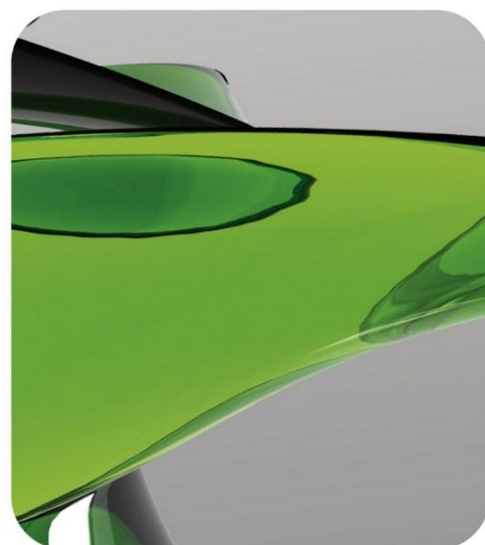




AESKULISA[®]
THE DIAGNOSTIC TOOL THAT WORKS

INSTRUCTION MANUAL

AESKULISA[®] Clostridium tetani IgG
Ref 6102



Updates	
Current Version	V.003 as of 2025-03-13
Previous Version	V.002 as of 2021-04-07
Update in Section	address, chapter 13
Reasons for Updates	UDI implementation, update address, adding chapter 13



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1 Intended Use

The AESKULISA® Clostridium tetani IgG test is a qualitative and quantitative immunoassay for the demonstration of human IgG antibodies in serum or plasma directed against tetanus toxoid of *Clostridium tetani*. The AESKULISA® Clostridium tetani IgG test serves for immune status determination.

The interpretation of test results has to be considered in combination with the patient's clinical picture. A diagnosis should not be based on the results of the performed test only, but should be made after all clinical and laboratory findings have been evaluated. For confirmation, further investigations should be carried out. AESKULISA® immunoassays are designed exclusively for *in vitro* diagnostic use by qualified personnel only, who are trained, specially advised and familiar with the laboratory methods.

2 Diagnostic Relevance

Clostridium tetani is an obligate anaerobic, gram-positive, rod shaped bacterium distributed globally in the soil. The causative agent of tetanus (lockjaw) gains entry into the organism through open wounds. The pathogen proliferates and produces toxins under anaerobic conditions. The proteolytic tetanospasmin damages the motor neurons which results in the characteristic muscle cramps.

The incubation time varies between three days and three weeks and maybe, occasionally, as long as several months. Initially, flu-like symptoms with sweating occur. Inhibition of opening the mouth (trismus) and facial muscle spasms produce a characteristic grimacing facial expression (*risus sardonicus*). Subsequently, muscle cramps occur in the torso and the extremities. The disease is often fatal if left untreated. The diagnosis is performed on the basis of the typical clinical picture. The disease is treated by the administration of penicillin or other antibiotics.

Vaccines against tetanus have been available for several years. In Germany, the Standing Committee on Vaccination located at the Robert-Koch-Institute recommends the administration to all children after the second month of age. In general, a combined immunization against tetanus and diphtheria is performed. In order to maintain immunity, refreshing immunizations in regular intervals should be carried out.

3 AESKULISA® Test Principle

The AESKULISA® (AESKU Enzyme Linked Immunosorbent Assay) is an immunoassay, which is particularly suited to the determination of antibodies. The reaction is based on the specific interaction of antibodies with their corresponding antigen. The test strips of the AESKULISA® microtiter plate are coated with specific antigens of the pathogen of interest. If antibodies in the patient's sample are present, they bind to the fixed antigen. A secondary antibody, which has been conjugated with the enzyme peroxidase, detects and binds to the immune complex. A colorless substrate is then converted into the colored product. The signal intensity of this reaction product is proportional to the antibody activity in the sample and is measured photometrically.

4 Antigen

Antibody detection with the AESKULISA® Clostridium tetani IgG immunoassay is based on tetanus toxoid of *Clostridium tetani*.

