Instructions for Use

Calcitonin ELISA

Specific quantitative assay for the determination of calcitonin in human serum.

REF **NM59011**

Σ **12x8**

 **2-8°C**

EU: IVD CE

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1. INTENDED USE

Specific quantitative assay for the determination of calcitonin in human serum. For in vitro diagnostic use.

2. SUMMARY AND EXPLANATION

Calcitonin, a 32-amino-acid polypeptide, is secreted primarily by the thyroidal parafollicular C-cells. Its main biological effect is to inhibit osteoclastic bone resorption. This property has led to Calcitonin's use for disorders characterized by increased resorption such as Paget's disease, for some patients with osteoporosis.

The most prominent clinical syndrome associated with a disordered hypersecretion of Calcitonin is medullary carcinoma of the thyroid (MTC). MTC is a tumor of the Calcitonin producing C-cells of the thyroid gland. Although MTC is rare, comprising 5-10% of all thyroid cancer, it is often fatal. It may occur sporadically or in a familial form that is transmitted as an autosomal dominant trait. MTC has great clinical importance because of its familial distribution. Further, it leant itself to be diagnosed early by serum Calcitonin and total cure for early sub-clinical disease is possible[1]. This is frequently associated with other clinical features and it has good potential for cure with surgery. Although a rare tumor, it can occur in a familial pattern[1,3,4] as a Type II multiple endocrine neoplasia. These tumors usually produce diagnostically elevated serum concentrations of Calcitonin. Therefore, the immunoassay for Calcitonin in serum can be used to diagnose the presence of MTC with an exceptional degree of accuracy and specificity. In the small but increasing percentage of patients, however, basal hormone levels are indistinguishable from normal[1]. Some of these subjects represent the early stages of C-cell neoplasia or hyperplasia that are most amenable to surgical cure. To identify these patients with early disease, provocative tests for Calcitonin secretion is necessary to preclude false negatives if only basal Calcitonin determination are performed. Most tumors respond with increased Calcitonin level to the administration of either calcium[5] or pentagastrin[6] or their combination[7], but either agent can still give misleading results. Therefore, in cases with clinical manifestations, both agents should be considered for diagnostic testing. Further, Calcitonin measurements can also be used to monitor the efficacy of therapy in patients with Calcitonin producing tumors.

It has been reported[8] that multiple forms of immunoreactive calcitonin are found in either normal subjects or patients with MTC. These various forms of calcitonin have molecular weights varying from 3.400 (monomeric) up to 70.000 Dalton (polymeric).

Neoplastic disorders of other neuroendocrine cells can also elevate Calcitonin. The best example is small cell lung cancer. Other tumors such as carcinoids and islet cell tumors of the pancreas can also result in elevated serum Calcitonin.

Increases in serum Calcitonin has also been noted in both acute and chronic renal failure, hypercalciuria and hypercalcemia.

3. TEST PRINCIPLE

The Calcitonin Immunoassay is a two-site ELISA [Enzyme-Linked ImmunoSorbent Assay] for the measurement of the biologically intact 32 amino acid chain of Calcitonin. It utilizes two different mouse monoclonal antibodies to human calcitonin specific for well-defined regions on the calcitonin molecule. One antibody binds only to Calcitonin 11-23 and this antibody is biotinylated. The other antibody binds only to Calcitonin 21-32 and this antibody is labeled with horseradish peroxidase [HRP] for detection.

In this assay, calibrators, controls, or patient samples are simultaneously incubated with the enzyme labeled antibody and a biotin coupled antibody in a streptavidin-coated microplate well. Thus the calcitonin in the sample is "sandwiched" between these two antibodies. At the end of the assay incubation, the microwell is washed to remove unbound components and the enzyme bound to the solid phase is incubated with the substrate, tetramethylbenzidine (TMB). An acidic stopping solution is then added to stop the reaction and converts the color to yellow. The intensity of the yellow color is directly proportional to the concentration of calcitonin in the sample. A dose response curve of absorbance unit vs. concentration is generated using results obtained from the calibrators. Concentrations of calcitonin present in the controls and patient samples are determined directly from this curve.

