Product information

Useŕs Manual

Distribuito in ITALIA da
Li StarFish S.r.l.
Via Cavour, 35
20063 Cernusco S/N (MI)
telefono 02-92150794
fax 02-92157285
info@listarfish.it
www.listarfish.it

Aldosterone ELISA

Enzyme immunoassay for the quantitative measurement of aldosterone in serum, plasma and urine

CE IVD

REF **DE5298**

Σ **96 wells**

Version 07-02/17
JS
Updated 170207

Please use only the valid version of the Instructions for Use provided with the kit.
Verwenden Sie nur die jeweils gültige, im Testkit enthaltene, Gebrauchsanweisung.
Si prega di usare la versione valida delle istruzioni per l'uso a disposizione con il kit.
Por favor, se usa solo la version valida de la metodico técnico incluido aqui en el kit.

Table of Contents / Inhaltsverzeichnis / Tabella die Contenuti / Tabla de Contenidos / Sommaire

1 INTRODUCTION

1.1 Intended Use

The **Aldosterone ELISA** is an enzyme immunoassay for the quantitative *in vitro diagnostic* measurement of aldosterone in serum, plasma (EDTA-, heparin- or citrate plasma) and urine.

1.2 Summary and Explanation

The steroid hormone aldosterone is a potent mineral corticoid that is produced by the zona glomerulosa of the adrenal cortex in the adrenal gland. The synthesis and release are controlled by the renin-angiotensin-aldosterone system (RAAS)[1], as well as by plasma potassium concentration [2], the pituitary peptide ACTH, and by the blood pressure via pressure sensitive baroreceptors in the vessel walls of nearly all large arteries of the body [3]. Aldosterone binds to mineralocorticoid receptors (MR) and triggers the transcription of hormone-responsive genes. In consequence, aldosterone increases the blood pressure by reabsorption of sodium and water from the distal tubules of the kidney into the blood, secretion of potassium into the urine, and elevation of circulating blood volume. Chronic overproduction and secretion of aldosterone leads to hypertension. Aldosterone activity is reduced in Addison's disease and increased in Conn's syndrome.

Measurement of aldosterone levels in serum in conjunction with plasma renin levels (aldosterone/renin-ratio; ARR) can be used to differentiate between primary and secondary aldosteronism [4,8,9].

Condition	Serum Aldosterone	Plasma Renin
Primary Aldosteronism	High	Low
Secondary Aldosteronism	High	High

The measurement of aldosterone in concert with selective suppression and stimulation tests can be used to further differentiate primary aldosteronism into two basic types [5]:

- Primary aldosteronism caused by an adenoma of one or both adrenals.
- Primary aldosteronism caused by adrenal hyperplasia.

This differentiation is vital in the treatment and management of the disease. The adrenal adenomas respond well to surgery whereas hyperplastic disease of the adrenals is generally better managed medically [6].
In addition, pharmacological modulation of nuclear hormone receptors is a common strategy for the treatment of cardiovascular disease [7]. Therefore, determining the effects of such treatments on the RAAS is of increasing value in evaluating the safety and efficacy of new therapeutics.
In summary, the precise and accurate measurement of serum aldosterone by enzyme immunoassay can be an important adjunct to a diagnostic laboratory battery for the differential diagnosis of hypertensive disease.

2 PRINCIPLE OF THE TEST

The Aldosterone ELISA Kit is a solid phase enzyme-linked immunosorbent assay (ELISA), based on the principle of competitive binding.
The microtiter wells are coated with a polyclonal rabbit antibody directed towards an antigenic site of the aldosterone molecule. Endogenous aldosterone of a patient sample competes with an aldosterone-horseradish peroxidase conjugate for binding to the coated antibody. After incubation the unbound conjugate is washed off.
After addition of the substrate solution, the intensity of colour developed is inversely proportional to the concentration of aldosterone in the patient sample.