5 AESKULISA® Test Components

Test Component	Color of Solution	Color of Cap	Pieces / Volume
Break apart microtiter test strips [MP] each with eight antigen coated single wells (altogether 96), 1 frame. The test-specific coating material is inactivated.	-	-	12 pieces
Calibrator A – D [CAL] (ready-to-use) Human serum or chimeric antibody in protein containing solution (BSA); colored; preservative ProClin. The antibody activities of the calibrators are indicated on their labels and on the quality control certificate of the AESKULISA® immunoassay.	yellow*	white	4 x 1,5 ml
Positive Control [CON +] (ready-to-use) Human serum or chimeric antibody in protein containing solution (BSA); colored; preservative ProClin.	yellow*	red	1 x 1,5 ml
Negative Control [CON –] (ready-to-use) Human serum or chimeric antibody in protein containing solution (BSA); colored; preservative ProClin.	yellow*	green	1 x 1,5 ml
Sample Buffer [SB 5x], 5x conc. Protein containing solution (BSA); colored; preservative < 0.1 % sodium azide. The sample buffer of AESKULISA® IgM immunoassays contains Rf absorbent.	IgG, IgA: yellow IgM: green	white	1 x 20 ml
Wash Buffer [WASHB 50x], 50x conc. Solution with tween 20; colored; preservative ProClin.	green	white	1 x 20 ml
Anti-Human IgA, IgG or IgM Conjugate [CONJ] (ready-to-use) Anti-human IgA, IgG or IgM polyclonal antibody, conjugated to horseradish peroxidase, stabilized with protein containing solution (BSA); colored; preservative ProClin.	IgA: red IgG: blue IgM: green	IgA: red IgG: blue IgM: green	1 x 15 ml
Substrate [SUB] (ready-to-use) Stabilized TMB/H ₂ O ₂ .	colorless	black	1 x 15 ml
Stop Solution [STOP] (ready-to-use) 1 M Hydrochloric Acid (HCl).	colorless	white	1 x 15 ml
Quality Control Certificate	-	-	1 piece
Instruction for Use	-	-	1 piece

*Color intensity is increasing with antibody activity.

6 Material required, but not provided

- Common laboratory equipment including glassware (cylinder 100 – 1000 ml), test tubes for dilutions, vortex mixer, precision pipettes (10, 100, 200, 500, 1000 µl) or adjustable multipipette (100 – 1000 µl).
- Photometer for microtiter plates with filter, wavelength 450 nm, recommended reference wavelength 600 nm – 690 nm (e.g. 620 nm)
- Microplate washing device
(300 µl repeating or multichannel pipette or automated wash system)
- Adsorbent paper
- *Aqua dest.*
AESKULISA® immunoassays are designed to be used with purified water according to the definition of the United States Pharmacopeia (USP 26 - NF 21) and the European Pharmacopeia (Eur. Ph. 4th ed.).

7 Storage and Stability

The microtiter test strips should always be stored with desiccant in the properly sealed aluminum bag. If stored properly in their original containers and at 2 – 8 °C / 35.6 – 46.4 °F, all reagents and the microtiter plate are stable – even after opening – until their expiry date indicated on the label. Diluted solutions are stable at 2 – 8 °C / 35.6 – 46.4 °F for four weeks.

8 AESKULISA® Test Procedure

8.1 General Directions for Use

Optimum results can only be achieved if the instructions are strictly followed. Only use AESKULISA® reagents when using AESKULISA® immunoassays. The test components must not be exchanged for reagents of other manufacturers.

Microtiter plates, calibrators, controls and conjugates of AESKULISA® immunoassays are test- and lot-specific and must not be used in other lots. The evaluations of the calibrators and controls are indicated on the quality control certificate provided with the AESKULISA® test kit. Washing solution, substrate and stop solution can be used for all AESKULISA® immunoassays irrespective of lot and test.

The sample buffer of the AESKULISA® IgA and IgG immunoassays can be used for all AESKULISA® IgA and IgG immunoassays (REF 6xxx) irrespective of lot and test. The sample buffer of the AESKULISA® IgM immunoassays contains Rf absorbent and can be used for all AESKULISA® IgM immunoassays for the diagnosis of infectious diseases (REF 6xxx) irrespective of lot and test.

