Instructions for Use

PTH Intact ELISA (Parathyroid Hormone)

Specific quantitative assay for the determination of Intact parathyroid hormone in human serum.

REF **NM59041**

Σ **12x8**

2-8 °C

EU: IVD CE

U.S.: *For research use only.*
Not for use in diagnostic procedures.

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1. INTENDED USE

Specific quantitative assay for the determination of Intact parathyroid hormone in human serum. For in vitro diagnostic use.

2. SUMMARY AND EXPLANATION

PTH (Parathyroid hormone, Parathormone, Parathyrin) is biosynthesized in the parathyroid gland as a pre-proparathyroid hormone, a larger molecular precursor consisting of 115 amino acids. Following sequential intracellular cleavage of a 25-amino acid sequence, preproparathyroid hormone is converted to an intermediate, a 90-amino acid polypetide, proparathyroid hormone. With additional proteolytic modification, proparathyroid hormone is then converted to parathyroid hormone, an 84 amino acid polypeptide. In healthy individuals, regulation of parathyroid hormone secretion normally occurs via a negative feedback action of serum calcium on the parathyroid glands. Intact PTH is biologically active and clears very rapidly from the circulation with a half-life of less than four minutes[1]. PTH undergoes proteolysis in the parathyroid glands, but mostly peripherally, particularly in the liver but also in the kidneys and bone, to give N-terminal fragments and longer lived C-terminal and midregion fragments. In subjects with renal insufficiency, C-terminal and midregion PTH assays typically give elevated PTH results, as reflected by impaired renal clearance[2].
Intact PTH assays are important for the differentiation of primary hyperparathyroidism from other (non-parathyroid-mediated) forms of hypercalcemia, such as malignancy, sarcoidosis and thyrotoxicosis[2]. The measurement of parathyroid hormone is the most specific way of making the diagnosis of primary hyperparathyroidism. In the presence of hypercalcemia, an elevated level of parathyroid hormone virtually establishes the diagnosis. In over 90% of patients with primary hyperparathyroidism, the parathyroid hormone will be elevated[3].

The most common other cause of hypercalcemia, namely hypercalcemia of malignancy, is associated with suppressed levels of parathyroid hormone[3] or PTH levels within the normal range[4]. When intact PTH level is plotted against serum calcium, the intact PTH concentration for patients with hypercalcemia of malignancy is almost always found to be inappropriately low when interpreted in view of the elevated serum calcium[3,4,5].

Unlike C-terminal and midregion PTH, which typically are grossly elevated in subjects with renal insufficiency, intact PTH assays are less influenced by the declining renal function[5].

PTH values are typically undetectable in hypocalcemia due to total hypoparathyroidism, but are found within the normal range in hypocalcemia due to partial loss or inhibition of parathyroid function.

3. TEST PRINCIPLE

The Intact PTH Immunoassay is a two-site ELISA [Enzyme-Linked ImmunoSorbent Assay] for the measurement of the biologically intact 84 amino acid chain of PTH. Two different goat polyclonal antibodies to human PTH have been purified by affinity chromatography to be specific for well defined regions on the PTH molecule. One antibody is prepared to bind only the mid-region and C-terminal PTH 39-84 and this antibody is biotinylated.
The other antibody is prepared to bind only the N-terminal PTH 1-34 and this antibody is labeled with horseradish peroxidase [HRP] for detection.

Although mid-region and C-terminal fragments are bound by the biotinylated anti-PTH (39-84), only the intact PTH 1-84 forms the sandwich complex necessary for detection. The capacity of the biotinylated antibody and the streptavidin coated microwell both have been adjusted to exhibit negligible interference by inactive fragments, even at very elevated levels.