3 WARNINGS AND PRECAUTIONS

1. This kit is for in vitro diagnostic use only. For professional use only.
2. All reagents of this test kit which contain human serum or plasma have been tested and confirmed negative for HIV I/II, HBsAg and HCV by FDA approved procedures. All reagents, however, should be treated as potential biohazards in use and for disposal.
3. Before starting the assay, read the instructions completely and carefully. Use the valid version of instructions for use provided with the kit. Be sure that everything is understood.
4. The microplate contains snap-off strips. Unused wells must be stored at 2 °C - 8 °C in the sealed foil pouch and used in the frame provided.
5. Pipetting of samples and reagents must be done as quickly as possible and in the same sequence for each step.
6. Use reservoirs only for single reagents. This especially applies to the substrate reservoirs. Using a reservoir for dispensing a substrate solution that had previously been used for the conjugate solution may turn solution colored. Do not pour reagents back into vials as reagent contamination may occur.
7. Mix the contents of the microplate wells thoroughly to ensure good test results. Do not reuse microwells.
8. Do not let wells dry during assay; add reagents immediately after completing the rinsing steps.
9. Allow the reagents to reach room temperature (21 °C - 26 °C) before starting the test. Temperature will affect the absorbance readings of the assay. However, values for the patient samples will not be affected.
10. Never pipet by mouth and avoid contact of reagents and specimens with skin and mucous membranes.
11. Do not smoke, eat, drink or apply cosmetics in areas where specimens or kit reagents are handled.
12. Wear disposable latex gloves when handling specimens and reagents. Microbial contamination of reagents or specimens may give false results.
13. Handling should be done in accordance with the procedures defined by an appropriate national biohazard safety guideline or regulation.
14. Do not use reagents beyond expiry date as shown on the kit labels.
15. All indicated volumes have to be performed according to the protocol. Optimal test results are only obtained when using calibrated pipettes and microtiterplate readers.
16. Do not mix or use components from kits with different lot numbers. It is advised not to exchange wells of different plates even of the same lot. The kits may have been shipped or stored under different conditions and the binding characteristics of the plates may result slightly different.
17. Avoid contact with *Stop Solution* containing 0.5 M H_2SO_4. It may cause skin irritation and burns.
18. Some reagents contain Proclin 300, BND and/or MIT as preservatives. In case of contact with eyes or skin, flush immediately with water.
19. TMB substrate has an irritant effect on skin and mucosa. In case of possible contact, wash eyes with an abundant volume of water and skin with soap and abundant water. Wash contaminated objects before reusing them. If inhaled, take the person to open air.
20. Chemicals and prepared or used reagents have to be treated as hazardous waste according to the national biohazard safety guideline or regulation.
21. For information on hazardous substances included in the kit please refer to Safety Data Sheets. Safety Data Sheets for this product are available upon request directly from DEMEDITEC.

4 REAGENTS

4.1 Reagents provided

1. **SORB MT Microtiterwells**, 12 x 8 (break apart) strips, 96 wells; Wells coated with anti-aldosterone antibody (polyclonal rabbit).
2. **CAL 0 – 5 Standard (Standard 0-5)**, 6 vials (lyophilized); 1.0 mL; Concentrations: 0 – 20 – 80 – 200 – 500 – 1000 pg/mL. Conversion: 1 pg/mL corresponds to 2.77 pmol/L. See "Reagents Preparation"; Contain non-mercury preservative.
3. **CONTROL low & high Control Low & High**, 2 vials (lyophilized), 1 mL. For control values and ranges please refer to vial label or QC-Datasheet. See "Reagents Preparation"; Contain non-mercury preservative.
4. **ENZ CONJ Enzyme Conjugate**, 1 vial, 20 mL, ready to use, Aldosterone conjugated to horseradish peroxidase; Contains non-mercury preservative.
5. **SUB TMB Substrate Solution**, 1 vial, 25 mL, ready to use, Tetramethylbenzidine (TMB).
6. **STOP SOLN Stop Solution**, 1 vial, 14 mL, ready to use, contains 0.5 M H_2SO_4, Avoid contact with the stop solution. It may cause skin irritations and burns.
7. **WASH SOLN 40x Wash Solution**, 1 vial, 30 mL (40X concentrated), see „Preparation of Reagents".

Note: Additional *Standard 0* for sample dilution is available upon request.

4.2 Materials required but not provided

- A microtiter plate calibrated reader (450 ± 10 nm)
- Calibrated variable precision micropipettes.
- Absorbent paper.
- Distilled or deionized water
- Timer
- Scale paper or semi-logarithmic graph paper or software for data reduction
- **Optional**: Reagents for determination of **Aldosterone in urine** (REF DE5298URIN) – **Contents:**
  1) ***Release Reagent***, 1 vial, 3 mL, ready to use. Containing 1M HCl. Avoid contact with *Release Reagent*. It may cause skin irritation.
  2) ***Neutralization Buffer***, 1 vial, 3 mL, ready to use. Containing Tris buffer, pH 8.5.
  3) ***Dilution Buffer***, 2 vials, 25 mL each, ready to use. Containing PBS.
- Optional: Plastic tubes (e.g. 0.5 - 1.5 mL) for pre-treatment of urine samples

4.3 Storage Conditions

When stored at 2 °C to 8 °C unopened reagents will retain reactivity until expiration date. Do not use reagents beyond this date. Opened reagents must be stored at 2 °C to 8 °C. Microtiter wells must be stored at 2 °C to 8 °C. Once the foil bag has been opened, care should be taken to close it tightly again. Opened kits retain activity for two months if stored as described above.