To avoid contamination, aseptic techniques should be used when removing aliquots from the reagent tubes. Conjugate and substrate solution should never be pipetted with tips that are contaminated with other reagents. Reproducibility of test results is dependent on thorough homogenization of the reagents. Therefore, reagent and sample dilutions should be agitated before use. Inappropriate dilution may result in a loss of sensitivity.

Be sure to pipette carefully and comply with the given incubation times and temperatures. Adequate washing avoids test unspecificities.

Avoid the exposure of reagents to strong light during storage and incubation. Never allow the test components to reach temperatures higher than 37 °C / 98.6 °F. Reagents must be tightly closed after use to avoid evaporation and contamination. Take care to not mix-up the caps of the vials. The test components must not reach temperatures above 37 °C / 98.6 °F.

AESKULISA® immunoassay test runs are only valid if the validation criteria are fulfilled.

8.2 Preparation of Reagents

All components and the microtiter plate must be brought to room temperature (20 – 25 °C / 68 – 77 °F) before use. Liquid reagents must be mixed thoroughly. For the dilution of buffer concentrates only clean glass ware must be used.

8.2.1 Microtiter Strips (ready-to-use)

The microtiter test strips are labeled with abbreviations for the coated antigen.

8.2.2 Calibrators (ready-to-use)

The calibrators CAL A – CAL D are ready-to-use and must not be diluted any further. Calibrators must be used for each test run, independent of the number of microtiter test strips to be used.

8.2.3 Controls (ready-to-use)

The positive control CON+ and the negative control CON– are ready-to-use and must not be diluted any further. Controls must be used for each test run, independent of the number of microtiter test strips to be used.

Depending on national guidelines, laboratories can also validate their own controls and use them alternatively.

8.2.4 Sample Buffer (5x conc.)

The concentrated sample buffer is to be diluted 1:5 with distilled water prior to use (e. g. 20 ml + 80 ml). The sample buffer of AESKULISA® IgM immunoassays contains Rf absorbent.

8.2.5 Wash Buffer (50x conc.)

The concentrated wash buffer is to be diluted 1:50 with distilled water prior to use (e. g. 20 ml + 980 ml).

8.2.6 Anti-Human IgA, IgG or IgM POD Conjugate (ready-to-use)

The conjugate is ready-to-use.

8.2.7 Substrate (ready-to-use)

The TMB substrate must always be pipetted with brand new tips in order to avoid contamination. Avoid intense exposure of TMB solution to light.

8.2.8 Stop Solution (ready-to-use)

The stop solution is ready-to-use.

8.3 Preparation of Samples

8.3.1 Sample Material

The use of freshly collected serum or EDTA plasma samples is recommended. Icteric, lipemic, hemolytic or bacterially contaminated samples should not be used. Samples with particles should be cleared by centrifugation ($< 1000 \times g$). The supernatant should be taken off and used for further analysis. Samples must not be thermally inactivated.

8.3.2 Sample Dilution

The samples are to be diluted 1:101 (e. g. $10 \mu\text{l} + 1000 \mu\text{l}$) with 1x sample buffer and mixed thoroughly.

8.3.3 Pre-Absorption of Rheumatoid Factors with AESKULISA® IgM

Rheumatoid factors (Rf) are autoantibodies mainly of the IgM class, which preferably bind to IgG immune complexes. The demonstration of pathogen-specific IgM antibodies might lead to false-positive test results by the presence of such unspecific rheumatoid factors. Furthermore weak-binding pathogen-specific IgM antibodies might be displaced by stronger-binding IgG antibodies leading to false-negative IgM test results. Therefore, the sample buffer of AESKULISA® IgM immunoassays contains a specific Rf absorbent. Rf absorption is performed by dilution of the patient's sample in 1x dilution buffer of the AESKULISA® IgM immunoassay and subsequent incubation for a minimum of 15 minutes at room temperature.

8.3.4 Sample Storage

Patient samples should be used within 8 hours, respectively stored tightly closed at $2 - 8 \text{ }^{\circ}\text{C}$ / $35.6 - 46.4 \text{ }^{\circ}\text{F}$ up to 48 hours. Extended storage is possible at $\leq -20 \text{ }^{\circ}\text{C}$ / $-4 \text{ }^{\circ}\text{F}$. Avoid repeated freezing and thawing.