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. 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 intact PTH in the sample. A dose response curve of absorbance unit vs. concentration is generated using results obtained from the calibrators. Concentrations of intact PTH 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, Plasma EDTA

The determination of Intact PTH should be performed with EDTA plasma or serum. EDTA plasma has been reported to demonstrate improved PTH stability as compared to serum[6]. To assay the specimen in duplicate, 50 µL of serum or EDTA plasma 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:	up to 8 h	4 mon	

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 PTH Antibody.
1 x 7.0 mL	RGT 2	**Reagent 2** Ready to use. Contains: Peroxidase (Enzym) labeled PTH Antibody.
1 x 2.0 mL	RGT 3	**Reagent 3** Ready to use. Contains: Diluent [equine serum] for Patient Samples read off-scale.
1 x 5.0 mL	RGT 4	**Reagent 4** Ready to use. Contains: Reconstitution Solution containing surfactant.
1 x 30 mL	RGT A CONC	**Reagent A** Ready to use. Contains: Wash Concentrate (Saline with surfactant).
1 x 20 mL	RGT B	**Reagent B** Ready to use. Contains: TMB Substrate.
2 x 1 x	CONTROL1+2 LYO	**Control 1+2** (lyophilized) Contains: 2 Levels. Synthetic h-PTH (1-84) in BSA solution with goat serum. Refer to vial labels for exact ranges.
1 x 6 x	CAL A-F LYO	**Standard A-F** (lyophilized) Contains: synthetic h-PTH. Zero calibrator [BSA solution with goat serum]. All other calibrators consist of synthetic h-PTH (1-84) in BSA solution with goat serum. 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: 25; 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. Patient samples with values greater than the highest calibrator (Calibrator F), which is approximately 700–1.000 pg/mL (see exact concentration on vial label), may be diluted with Reagent 3 (Sample Diluent) and reassayed. Multiply the result by the dilution factor.
11. If preferred, mix in equal volumes, in sufficient quantities for the assay, Reagent 1 (Biotinylated Antibody) and Reagent 2 (Enzyme Labeled Antibody) in a clean amber bottle. Then use 100 µL of the mixed antibody into each well. This alternative method should replace Step (2) and (3) of the test procedure, to be followed with the incubation with orbital shaker.

10. PRE-TEST SETUP INSTRUCTIONS

10.1. Preparation of lyophilized or concentrated components

Dilute / dissolve	Component	with	Diluent	Remarks	Storage	Stability
	CAL A-F **LYO** **CONTROL 1+2 LYO**	500 µL	RGT 4	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
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 mon

11. TEST PROCEDURE

1.	Pipette **25 µL** of each sample into the respective wells of the microtiter plate. **Freeze (-20°C) the remaining calibrators and controls as soon as possible after use.**
2.	**Pipette 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 foil and place it on an **orbital shaker or rotator** set at 170 ± 10 rpm for **3 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** against 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 700–1.000 pg/mL. Hence, patient samples with PTH > 200 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 PTH concentrations up to 200 pg/mL. PTH concentrations above 200 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 PTH concentrations up to 300 pg/mL. PTH 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	**Intact PTH pg/mL**	**Intact PTH pg/mL – Result to report**
Calibrator A	0.020	0.016	0.018		0
Calibrator B	0.056	0.051	0.054		7
Calibrator C	0.124	0.119	0.122		18
Calibrator D	0.388	0.393	0.391		55
Calibrator E	1.335	1.340	1.338		210
Control 1	0.200	0.200	0.200	27.6	27.6
Control 2	0.804	0.794	0.799	119	119
Patient Sample 1	0.147	0.136	0.142	19.1	19.1
Patient Sample 2	0.407	0.409	0.408	58.5	58.5
Patient Sample 3	2.375	2.454	2.415	> 200	*
Patient Sample 4	3.725	3.725	3.725	> 200	*

* Because the concentration readout is > 200 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	Intact PTH pg/mL	Intact PTH pg/mL – Result to report
Calibrator A	0.014	0.008	0.011		0
Calibrator D	0.124	0.128	0.126		55
Calibrator E	0.428	0.425	0.427		210
Calibrator F	1.309	1.317	1.313		700
Control 1	0.074	0.066	0.070	< 200	*
Control 2	0.260	0.251	0.256	121	**
Patient Sample 1	0.049	0.043	0.046	< 200	*
Patient Sample 2	0.132	0.133	0.133	< 200	*
Patient Sample 3	0.758	0.782	0.770	401	401
Patient Sample 4	1.314	1.321	1.318	> 700	***

* For samples with readout < 200 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.

** Although the readout for Control (2) < 200 pg/mL**,** it is recommended that the actual result be read out and recorded for quality control evaluation purposes. Further, absorbance for Control 2 is sufficiently high to be analytically valid.