4. WARNINGS AND PRECAUTIONS

1. For *in-vitro diagnostic* use only. For professional use only.
2. Before starting the assay, read the instructions completely and carefully. Use the valid version of the package insert provided with the kit. Be sure that everything is understood.
3. In case of severe damage of the kit package please contact IBL or your supplier in written form, latest one week after receiving the kit. Do not use damaged components in test runs, but keep safe for complaint related issues.
4. Obey lot number and expiry date. Do not mix reagents of different lots. Do not use expired reagents.
5. Follow good laboratory practice and safety guidelines. Wear lab coats, disposable latex gloves and protective glasses where necessary.
6. Reagents of this kit containing hazardous material may cause eye and skin irritations. See MATERIALS SUPPLIED and labels for details. Material Safety Data Sheets for this product are available on the IBL-Homepage or upon request directly from IBL.
7. Chemicals and prepared or used reagents have to be treated as hazardous waste according to national biohazard and safety guidelines or regulations.
8. Avoid contact with Stop solution. It may cause skin irritations and burns.
9. All reagents of this kit containing human serum or plasma have been tested and were found negative for anti-HIV I/II, HBsAg and anti-HCV. However, a presence of these or other infectious agents cannot be excluded absolutely and therefore reagents should be treated as potential biohazards in use and for disposal.

5. STORAGE AND STABILITY

The kit is shipped at ambient temperature and should be stored at 2-8°C. Keep away from heat or direct sun light. The storage and stability of specimen and prepared reagents is stated in the corresponding chapters.

The microtiter strips are stable up to the expiry date of the kit in the broken, but tightly closed bag when stored at 2–8°C.

6. SPECIMEN COLLECTION AND STORAGE

Serum

To assay the specimen in duplicate, 200 µL of serum is required. The usual precautions for venipuncture should be observed. It is important to preserve the chemical integrity of a blood specimen from the moment it is collected until it is assayed. Do not use grossly hemolytic, icteric or grossly lipemic specimens. Samples appearing turbid should be centrifuged before testing to remove any particulate material.

Storage:	2-8°C (Aliquots)	-20°C (Aliquots)	Keep away from heat or direct sun light. Avoid repeated freeze-thaw cycles.
Stability:	24 hours	12 months	

7. MATERIALS SUPPLIED

Quantity	Symbol	Component
1 x 12 x 8	PLA	**Microplate** Ready to use. Break apart strips. Coated with Streptavidin.
1 x 7.0 mL	RGT 1	**Reagent 1** Ready to use. Contains: Biotinylated Calcitonin Antibody.
1 x 7.0 mL	RGT 2	**Reagent 2** Ready to use. Contains: Peroxidase (Enzym) labeled Calcitonin Antibody.
1 x 10.0 mL	RGT 3	**Reagent 3** Ready to use. Contains: Reconstitution Solution containing EDTA.
1 x 30.0 mL	RGT A CONC	**Reagent A** Concentrate (20X) Contains: Wash Concentrate (Saline with surfactant).
1 x 20.0 mL	RGT B	**Reagent B** Ready to use. Contains: TMB Substrate.
1 x 2 x	CTRL1+2 LYO	**Control 1+2** (lyophilized) Contains: 2 Levels. Synthetic h-Calcitonin (1-32) in BSA solution. Refer to vial labels for exact concentrations.

Quantity	Symbol	Component
1 x 6 x	CAL A-F LYO	**Standard A-F** (lyophilized) Contains: synthetic h-Calcitonin. Zero calibrator [BSA solution]. All other calibrators consist of synthetic h-Calcitonin (1-32) in BSA solution, calibrated to *WHO 2nd IS 89/620.* Refer to vial labels for exact concentrations.
1 x 20 mL	SOLN	**Stopping Solution** Ready to use. Contains: 1 N sulphuric acid.