8.4 Test Performance

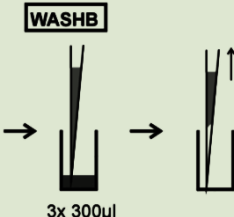
8.4.1 Pipetting Scheme

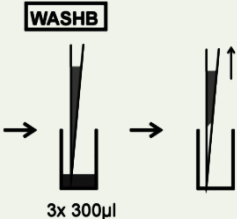
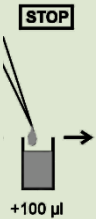
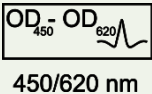
Depending on the intended quantitative or qualitative test evaluation when using AESKULISA® immunoassays, the following pipetting scheme is recommended:

Quantitative Evaluation					Qualitative Evaluation				
	1	2	3	4		1	2	3	4
A	CAL A	P3			A	CON–	P5		
B	CAL B	P4			B	CAL B	P6		
C	CAL C	P5			C	CAL B	...		
D	CAL D	P6			D	CON+			
E	CON–	...			E	P1			
F	CON+				F	P2			
G	P1				G	P3			
H	P2				H	P4			
	CAL A	Calibrator A				CON–	Negative Control		
	CAL B	Calibrator B				CAL B	cut off Control		
	CAL C	Calibrator C				CON+	Positive Control		
	CAL D	Calibrator D							
	CON–	Negative Control							
	CON+	Positive Control							

8.4.2 Test Procedure

Place the required number of cavities in the frame and prepare a protocol sheet.
For manual use processing at room temperature is recommended.

Step	Symbol	Description
1. Addition of calibrators, controls, and diluted samples		Addition of each 100 µl ready-to-use calibrators, controls and diluted samples into the appropriate wells.
2. Sample incubation		Incubation for 30 +/- 3 minutes at 20 – 32 °C / 68 – 89.6 °F.
3. 3 x Wash		Aspirate the solution, fill each well with 300 µl 1x wash buffer, aspirate the washing solution and repeat the washing procedure another two times; dry by tapping the microtiter plate on a paper towel.

4. Addition of conjugate		Addition of each 100 µl ready-to-use conjugate solution into the appropriate wells.
5. Conjugate incubation		Incubation for 30 +/- 3 minutes at 20 – 32 °C / 68 – 89.6 °F.
6. 3 x Wash		Aspirate the solution, fill each well with 300 µl 1x wash buffer, aspirate the washing solution and repeat the washing procedure another two times; dry by tapping the microtiter plate on a paper towel.
7. Addition of substrate		Addition of each 100 µl ready-to-use substrate solution into the appropriate wells.
8. Substrate incubation		Incubation for 30 +/- 3 minutes at 20 – 32 °C / 68 – 89.6 °F. Avoid exposure to strong light.
9. Addition of stop solution		Addition of each 100 µl ready-to-use stop solution into the appropriate wells using the same order as pipetting the substrate.
10. Incubation		Optional: Incubation for 5 minutes.
11. Agitation		Agitate the microtiter plate carefully for 5 seconds.
12. Analysis		Read optical density (OD) within 30 minutes at 450 nm against a recommended reference wavelength of 620 nm.

8.5 Automated Test Procedure

The automated processing of AESKULISA® immunoassays is performed analogous to manual use. The specified test procedure must be adhered to. The AESKULISA® immunoassays are evaluated for use with a range of different instruments; the corresponding assayfiles are available on request. For automated processing of AESKULISA® immunoassays on other instruments, evaluation of assayfiles by the test kit supplier in collaboration with and instrument provider is recommended. The correct automated processing of AESKULISA® immunoassays must finally be validated by the user.

9 AESKULISA® Test Evaluation

9.1 Standardization

The AESKULISA® Clostridium tetani IgG immunoassay has been standardized using the International Standard Preparation 13/240 of the World Health Organization (WHO) as a reference. Quantitative test results are expressed in IU/ml.