4.4 Reagent Preparation

Bring all reagents and required number of strips to room temperature prior to use.

Standards

Reconstitute the lyophilized contents of the standard vials with 1.0 mL deionized water and let stand for at least 10 minutes. Mix several times before use. **Note:** The reconstituted standards are stable for 8 weeks at 2- 8 °C. For longer storage freeze - only once - at -20 °C.

Controls

Reconstitute the lyophilized content of the controls with 1.0 mL deionized water and let stand for at least 10 minutes. Mix several times before use. **Note:** The reconstituted controls are stable for 8 weeks at 2 - 8 °C. For longer storage freeze - only once - at -20 °C.

Wash Solution

Add deionized water to the 40X concentrated Wash Solution. Dilute 30 mL of concentrated *Wash Solution* with 1170 mL deionized water to a final volume of 1200 mL. *The diluted Wash Solution is stable for 2 weeks at room temperature.*

4.5 Disposal of the Kit

The disposal of the kit must be made according to the national regulations. Special information for this product is given in the Material Safety Data Sheet.

4.6 Damaged Test Kits

In case of any severe damage to the test kit or components, DEMEDITEC has to be informed in writing, at the latest, one week after receiving the kit. Severely damaged single components should not be used for a test run. They have to be stored until a final solution has been found. After this, they should be disposed according to the official regulations.

5 SPECIMEN COLLECTION AND PREPARATION

Serum or plasma (EDTA-, heparin- or citrate plasma) and urine can be used in this assay.
Do not use haemolytic, icteric or lipaemic specimens.
Please note: Samples containing sodium azide should not be used in the assay.

5.1 Serum / Plasma Samples

5.1.1 Specimen Collection

Serum:

Collect blood by venipuncture (e.g. Sarstedt Monovette for serum), allow to clot, and separate serum by centrifugation at room temperature. Do not centrifuge before complete clotting has occurred. Patients receiving anticoagulant therapy may require increased clotting time.

Plasma:

Whole blood should be collected into centrifuge tubes containing anti-coagulant (e.g. Sarstedt Monovette with the appropriate plasma preparation) and centrifuged immediately after collection.

5.1.2 Specimen Storage and Preparation

Specimens should be capped and may be stored for up to 4 days at 2 °C to 8 °C prior to assaying. Specimens held for a longer time (up to two months) should be frozen only once at -20 °C prior to assay. Thawed samples should be inverted several times prior to testing.

5.1.3 Specimen Dilution

If in an initial assay, a specimen is found to contain more than the highest standard, the specimens can be diluted with *Standard 0* and reassayed as described in Assay Procedure.
For the calculation of the concentrations this dilution factor has to be taken into account.

Example:

a) dilution 1:10: 10 µL sample + 90 µL *Standard 0* (mix thoroughly)
b) dilution 1:100: 10 µL dilution a) 1:10 + 90 µL *Standard 0* (mix thoroughly).

5.2 Urine Samples

Aldosterone concentration can also be determined from urine samples. However, urine samples must be pre-treated before analysis. This will need additional reagents that are not included in this kit, but can be ordered separately (REF DE5298URIN).

5.2.1 Sample Collection

First clean genital area with mild disinfectant to prevent contamination. Then collect clean-catch mid-stream urine in an appropriate sterile container. Directly after collection, the urine should be centrifuged for 5 - 10 minutes (e.g. at 2,000 g) to remove cellular debris. Use supernatant for analyte quantification. The supernatant may be stored for up to 8 hours at 2 °C to 8 °C prior to assaying. Specimens held for a longer time should be frozen at -20 °C. Thawed supernatant should be inverted several times prior to testing.