8. MATERIALS REQUIRED BUT NOT SUPPLIED

1. Micropipettes (Multipette Eppendorf or similar devices, < 3% CV). Volume: 50; 100 and 150 µL
2. Orbital shaker
3. 8-Channel Micropipettor with reagent reservoirs
4. Wash bottle, automated or semi-automated microtiter plate washing system
5. Microtiter plate reader capable of reading absorbance at 450 nm and 405 nm (reference wavelength 600-650 nm)
6. Bidistilled or deionised water
7. Paper towels, pipette tips and timer

9. PROCEDURE NOTES

1. Any improper handling of samples or modification of the test procedure may influence the results. The indicated pipetting volumes, incubation times, temperatures and pretreatment steps have to be performed strictly according to the instructions. Use calibrated pipettes and devices only.
2. Once the test has been started, all steps should be completed without interruption. Make sure that required reagents, materials and devices are prepared ready at the appropriate time. Allow all reagents and specimens to reach room temperature (18-25°C) and gently swirl each vial of liquid reagent and sample before use. Mix reagents without foaming.
3. Avoid contamination of reagents, pipettes and wells/tubes. Use new disposable plastic pipette tips for each component and specimen. Do not interchange caps. Always cap not used vials. Do not reuse wells/tubes or reagents.
4. It is advised to determine samples in duplicate to be able to identify potential pipetting errors.
5. Use a pipetting scheme to verify an appropriate plate layout.
6. Incubation time affects results. All wells should be handled in the same order and time sequences. It is recommended to use an 8-channel Micropipettor for pipetting of solutions in all wells.
7. Microplate washing is important. Improperly washed wells will give erroneous results. It is recommended to use a multichannel pipette or an automatic microplate washing system. Do not allow the wells to dry between incubations. Do not scratch coated wells during rinsing and aspiration. Rinse and fill all reagents with care. While rinsing, check that all wells are filled precisely with Wash Buffer, and that there are no residues in the wells.
8. Humidity affects the coated wells/tubes. Do not open the pouch until it reaches room temperature. Unused wells/tubes should be returned immediately to the resealed pouch including the desiccant.
9. Each test run needs a standard curve.

10. PRE-TEST SETUP INSTRUCTIONS

10.1. Preparation of lyophilized or concentrated components

Dilute / dissolve	Component	with	Diluent	Remarks	Storage	Stability
	CAL A **LYO**	2 mL	bidist. water	Allow the vials to stand for 10 minutes and then mix thoroughly by gentle inversion to insure complete reconstitution.	-20°C 3 Freeze-thaw cycles only.	6 weeks
	CAL B-F **LYO**	1 mL	**RGT 3**			
	CTRL 1+2 **LYO**	1 mL				
30 mL	**RGT A** **CONC**	570 mL	bidist. water	Warm up at 37°C to dissolve crystals, if necessary. Mix vigorously.	18-25°C	3 months

11. TEST PROCEDURE

1.	Pipette **100 µL** of each **calibrators, controls** and **samples** into the respective wells of the microtiter plate. **At a minimum, designate two wells to serve as "blanks". Refer to Step 9 for final plate reading. Freeze (-20°C) the remaining calibrators and controls as soon as possible after use, in a non-self-defrosting freezer.**
2.	**Add** or dispense **50 µL** of **Reagent 1** (Biotinylated Antibody) into each Well.
3.	**Add** or dispense **50 µL** of **Reagent 2** (Enzyme Labeled Antibody) into each of the same wells.
4.	Cover plate with adhesive foil to avoid light exposure and place the microplate on an **orbital shaker or rotator** set at 170 ± 10 rpm for **4 hours** ± 30 minutes at room temperature (18-25°C).
5.	First aspirate the fluid completely and then wash/aspirate each well **5 x** with the **Working Wash Solution** (prepared from Reagent A), using an automatic microplate washer. The wash solution volume should be set to dispense 0.35 mL into each well.
6.	Add or dispense **150 µL** of the **Reagent B** (TMB Substrate) into each of the wells.
7.	Cover plate with adhesive foil to avoid light exposure. Place the microplate on an **orbital shaker or rotator** set at 170 ± 10 rpm for **30 ± 5 minutes** at room temperature (18-25°C).
8.	Add or dispense **100 µL** of the **Stopping Solution** into each of the wells. Mix gently.
9.	Read the absorbance of the solution in the wells within 10 minutes, using a microplate reader set to **450 nm. Prior to reading, ensure both "blank wells" as mentioned in Step 1 are filled with 250 µL of distilled or deionized water. Read** the plate **again** with the reader set to **405 nm** against distilled or deionized water.*