*** The absorbance readout is off-scale or higher than the average absorbance of the highest calibrator. Sample should be repeated with dilution.

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

Intact PTH levels were measured in 148 apparently normal individuals in the U.S. with the Intact PTH ELISA. The values obtained ranged from 9.0 to 94 pg/mL for serum. Based on statistical tests on skewness and kurtosis, the population, when transformed logarithmically, follows the normal or Gaussian distribution. The geometric mean $\pm$ 2 standard deviations of the mean were calculated to be 10.4 to 66.5 pg/mL for serum.

15. LIMITATIONS OF THE PROCEDURE

The PTH ELISA kit has exhibited no “high dose hook effect” with samples spiked with 2.100.000 pg/mL of Intact PTH. Samples with intact PTH levels greater than the highest calibrator, however, should be diluted and reassayed for correct values. Like any analyte used as a diagnostic adjunct, intact PTH results must be interpreted carefully with the overall clinical presentations and other supportive diagnostic tests.

16. PERFORMANCE

Accuracy

Three hundred and nine patient samples, with intact PTH values ranging from 1.0 to 833 pg/mL were assayed by the previous PTH kit and the updated PTH kit. Linear regression analysis gives the following statistics:

ELISA = 1.06 - 1.49 pg/mL
r = 0.998 n = 309

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 PTH ELISA has a calculated sensitivity of 1.57 pg/mL.

Specificity and Cross-Reactivity
The antibodies used in the PTH ELISA were purified by affinity chromatography to be specific for well-defined regions on the PTH molecule. The peroxidase labeled antibody recognizes only the N-terminal region or the 1-34 amino acid sequence of the PTH molecule; whereas the biotinylated antibody is specific to the 39-84 segment. Accordingly, only intact PTH, which requires binding by both the enzyme conjugated and biotinylated antibodies, can be detected by this assay.

To further achieve the specificity of this assay, conjugation and biotinylation and the molar ratios thereof, have been optimized to minimize detection of fragments of PTH. Human PTH 1-34 at levels up to 300 pg/mL and the C-terminal 39-84 fragment at levels up to 300.000 pg/mL give molar crossreactivites to PTH of less than 2% and 0.02%, respectively.

Precision and Reproducibility
The precision (intra-assay variation) of the PTH ELISA Test was calculated from 25 replicate determinations on each of the two samples.

Intra-Assay Variation

Sample	Mean Value (pg/mL)	N	CV %
A	32.4	25	6.08
B	178.2	25	3.68

The total precision (inter-assay variation) of the Calcitonin ELISA Test was calculated from data on two samples obtained in 21 different assays, by three technicians on two different lots of reagents, on three diferent lots of reagents.

Inter-Assay Variation

Sample	Mean Value (pg/mL)	N	CV %
A	30.3	21	3.6
B	159.1	21	2.8

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

Serum Sample	**PTH Endogenous** (pg/mL)	**PTH** Added (pg/mL)	**Expected** Value (pg/mL)	**Measured** Value (pg/mL)	**Recovery** (%)
A	32.7	132	165	168	102%
	20.6	264	285	288	101%
	13.5	396	410	413	101%
B	68.6	132	201	191	95%
	51.7	264	316	344	109%
	45.0	396	441	462	105%
C	19.9	132	152	165	109%
	15.4	264	279	275	99%
	13.3	396	409	424	104%

Average 103%

Linearity of Patient Sample Dilutions: Parallelism

Four patient serum samples were diluted with Reagent 3 (the Diluent for Patient Samples read off scale). Results in pg/mL are shown below:

Sample	Dilution	Expected	Observed	% Observed ÷ Expected
A	Undiluted	-	322	-
	1:2	161	148	92%
	1:4	80.5	73.1	91%
	1:8	40.3	41.5	103%
B	Undiluted	-	230	-
	1:2	115	97	84%
	1:4	58	55	95%
	1:8	29	30	103%
C	Undiluted	-	176	-
	1:2	88	82	93%
	1:4	44	45	102%
	1:8	22	24	109%
D	Undiluted	-	426	-
	1:2	213	192	90%
	1:4	107	90	84%
	1:8	53	47	89%

Average 95%

17. PRODUCT LITERATURE REFERENCES

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Further Suggested Reading:

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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.

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