5.2.2 Protocol for Urine Sample Pre-treatment

1. Secure the desired number of vials (e.g. 0.5 - 1.5 mL plastic tubes; not included in this kit).
2. Dispense **25 µL** of **urine** with new disposable tips into appropriate tubes.
3. Dispense **25 µL** ***Release Reagent*** into each tube.
   Thoroughly mix for 10 seconds. It is important to have a complete mixing in this step.
4. Incubate over night at 2 °C to 8 °C.
5. Add **25 µL** ***Neutralization Reagent*** to each tube and mix thoroughly.
6. Add **400 µL** ***Dilution Buffer*** to each tube and mix thoroughly
   (This pre-treatment leads to a 1:19 dilution. Therefore the dilution factor 19 has to be taken into account for calculation of the final concentration of the urine sample.)
7. Transfer **50 µL of pre-treated and diluted urine samples** directly to the microtiter well and continue with step 3 of Test Procedure (Chapter 6.2).

5.2.3 Specimen Dilution

If in an initial assay, an urine sample is found to contain more than the highest standard, the pre-treated and diluted urine sample can be further diluted with *Dilution Buffer* and reassayed as described in Assay Procedure.
For the calculation of the concentrations this dilution factor has to be taken into account too.

Example:
a) dilution 1:10: 10 µL pre-treated and diluted urine sample + 90 µL *Dilution Buffer* (mix thoroughly)
(final dilution factor = 19 x 10 = 190)

6 ASSAY PROCEDURE

6.1 General Remarks

- All reagents and specimens must be allowed to come to room temperature before use. All reagents must be mixed without foaming.
- Once the test has been started, all steps should be completed without interruption.
- Use new disposal plastic pipette tips for each standard, control or sample in order to avoid cross contamination.
- Absorbance is a function of the incubation time and temperature. Before starting the assay, it is recommended that all reagents are ready, caps removed, all needed wells secured in holder, etc. This will ensure equal elapsed time for each pipetting step without interruption.
- As a general rule the enzymatic reaction is linearly proportional to time and temperature.

6.2 Test Procedure

Each run must include a standard curve.

1. Secure the desired number of Microtiter wells in the frame holder.
2. Dispense **50 µL** of each ***Standard, Control*** and **samples** with new disposable tips into appropriate wells. For urine samples dispense 50 µL of the pre-treated and diluted urine samples (see chapter 5.2.2 Protocol for Urine Sample Pre-treatment, step 7).
3. Incubate for 30 minutes at room temperature.
4. Dispense **150 µL** ***Enzyme Conjugate*** into each well. Thoroughly mix for 10 seconds. It is important to have a complete mixing in this step.
5. Incubate for **60 minutes** at room temperature.
6. Briskly shake out the contents of the wells. Rinse the wells **5 x** with **400 µL** diluted *Wash Solution* per well (if a plate washer is used) – or **5 x** with **300 µL**/well for manual washing. Strike the wells sharply on absorbent paper to remove residual droplets. **Important note:** The sensitivity and precision of this assay is markedly influenced by the correct performance of the washing procedure!
7. Add **200 µL** of ***Substrate Solution*** to each well.
8. Incubate for **30 minutes** at room temperature.
9. Stop the enzymatic reaction by adding **100 µL** of ***Stop Solution*** to each well.
10. Determine the absorbance (OD) of each well at **450 ± 10 nm** with a microtiter plate reader. It is recommended that the wells be read **within 10 minutes** after adding the *Stop Solution*.

6.3 Calculation of Results

1. Calculate the average absorbance values for each set of standards, controls and patient samples.
2. Using scale paper or semi-logarithmic graph paper, construct a standard curve by plotting the mean absorbance obtained from each standard against its concentration with absorbance value on the vertical (Y) axis and concentration on the horizontal (X) axis.
3. Using the mean absorbance value for each sample determine the corresponding concentration from the standard curve.
4. Automated method: The results in the Instructions for Use have been calculated automatically using a 4 Parameter curve fit. (4 Parameter Rodbard or 4 Parameter Marquardt are the preferred methods.) Other data reduction functions may give slightly different results.
5. The concentration of the **serum** / **plasma samples** can be read **directly** from this standard curve. For **urine samples** the concentration read from the standard curve, has to be **multiplied** with the **dilution factor 19** (see chapter 5.2.2).
6. Samples with concentrations higher than that of the highest standard have to be further diluted or reported as > 1000 pg/mL. For the calculation of the concentrations this dilution factor has to be taken into account too.

6.3.1 Example of Typical Standard Curve

The following data is for demonstration only and **cannot** be used in place of data generations at the time of assay.