***Note:** The second reading is designed to extend the analytical validity of the calibration curve to the value represented by the highest calibrator, which is approximately 1.000 pg/mL. Hence, patient samples with calcitonin > 300 pg/mL can be quantified against a calibration curve consisting of the readings all the way up to the concentration equivalent to the highest calibrator using the 405 nm reading, away from the wavelength of maximum absorbance. In general, patient and control samples should be read using the 450 nm for calcitonin concentrations up to 300 pg/mL. Calcitonin concentrations above 300 pg/mL should be interpolated using the 405 nm reading.

12. QUALITY CONTROL

Control serum or serum pools should be analyzed with each run of calibrators and patient samples. Results generated from the analysis of the control samples should be evaluated for acceptability using appropriate statistical methods. In assays in which one or more of the quality control sample values lie outside the acceptable limits, the results for the patient sample may not be valid.

13. CALCULATION OF RESULTS

13.1. Manual Method

1. For the 450 nm readings, construct a dose response curve (calibration curve) using the first five calibrators provided, i.e. Calibrators A, B, C, D and E. For the 405 nm readings, construct a second dose response curve using the three calibrators with the highest concentrations, i.e. Calibrators D, E and F.
2. Assign the concentration for each calibrator stated on the vial in pg/mL. Plot the data from the calibration curve on linear graph paper with the concentration on the X-axis and the corresponding A.U. on the Y-axis.
3. Draw a straight line between 2 adjacent points. This mathematical algorithm is commonly known as the "point-to-point" calculation. Obtain the concentration of the sample by locating the absorbance unit on the Y-axis and finding the corresponding concentration value on the X-axis. Patient and control samples should be read using the 450 nm for Calcitonin concentrations up to 300 pg/mL. Calcitonin concentrations above 300 pg/mL should be interpolated using the 405 nm reading.

13.2. Automated Method:

Computer programs using cubic spline or 4 PL [4 Parameter Logistics] or Point-to-Point can generally give a good fit.

Sample Data *at 450 nm* [raw A.U. readout against distilled or deionized water]

Microplate Well	**1st Reading** Absorbance Unit	**2nd Reading** Absorbance Unit	**Average** Absorbance Unit	**Calcitonin pg/mL**	**Calcitonin pg/mL – Result to report**
Calibrator A	0.008	0.009	0.0085		0
Calibrator B	0.059	0.064	0.0615		10
Calibrator C	0.186	0.194	0.190		30
Calibrator D	0.578	0.602	0.590		100
Calibrator E	1.900	1.882	1.891		300
Control 1	0.127	0.122	0.125	20.6	20.6
Control 2	2.554	2.565	2.560	> 300	*
Patient Sample 1	0.034	0.040	0.037	4.7	4.7
Patient Sample 2	0.104	0.098	0.101	16.3	16.3
Patient Sample 3	0.397	0.411	0.404	68.7	68.7
Patient Sample 4	2.195	2.173	2.184	> 300	*

* Because the concentration readout is > 300 pg/mL, it is recommended to use the data obtained at 405 nm as shown in **Sample Data** *at 405 nm* in the table below.

