Instructions for Use

Histamine ELISA

Enzyme immunoassay for the quantitative determination of histamine in human plasma, urine and EDTA whole blood. For research of cell culture supernatants.

REF **RE59221**

Σ **96**

2-8°C

EU: IVD CE

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1. INTENDED USE

Enzyme immunoassay for the quantitative determination of histamine in human plasma, urine and EDTA whole blood. For research of cell culture supernatants.

2. SUMMARY AND EXPLANATION

In humans, histamine (ß-imidazolethylamine) is the most important mediator and is mostly found in the initial phase of an anaphylactic reaction ("immediate type" allergy). Histamine is derived by the enzymatic decarboxylation of histidine. In the organism, histamine is present in nearly all tissues, and it is mainly stored in the metachromatic granula of mast cells and the basophilic leukocytes. It is present in an inactive bound form and is only released as required. Like several other mediators, histamine does not only mediate various clinical symptoms of anaphylaxis but also induces a series of effects which are directed towards a termination of the anaphylactic reaction. The biological action of histamine in tissue is guaranteed by three different surface receptors, i.e. H1, H2 and H3 receptors. Of clinical interest in the histamine determination is the quantification of the histamine release from basophilic leukocytes in allergies of the "immediate type" as well as of the histamine quantity which is present in various body fluids (plasma, urine, cell culture supernatants), after allergen administration.
IBL offers additional reagents for the performance of a **Histamine Release** test in heparinized whole blood (REF RE95000).

3. TEST PRINCIPLE

Solid phase enzyme-linked immunosorbent assay (ELISA) based on the competition principle. An unknown amount of antigen present in the sample and a fixed amount of enzyme labelled antigen compete for the binding sites of the antibodies coated onto the wells. After incubation the wells are washed to stop the competition reaction. After the substrate reaction the intensity of the developed colour is inversely proportional to the amount of the antigen in the sample. Results of samples can be determined directly using the standard 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. The cleaning staff should be guided by the professionals regarding potential hazards and handling.
9. Avoid contact with Stop solution. It may cause skin irritations and burns.
10. Some reagents contain sodium azide (NaN_3) as preservatives. In case of contact with eyes or skin, flush immediately with water. NaN_3 may react with lead and copper plumbing to form explosive metal azides. When disposing reagents, flush with a large volume of water to avoid azide build-up.
11. 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. For this reason 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 sunlight. The storage and stability of specimens 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

Plasma (EDTA, Heparin)

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	≤ -20°C (Aliquots)	≤ -70°C (Aliquots)	Keep away from heat or direct sunlight. Avoid repeated freeze-thaw cycles. Ship samples frozen.
Stability:	5 h	3 months	2 years	

Urine

It is possible to use spontaneous as well as 24 h urine. The total volume of urine excreted during a 24 h period should be collected and mixed in a single bottle containing 10-15 mL of 6 N HCl as preservative. Determine total volume for calculation of results. **Mix and centrifuge samples before use in the assay.**

	spontaneous	acidified		
Storage:	2-8°C	2-8°C	≤ -20°C (Aliquots)	Keep away from heat or direct sunlight. Avoid repeated freeze-thaw cycles. Ship samples frozen.
Stability:	8 h	3 days	6 months	

Cell Culture Supernatants

Cell culture supernatants may be used without special precautions.
Cell culture media may contain histamine in higher amounts.

Whole Blood

Total Histamine in EDTA whole Blood. Additional reagents can be ordered separately from IBL under:
Hypotonic Medium REF: KSHI771 , Release Buffer REF: KSHI751

The histamine release is performed with heparinized whole blood for research use only.
For further information see instructions for use of Histamine Release (REF RE95000).

7. MATERIALS SUPPLIED

⚠	The reagents provided with this kit are sufficient for up to 96 single determinations or up to 48 duplicates in plasma and urine.

Quantity	Symbol	Component
1 x 12x8	MTP	**Microtiter Plate** Break apart strips. Coated with anti-rabbit antiserum (goat).
1 x 7 mL	ANTISERUM	**Histamine Antiserum** Blue colored. Ready to use. Contains: Antiserum (rabbit), Tris buffer, 0.01 % Thimerosal.
1 x 100 µL	ENZCONJ CONC	**Enzyme Conjugate** Concentrate (200x) Contains: Histamine, conjugated to peroxidase.
7 x 1.0 mL	CAL P A-G	**Plasma Standards A-G** 0.0, 0.35; 1.1; 4.0; 14; 50;150 ng/mL Ready to use. For calibration of plasma samples. Standard A = Diluent for plasma samples. Contains: Histamine, human plasma.
2 x 1.0 mL	CONTROL P 1+2	**Plasma Controls 1+2** Ready to use. Contains: Histamine, human plasma. Concentrations / acceptable ranges see QC certificate.
1 x 2.0 mL	CAL U/C A	**Urine/Cell Culture Standards A** 0 ng/mL Ready to use. For calibration of urine and cell culture samples. Standard Contains: 0.1 M HCl.
5 x 0.25 mL	CAL U/C B-F	**Urine/Cell Culture Standards B-F** 2.7; 8.1; 24.3; 73; 219 ng/mL Ready to use. For calibration of urine and cell culture samples. Standard Contains: Histamine, 0.1 M HCl.
2 x 0.25 mL	CONTROL U/C 1+2	**Urine/Cell Culture Controls 1+2** Ready to use. Contains: Histamine, human urine (acidified). Concentrations / acceptable ranges see QC certificate.
1 x 2.25 mL	ACYLREAG	**Acylation Reagent** Ready to use. Contains: DMF.
1 x 60 mL	ASSAYBUF CONC	**Assay Buffer** Concentrate (5x) Contains: Tris buffer, Tween, BSA, 0.05 % Thimerosal.
1 x 50 mL	WASHBUF CONC	**Wash Buffer** Concentrate (20x) Contains: phosphate buffer, Tween, 0.1 % Thimerosal.
1 x 11 mL	INDICATORBUF	**Indicator Buffer** Purple colored. Ready to use. Contains: Tris buffer, phenol red (color change at pH < 7.5), 0.01 % Thimerosal.
1 x 15 mL	TMB SUBS	**TMB Substrate Solution** Ready to use. Contains: TMB, Buffer, stabilizers.
1 x 15 mL	TMB STOP	**TMB Stop Solution** Ready to use. 1 M H_2SO_4.
3 x	FOIL	**Adhesive Foil**