Standard	Optical Units (450 nm)
Standard 0 (0 pg/mL)	2.11
Standard 1 (20 pg/mL)	1.90
Standard 2 (80 pg/mL)	1.55
Standard 3 (200 pg/mL)	1.15
Standard 4 (500 pg/mL)	0.76
Standard 5 (1000 pg/mL)	0.54

6.4 Final Calculation for Urine Samples

Calculate the 24 hours excretion for each urine sample: µg/24 h = **µg/L x L/24 h**

Example:
Concentration for urine sample read from the standard curve = 500 pg/mL
Result after correction with the dilution factor 19 = 9500 pg/mL
9500 pg/mL / 1000 = 9.5 µg/L

Total volume of 24 h-urine = 1.3 L (example)
9.5 µg/L × 1.3 L/24 h = **12.35 µg/24 h**

7 EXPECTED NORMAL VALUES

It is strongly recommended that each laboratory should determine its own normal and abnormal values.

In a study conducted with **EDTA plasma samples** of apparently normal healthy adults, using the DEMEDITEC Aldosterone ELISA the following values are observed:

Healthy Adults	Valid N	Mean (pg/mL)	Median (pg/mL)	5. Percentile (pg/mL)	95. Percentile (pg/mL)
Supine position	60	62.8	50.9	12.0	157.5
Upright position	60	68.8	52.5	13.3	231.4

These values are also valid for serum, heparin plasma and citrate plasma.
These results correspond well to published reference ranges [8,9].

In a study conducted with apparently normal healthy adults, using the DEMEDITEC Aldosterone ELISA (DE5298) and the DEMEDITEC Renin ELISA (DE5125) the following ***Aldosterone-Renin Ratios*** were determined in plasma:

Ratio Aldosterone Renin (pg/mL / pg/mL)

n	Mean	Median	99th percentile	95th percentile	5th percentile	1st percentile
89	8.68	5.30	49.65	28.06	0.68	0.45

These values are also valid for serum.

In a study conducted with **urine samples** of apparently normal healthy adults, using the DEMEDITEC Aldosterone ELISA the following values are observed:

n	Mean (µg/24 h)	Median (µg/24 h)	5th Percentile (µg/24 h)	95th Percentile (µg/24 h)
40	11.34	9.40	3.55	23.01

These results correspond well to published reference ranges [8].

The results alone should not be the only reason for any therapeutic consequences. The results should be correlated to other clinical observations and diagnostic tests.

8 QUALITY CONTROL

Good laboratory practice requires that controls be run with each calibration curve. A statistically significant number of controls should be assayed to establish mean values and acceptable ranges to assure proper performance. It is recommended to use control samples according to state and federal regulations. The use of control samples is advised to assure the day to day validity of results. Use controls at both normal and pathological levels. The controls and the corresponding results of the QC-Laboratory are stated in the QC certificate added to the kit. The values and ranges stated on the QC sheet always refer to the current kit lot and should be used for direct comparison of the results. It is also recommended to make use of national or international Quality Assessment programs in order to ensure the accuracy of the results. Employ appropriate statistical methods for analysing control values and trends. If the results of the assay do not fit to the established acceptable ranges of control materials patient results should be considered invalid. In this case, please check the following technical areas: Pipetting and timing devices; photometer, expiration dates of reagents, storage and incubation conditions, aspiration and washing methods. After checking the above mentioned items without finding any error contact your distributor or DEMEDITEC directly.

9 PERFORMANCE CHARACTERISTICS

9.1 Assay Dynamic Range

The range of the assay is between 5.7 pg/mL – 1000 pg/mL.

9.2 Specificity of Antibodies (Cross Reactivity)

The following substances were tested for cross reactivity of the assay:

3 β, 5 α Tetrahydroaldosterone:	17.2 %
3 β, 5 β Tetrahydroaldosterone:	0.12 %
Prednisolone:	0.017 %
Cortisol:	< 0.003 %
11-Deoxycortisol:	< 0.003 %
Progesterone:	< 0.003 %
Testosterone:	< 0.002 %
Androstenedione:	< 0.002 %

9.3 Sensitivity

The analytical sensitivity of the DEMEDITEC ELISA was calculated by subtracting 2 standard deviations from the mean of 20 replicate analyses of the *Standard 0* (S0) and was found to be < 5.7 pg/mL.