Sample Data *at 405 nm* [raw A.U. readout against distilled or deionized water]

Microplate Well	**1st Reading** Absorbance Unit	**2nd Reading** Absorbance Unit	**Average** Absorbance Unit	**Calcitonin pg/mL**	**Calcitonin pg/mL – Result to report**
Calibrator A	0.005	0.005	0.005		0
Calibrator D	0.187	0.198	0.193		100
Calibrator E	0.602	0.597	0.599		300
Calibrator F	1.898	1.910	1.904		1000
Control 1	0.045	0.044	0.045	< 300	**
Control 2	0.814	0.816	.815	403	403
Patient Sample 1	0.016	0.020	0.018	< 300	**
Patient Sample 2	0.039	0.035	0.037	< 300	**
Patient Sample 3	0.128	0.134	0.131	< 300	**
Patient Sample 4	0.697	0.689	0.693	345	345

** For samples with readout < 300 pg/mL, it is recommended to use the data obtained at 450 nm as shown in **Sample Data** *at 450 nm* in the table above. This practice should give the results with optimum sensitivity of the assay.

NOTE: The data presented are for illustration purposes only and must not be used in place of data generated at the time of the assay.

14. EXPECTED VALUES

It is recommended that each laboratory establishes its own range of normal values. The data provided should be used only as a guideline. Calcitonin levels were measured in 59 apparently normal female individuals and 52 apparently normal male individuals with the Calcitonin ELISA. The values obtained on the normal females ranged from 0.1 to 10.9 pg/mL and the values obtained on the normal males ranged from 0.2 to 27.7 pg/mL. Based on statistical tests on skewness and kurtosis, the population, when transformed logarithmically, follows the normal or Gaussian distribution. The geometric mean + 2 standard deviations of the mean for the normal females were calculated to be 0.07 to 12.97 pg/mL and 0.68 to 30.26 pg/mL for the normal males. Consistent with the literature, calcitonin levels were found to be generally lower in normal females than in normal males. Hence, the reference range should be less than 13 and 30 pg/mL, for females and males, respectively.

15. LIMITATIONS OF THE PROCEDURE

The Calcitonin ELISA kit has exhibited no “high dose hook effect” with samples spiked with 1.000.000 pg/mL of pure intact calcitonin (1-32). The spiked sample gave a result greater than the highest standard, i.e. 1.000 pg/mL. Samples with calcitonin levels greater than the highest calibrator, however, should be diluted and reassayed for correct values.

Like any analyte used as a diagnostic adjunct, calcitonin results must be interpreted carefully with the overall clinical presentations and other supportive diagnostic tests.

Samples from patients routinely exposed to animal or animal serum products may contain heterophilic antibodies causing atypical results. This assay has been formulated to mitigate the risk of this type of interference. However, potential interactions between rare sera and test components can occur.

16. PERFORMANCE

Accuracy

Seventy-seven patient samples, with calcitonin values ranging from 0.8 to 3.113 pg/mL were assayed by the ELISA procedure and an ImmunoRadioMetricAssay Calcitonin (IRMA Kit). Linear regression analysis gives the following statistics:

ELISA = 0.940 IRMA Kit + 6.55 pg/mL
r = 0.993 n = 123

Further, fifty-one patient samples, with calcitonin values ranging from < 0.7 to 2.240 pg/mL were assayed by the ELISA procedure and Chemiluminescence Immunoassay for Calcitonin Kit [or ImmunoChemiluminescentMetricAssay (ICMA)]. Linear regression analysis gives the following statistics:

ELISA = 1.094 ICMA Kit - 6.13 pg/mL
r = 0.995 n = 123

Sensitivity

The sensitivity, or minimum detection limit, of this assay is defined as the smallest single value, which can be distinguished from zero at the 95% confidence limit.

The Calcitonin ELISA has a calculated sensitivity of 1.0 pg/mL.

Precision and Reproducibility

The precision (intra-assay variation) of the Calcitonin ELISA Test was calculated from 20 replicate determinations on each of the three samples.

