za uporabo/ se bruksanvisningen/ figyelembe kell venni a használati utasítást

Manufacturer

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