9.4 Reproducibility

9.4.1 Intra Assay

The within assay variability is shown below:

Sample	n	Mean (pg/mL)	CV (%)
Serum 1	20	85.1	9.7
Serum 2	20	210.3	7.4
Serum 3	20	532.2	3.9
Urine 1	20	191.8	5.0
Urine 2	20	391.3	5.6
Urine 3	20	936.8	3.8

9.4.2 Inter Assay

The between assay variability is shown below:

Sample	n	Mean (pg/mL)	CV (%)
1	40	101.0	9.9
2	40	315.1	8.6
3	40	656.8	9.4
Urine 1	32	386.7	11.5
Urine 2	32	444.0	11.1
Urine 3	32	876.7	10.4

9.5 Recovery

Samples have been spiked by adding aldosterone solutions with known concentrations in a 1:1 ratio. The % recovery has been calculated by multiplication of the ratio of the measurements and the expected values with 100 (expected value = (endogenous aldosterone + added aldosterone) / 2; because of a 1:2 dilution of serum with spike material).

		Serum 1	Serum 2	Serum 3
Concentration [pg/mL]		82.7	96.1	167.9
Average Recovery		112.5	111.0	106.8
Range of Recovery [%]	from	108.2	108.9	92.4
	to	114.6	114.5	114.8

9.6 Linearity

		Serum 1	Serum 2	Serum 3	Urine 1	Urine 2	Urine 3
Concentration [pg/mL]		600.5	546.2	672.0	559.0	645.0	464.0
Average Recovery		98.4	95.5	96.4	106.8	98.2	98.0
Range of Recovery [%]	from	95.5	87.8	86.0	104.5	87.8	86.2
	to	103.0	103.6	102.5	111.6	107.9	105.6

10 LIMITATIONS OF USE

Reliable and reproducible results will be obtained when the assay procedure is performed with a complete understanding of the package insert instruction and with adherence to good laboratory practice. Any improper handling of samples or modification of this test might influence the results.

10.1 Interfering Substances

Haemoglobin (up to 4 mg/mL), Bilirubin (up to 0.125 mg/mL) and Triglyceride (up to 30 mg/mL) have no influence on the assay results.

10.2 Drug Interferences

Until today no substances (drugs) are known to us, which have an influence to the measurement of aldosterone in a sample.

10.3 High-Dose-Hook Effect

No hook effect was observed in this test.

11 LEGAL ASPECTS

11.1 Reliability of Results

The test must be performed exactly as per the manufacturer's instructions for use. Moreover the user must strictly adhere to the rules of GLP (Good Laboratory Practice) or other applicable national standards and/or laws. This is especially relevant for the use of control reagents. It is important to always include, within the test procedure, a sufficient number of controls for validating the accuracy and precision of the test. The test results are valid only if all controls are within the specified ranges and if all other test parameters are also within the given assay specifications. In case of any doubt or concern please contact DEMEDITEC.

11.2 Therapeutic Consequences

Therapeutic consequences should never be based on laboratory results alone even if all test results are in agreement with the items as stated under point 11.1. Any laboratory result is only a part of the total clinical picture of a patient. Only in cases where the laboratory results are in acceptable agreement with the overall clinical picture of the patient should therapeutic consequences be derived. The test result itself should never be the sole determinant for deriving any therapeutic consequences.

11.3 Liability

Any modification of the test kit and/or exchange or mixture of any components of different lots from one test kit to another could negatively affect the intended results and validity of the overall test. Such modification and/or exchanges invalidate any claim for replacement. Claims submitted due to customer misinterpretation of laboratory results subject to point 11.2. are also invalid. Regardless, in the event of any claim, the manufacturer's liability is not to exceed the value of the test kit. Any damage caused to the test kit during transportation is not subject to the liability of the manufacturer.

SYMBOLS USED WITH ASSAYS

Symbol	English	Deutsch	Francais	Espanol	Italiano
CE	European Conformity	CE-Konfirmitäts-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	Ussage 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 Cat.
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	Temperature de conservation	Temperatura de conservacion	Temperatura di conservazione
	Expiration Date	Mindesthaltbarkeits-datum	Date limite d'utilisation	Fecha de caducidad	Data di scadenza
	Legal Manufacturer	Hersteller	Fabricant	Fabricante	Fabbricante
Distributed by	Distributor	Vertreiber	Distributeur	Distribuidor	Distributtore

Distribuito in ITALIA da
Li StarFish S.r.l.
Via Cavour, 35
20063 Cernusco S/N (MI)
telefono 02-92150794
fax 02-92157285
info@listarfish.it
www.listarfish.it