Intra-Assay Variation

Sample	Mean Value (pg/mL)	N	CV %
A	24.3	20	5.7
B	94.9	20	4.3
C	403	20	2.8

The total precision (inter-assay variation) of the Calcitonin ELISA Test was calculated from data on three samples obtained in 15 different assays, by three technicians on two different lots of reagents, over a three-week period.

Inter-Assay Variation

Sample	Mean Value (pg/mL)	N	CV %
A	16.5	15	7.4
B	64.5	15	7.4
C	340	15	6.1

Recovery

Various amounts of Calcitonin were added to four different patient sera to determine the recovery. The results are described in the following table:

Serum Sample	**Endogenous** Calcitonin (pg/mL)	**Calcitonin** Added (pg/mL)	**Expected** Value (pg/mL)	**Measured** Value (pg/mL)	**Recovery** (%)
A	0 0 0	-- 100 200	-- 100 200	-- 110 217	-- 110% 109%
B	9.7 8.7 7.8	-- 100 200	-- 109 208	-- 106 207	-- 97% 100%
C	0 0 0	-- 100 200	-- 100 200	-- 104 205	-- 104% 103%
D	5.7 5.1 4.6	-- 126 220	-- 131 225	-- 119 203	-- 91% 90%

Specificity and Cross-Reactivity

Crossreactant	Concentration of crossreactant	Calcitonin without crossreactant [pg/mL]	Calcitonin with crossreactant [pg/mL]	Change in Calcitonin [pg/mL]	% Crossreactivity
PTH(1-84)	100.000 pg/mL	186	194	8	0.00800%
	30.000 pg/mL	186	200	14	0.04667%
	10.000 pg/mL	186	194	8	0.08000%
Calcitonin Gene Related Peptide	1.000.000 pg/mL	200	202	2	0.00020%
	100.000 pg/mL	200	204	4	0.00400%
Salmon Calcitonin	1.000.000 pg/mL	191	194	3	0.00030%
	100.000 pg/mL	191	199	8	0.00800%
TSH	5000 uIU/mL	198	203	5	0.00061%
	500 uIU/mL	198	193	0	0.00000%
	50 uIU/mL	198	199	1	0.01220%

Each crossreactant is spiked into a sample containing Calcitonin. Calcitonin level is measured before and after the spike. None of the crossreactants interfere with this Calcitonin ELISA. The small changes in Calcitonin measured are well within the intra-assay precision statistics.

Kinetic Effect of the Assay

To determine whether there is any systematic kinetic effect between the beginning of the run and the end of the run, three spiked patient serum pools, selected to represent a good cross section of the calcitonin concentration, were placed in sequence throughout the run of one microplate or 96 wells [with twelve 8-well strips].

Linearity of Patient Sample Dilutions: Parallelism

Six patient serum samples were diluted with Calibrator A (Zero Calibrator). Results in pg/mL are shown below:

Sample	Dilution	Expected	Observed	% Observed ÷ Expected
A	Undiluted	-	343	-
	1:2	172	168	98%
	1:4	85.8	81.3	95%
	1:8	42.9	40.3	94%
B	Undiluted	-	271	-
	1:2	136	131	97%
	1:4	67.8	70	103%
	1:8	33.9	34.3	101%
C	Undiluted	-	265	-
	1:2	133	134	101%
	1:4	66	70.4	106%
	1:8	33.1	32.5	98%
D	Undiluted	-	>1000	-
	1:2	-	1060	-
	1:4	530	504	95%
	1:8	265	271	102%
E	Undiluted	-	231	-
	1:2	116	116	100%
	1:4	57.8	58.8	102%
	1:8	28.9	27.1	94%
	1:16	14.4	12.1	84%
F	Undiluted	-	>1000	-
	1:2	-	997	-
	1:4	499	429	86%
	1:8	249	223	89%
	1:16	125	119	95%