9.2 Quantitative Evaluation

Generally, the quantitative data evaluation is recommended when using AESKULISA® immunoassays. For generation of a standard curve, the optical measurement signals (optical density, OD) of the calibrators are plotted against their antibody activity (in IU/ml or U/ml). The antibody activities of the calibrators are indicated on the lot-specific quality control certificate provided with the AESKULISA® test kit. For optimal results, log/lin coordinates and a 4-parameter logistic (4 PL) fit is recommended. Using the generated curve, antibody activities of the samples can be directly evaluated from the optical measurement signals.

9.3 Borderline Range

The borderline range of the AESKULISA® immunoassay is specified on the quality control certificates provided with the test kit 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. As a consequence of different seroprevalences and vaccination programs in individual countries, we recommend to verify the borderline range by own analysis and adapt if necessary.

9.4 Measurement Range

The measurement range of the AESKULISA® immunoassay is specified on the quality control certificate provided with the test kit. The linearity of dilution as well as a high precision and reproducibility of test results has been demonstrated within this range in comprehensive evaluation studies. Samples with test results above the upper limit of quantification should be reported as >max. Samples with test results below the lower limit of quantification should be reported as <min. 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.

9.5 Qualitative Evaluation

The qualitative data evaluation when using AESKULISA® immunoassays is performed by comparison of the optical measurement signal (optical density, OD) of the patient's sample with the mean optical measurement signal of the calibrator B (cut off calibrator CAL B) tested in duplicate. If the patient's sample reaches OD values within the borderline range of +/- 20 % around the mean OD of the cut off calibrator CAL B, the sample is considered as equivocal. Samples with higher OD values are evaluated as positive, samples with lower OD values are evaluated as negative.

9.6 Criteria of Validity

The following criteria of validity have to be fulfilled for a valid test run:

- OD CAL A < 0.3
- OD CAL A < OD CAL B < OD CAL C < OD CAL D
- OD CAL D > 1.3
- The negative control must be evaluated as negative.
- The positive control must not be evaluated as negative.
- By use of quantitative AESKULISA® immunoassays, the positive control must present an antibody activity within the validity range indicated on the quality control certificate of the AESKULISA®.
- By use of qualitative AESKULISA® immunoassays, the variation of the OD values of the cut off calibrator B, tested in duplicate, must not be higher than 20 %.

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

In case of an invalid test run, the expiration dates of the (ready-to-use) reagents, the storage conditions, the incubation times and temperatures, the pipettes, the washer incl. washing cycles, the photometer as well as other devices used should be verified. If no explicable cause for an invalid test run or other aberrant results can be identified, please contact the supplier or manufacturer of the test kit.

9.7 Interpretation of Test Results

A positive test result in AESKULISA® immunoassays confirms the presence of specific antibodies. A negative result indicates that no clinically relevant antibody activity 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 week intervals, in parallel.

Basic Interpretation Scheme of Serological Test Results

IgG Activity	Evaluation
< 0,01 IU/ml	No immune protection Booster shot or basic immunization
0,01 – 0,1 IU/ml	No safe immune protection Booster shot recommended
0,1 – 0,5 IU/ml	Adequate immune protection Booster shot leads to long-term immune protection
0,5 – 1,0 IU/ml	Adequate immune protection Control of antibody activity in 2 years
1,0 – 5,0 IU/ml	Long-term immune protection Control of antibody activity in 5 - 10 years
> 5,0 IU/ml	Long-term immune protection Control of antibody activity after 10 years

The interpretation of test results has to be considered in combination with the patient's clinical picture. A diagnosis should not be based on the results of the performed test only, but should be made after all clinical and laboratory findings have been evaluated. For confirmation, further investigations should be carried out.

10 AESKULISA® Performance Characteristics

10.1 Analytical Sensitivity and Specificity

The Limit of Blank (LoB) was assessed by multiple analysis of wells containing sample buffer only. The Limit of Detection (LoD) was assessed by multiple analysis of negative samples.