17. PRODUCT LITERATURE REFERENCES

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Symbols / Symbole / Symbôles / Símbolos / Símbolos / Σύμβολα

REF	Cat.-No.: / Kat.-Nr.: / No.- Cat.: / Cat.-No.: / N.º Cat.: / N.–Cat.: / Αριθμός-Κατ.:
LOT	Lot-No.: / Chargen-Bez.: / No. Lot: / Lot-No.: / Lote N.º: / Lotto n.: / Αριθμός -Παραγωγή:
	Use by: / Verwendbar bis: / Utiliser à: / Usado por: / Usar até: / Da utilizzare entro: / Χρησιμοποιείται από:
	No. of Tests: / Kitgröße: / Nb. de Tests: / No. de Determ.: / N.º de Testes: / Quantità dei tests: / Αριθμός εξετάσεων:
CONC	Concentrate / Konzentrat / Concentré / Concentrar / Concentrado / Concentrato / Συμπύκνωμα
LYO	Lyophilized / Lyophilisat / Lyophilisé / Liofilizado / Liofilizado / Liofilizzato / Λυοφιλιασμένο
IVD	In Vitro Diagnostic Medical Device. / In-vitro-Diagnostikum. / Appareil Médical pour Diagnostics In Vitro. / Dispositivo Médico para Diagnóstico In Vitro. / Equipamento Médico de Diagnóstico In Vitro. / Dispositivo Medico Diagnostico In vitro. / Ιατρική συσκευή για In-Vitro Διάγνωση.
	Evaluation kit. / Nur für Leistungsbewertungszwecke. / Kit pour évaluation. / Juego de Reactivos para Evaluació. / Kit de avaliação. / Kit di evaluazione. / Κιτ Αξιολόγησης.
	Read instructions before use. / Arbeitsanleitung lesen. / Lire la fiche technique avant emploi. / Lea las instrucciones antes de usar. / Ler as instruções antes de usar. / Leggere le istruzioni prima dell'uso. / Διαβάστε τις οδηγίες πριν την χρήση.
	Keep away from heat or direct sun light. / Vor Hitze und direkter Sonneneinstrahlung schützen. / Garder à l'abri de la chaleur et de toute exposition lumineuse. / Manténgase alejado del calor o la luz solar directa. / Manter longe do calor ou luz solar directa. / Non esporre ai raggi solari. / Να φυλάσσεται μακριά από θερμότητα και άμεση επαφή με το φως του ηλίου.
	Store at: / Lagern bei: / Stocker à: / Almacene a: / Armazenar a: / Conservare a: / Αποθήκευση στους:
	Manufacturer: / Hersteller: / Fabricant: / Productor: / Fabricante: / Fabbricante: / Παραγωγός:
	Caution! / Vorsicht! / Attention! / ¡Precaución! / Cuidado! / Attenzione! / Προσοχή!

Symbols of the kit components see MATERIALS SUPPLIED.
Die Symbole der Komponenten sind im Kapitel KOMPONENTEN DES KITS beschrieben.
Voir MATERIEL FOURNI pour les symbôles des composants du kit.
Símbolos de los componentes del juego de reactivos, vea MATERIALES SUMINISTRADOS.
Para símbolos dos componentes do kit ver MATERIAIS FORNECIDOS.
Per i simboli dei componenti del kit si veda COMPONENTI DEL KIT.
Για τα σύμβολα των συστατικών του κιτ συμβουλευτείτε το ΠΑΡΕΧΟΜΕΝΑ ΥΛΙΚΑ.

COMPLAINTS: Complaints may be submitted initially written or vocal. Subsequently they need to be filed including the test performance and results in writing in case of analytical reasons.

WARRANTY: The product is warranted to be free from material defects within the specific shelf life and to comply with product specifications delivered with the product. The product must be used according to the Intended use, all instructions given in the instructions for use and within the product specific shelf life. Any modification of the test procedure or exchange or mixing of components of different lots could negatively affect the results. These cases invalidate any claim for replacement.

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