	Analytical Sensitivity
Limit of Blank (LoB)	0.01 IU/ml
Limit of Detection (LoD)	0.03 IU/ml

The analytical specificity of the AESKULISA® immunoassays was assessed by addition of potentially interfering substances to samples and determination of their influence on the measurement. A significant influence of hemoglobin (up to 800 mg/dl), bilirubin (up to 20 mg/dl), bilirubin conjugate (up to 20 mg/dl) and triglycerides (up to 3000 mg/dl) on test results was not observed.

10.2 Diagnostic Sensitivity and Specificity

Sensitivity and specificity of the AESKULISA® Clostridium tetani IgG immunoassay were assessed by the analysis of 180 serum samples from healthy blood donors using the Tetanus IgG ELISA immunoassays of a leading European manufacturer as a reference test.

	AESKULISA® Clostridium tetani IgG
Sensitivity	> 99 %
Specificity	> 99 %

In both immunoassays an identical *cut off* of 0.1 IU/ml was used for the calculation of sensitivity and specificity.

10.3 Reference Range of Healthy Individuals

Testing of serum samples from unselected blood donors with AESKULISA® Clostridium tetani IgG immunoassay resulted in the following distribution:

AESKULISA®	Nr. of Samples	Negative	Borderline	Positive
Clostridium tetani IgG	100	2 (2.0 %)	0 (0.0 %)	98 (98.0 %)

A *cut off* of 0.1 IU/ml was used for the evaluation.

10.4 Precision

Precision and reproducibility of test results obtained with AESKULISA® Clostridium tetani IgG were assessed by the determination of the intra- and interassay precision as well as the lot-to-lot variance by the analysis of multiple samples of different antibody activities.

AESKULISA® Clostridium tetani IgG

Sample	Extinction (OD)	IgG Activity	Intraassay CV (IU/ml)	Interassay CV (IU/ml)	Lot-to-Lot CV (IU/ml)
Serum 1	0.283	0.06 IU/ml	7.8 %	8.6 %	6.8 %
Serum 2	0.408	0.10 IU/ml	5.2 %	7.0 %	6.8 %
Serum 3	0.949	0.30 IU/ml	6.3 %	9.1 %	6.1 %
Serum 4	1.508	0.57 IU/ml	4.9 %	6.3 %	6.5 %
Serum 5	2.023	0.89 IU/ml	5.6 %	6.4 %	7.6 %

More comprehensive study reports on additional performance characteristics such as analytical sensitivity, analytical specificity, trueness, precision, accuracy, recovery, linearity, limits of detection and measurement range are available on request.

11 Safety Measures

11.1 Recommendations and Precautions

AESKULISA® immunoassays are designed exclusively for *in vitro* diagnostic use by qualified personnel only, who are trained, specially advised and familiar with the laboratory methods. All kit reagents and human specimens should be handled carefully, using established good laboratory practice. If the product is damaged or product information - including the labelling - is wrong or incorrect, please contact the manufacturer or supplier of the test kit.

Do not pipette by mouth. Do not smoke, eat or drink in areas in which specimens or kit reagents are handled. Avoid direct contact by wearing disposable gloves, laboratory coat and safety glasses while handling kit reagents or specimens. Wash hands thoroughly afterwards.

This product contains dilutions of human serum samples. Although all serum samples have been tested and found negative for anti-HIV 1 and 2-ab, HBs-Ag (Hepatitis B-Virus-surface Antigen) and anti-HCV-ab, they should be considered potentially infectious. This product contains dilutions of animal origin. Please observe the relevant statutory requirements.

This kit contains potentially hazardous components, which might be irritant to eyes and skin.

Individual test components contain sodium azide (NaN₃) as a preservative. Sodium azide may be toxic if ingested or adsorbed by skin or eyes. Sodium azide may react with lead and copper plumbing to form highly explosive metal azides. On disposal, flush with a large volume of water to prevent azide build-up.

Calibrators and controls as well as patient samples should be considered potentially infectious and handled according to national laws. Patient samples and other potentially infectious material should be decontaminated after the test run.

Reagents should be stored safely and be inaccessible to children.

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the member state in which the user and/or the patient is established.

A summary of Safety and Performance is available via Eudamed as well as upon request.

11.2 Disposal

For decontamination and disposal please follow the recommendations of the CDC as well as the relevant local and national statutory requirements.

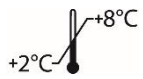
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13 Regulatory Symbols

IVD	- Diagnosi in vitro - Pour diagnostic in vitro - In Vitro Diagnostikum - Para uso Diagnóstico in vitro	- For in vitro diagnostic use - Para uso diagnóstico in vitro - In Vitro Διαγνωστικό μέσο
REF	- Numero d'ordine - Référence Catalogue - Bestellnummer - Número de catálogo	- Catalogue number - Número de catálogo - Αριθμός παραγγελίας
LOT	- Descrizione lotto - Lot - Chargen Bezeichnung - Lote	- Lot - Lote - Χαρακτηρισμός παρτίδας
UDI	- Identificatore univoco del dispositivo - Identifiant unique de l'appareil - eindeutige Produktidentifizierung - Identificador único do dispositivo	- Unique Device Identifier - Identificador único del dispositivo - Μοναδικό αναγνωριστικό συσκευής
CE	- Conformità europea - Déclaration CE de Conformité - Europäische Konformität - Declaração CE de Conformidade	- EC Declaration of Conformity - Declaración CE de Conformidad - Ευρωπαϊκή συμφωνία
	- 96 determinazioni - 96 tests - 96 Bestimmungen - 96 Testes	- 96 tests - 96 pruebas - 96 προσδιορισμοί
	- Rispettare le istruzioni per l'uso - Voir les instructions d'utilisation - Gebrauchsanweisung beachten - Ver as instruções de uso	- See instructions for use - Ver las instrucciones de uso - Λάβετε υπόψη τις οδηγίες χρήσης
	- Da utilizzarsi entro - Utilise avant le - Verwendbar bis - Utilizar antes de	- Use by - Utilizar antes de - Χρήση μέχρι
	- Conservare a 2-8°C (35.6-46.4°F) - Conserver à 2-8°C (35.6-46.4°F) - Lagerung bei 2-8°C (35.6-46.4°F) - Conservar entre 2-8°C (35.6-46.4°F)	- Store at 2-8°C (35.6-46.4°F) - Conservar a 2-8°C (35.6-46.4°F) - Φυλάσσεται στους 2-8°C (35.6-46.4°F)
	- Prodotto da - Fabriqué par - Hergestellt von - Fabricado por	- Manufactured by - Fabricado por - Κατασκευάζεται από
CON +	- Controllo positivo - Contrôle Positif - Positiv Kontrolle - Controllo positivo	- Positive Control - Control Positivo - Θετικός ορός ελέγχου
CON -	- Controllo negativo - Contrôle Négatif - Negativ Kontrolle - Controllo negativo	- Negative Control - Control Negativo - Αρνητικός ορός ελέγχου
CAL	- Calibratore - Etalon - Kalibrator - Calibrador	- Calibrator - Calibrador - Αντιδραστήριο βαθμονόμησης
CONJ	- Coniugato - Conjugué - Konjugat - Conjugado	- Conjugate - Conjugado - Σύζευγμα
MP	- Micropiastro rivestita - Microplaque sensibilisée - Beschichtete Mikrotiterplatte - Microplaca revestida	- Coated microtiter plate - Microplaca sensibilizada - Επικαλυμμένη μικροτίτλακα
WASHB 50x	- Tampone di lavaggio - Tampon de Lavage - Waschpuffer - Solução de lavagem	- Wash buffer - Solución de lavado - Ρυθμιστικό διάλυμα πλύσης
SUB	- Tampone substrato - Substrat - Substratpuffer - Substrato	- Substrate buffer - Tampón sustrato - Ρυθμιστικό διάλυμα υποστρώματος
STOP	- Reagente bloccante - Solution d'Arrêt - Stopreagenz - Solução de paragem	- Stop solution - Solución de parada - Αντιδραστήριο διακοπής αντίδρασης
SB 5x	- Tampone campione - Tampon Echantillons - Probenpuffer - Diluente de amostra	- Sample buffer - Tampón Muestras - Ρυθμιστικό διάλυμα δειγμάτων