8. MATERIALS REQUIRED BUT NOT SUPPLIED

1. Micropipettes (Multipette Eppendorf or similar devices, < 3 % CV). Volume: 10; 20; 50; 100; 1000 µL
2. Disposable polypropylene tubes, disposable glass tubes, (12 x 75 mm) or 96- deep well Acylation Plate (can be ordered separately from IBL under: REF ACYLPLATE: KEHP711)
3. Rack for test tubes
4. Orbital shaker (500 rpm)
5. Vortex mixer
6. 8-Channel Micropipettor with reagent reservoirs
7. Wash bottle, automated or semi-automated microtiter plate washing system
8. Microtiter plate reader capable of reading absorbance at 450 nm (reference wavelength 600-650 nm)
9. Bidistilled or deionised water
10. 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. Some components contain ≤ 250 µL solution. Take care that the solution is completely on the bottom of the vial before opening.
5. It is advised to determine samples in duplicate to be able to identify potential pipetting errors.
6. Use a pipetting scheme to verify an appropriate plate layout.
7. 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.
8. Microtiter plate washing is important. Improperly washed wells will give erroneous results. It is recommended to use a multichannel pipette or an automatic microtiter plate 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.
9. 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.

10. PRE-TEST SETUP INSTRUCTIONS

⚠	The contents of the kit for 96 determinations can be divided into 3 separate runs. **The volumes stated below are for one run with 4 strips (32 determinations).**

10.1. Preparation of lyophilized or concentrated components

Dilute / dissolve	Component		Diluent	Relation	Remarks	Storage	Stability
20 mL	**ASSAYBUF**	ad 100 mL	bidist. water	1:5		2-8°C	2 weeks
15 mL	**WASHBUF**	ad 300 mL	bidist. water	1:20	Resolve crystals at 18-25°C.	2-8°C	4 weeks
10 µL(*)	**ENZCONJ**	with 2 mL	diluted Assay Buffer	1:200	Prepare freshly and use only once.	18-25°C	30 min

(*) Prior to dilution make sure that no liquid will remain in the stopper.

10.2. Dilution of Samples

Samples suspected to contain concentrations higher than the highest standard have to be diluted prior to acylation with appropriate media:

Urine: 0.1 M HCl.

Plasma: sample diluent (REF: KEHP771), not provided in the kit.

10.3. Acylation of Samples

If processing a large number of samples, we recommend optionally the acylation in 96-deep well Acylation Plate. (can be ordered separately from IBL under REF: ACYLPLATE KEHP711)

⚠	It is not possible to determine acylated urine or cell culture samples by use of the plasma standard curve or to determine acylated plasma samples by use of the U/C standard curve.

Note: The acylated samples can be stored at 2-8°C overnight or better at –20°C for up to 2 d.

10.3.1. Acylation in disposable tubes.

The following procedure must be performed in two variants:

Plasma

1.	Pipette **100 µL** of each **Plasma Standard**, **Plasma Control** and **patient plasma** into the respective tubes**.**
2.	Pipette **100 µL** of **Indicator Buffer** into each tube. Vortex.
3.	Pipette **20 µL** of **Acylation Reagent** into each tube. Vortex each tube immediately after pipetting.
4.	Cover tubes. **Incubate 30 min** at **RT (18-25°C).**
5.	Pipette **750 µL** of diluted **Assay Buffer** into each tube. Vortex.

Urine, Cell Culture Supernatants

1.	Pipette **50 µL** of each **Urine/Cell Culture Standard**, **Urine/Cell Culture Control** and **patient urine / cell culture sample** into the respective tubes**.**
2.	Pipette **50 µL** of **Indicator Buffer** into each tube. Vortex. If the indicator becomes colorless, the pH of the solution is too low and the sample contains too much acid. In that case add another 50 µL of Indicator Buffer until the solution remains reddish.
3.	Pipette **10 µL** of **Acylation Reagent** into each tube. Vortex each tube immediately after pipetting.
4.	Cover tubes. **Incubate 30 min** at **RT (18-25°C).**
5.	Pipette **2000 µL** of diluted **Assay Buffer** into each tube. Vortex thoroughly.

Whole Blood (Total Histamine)

1.	Pipette **50 µL** of each EDTA **whole blood sample** into **glass tubes**.
2.	Pipette **950 µL** of **Hypotonic Medium** into each tube.
3.	**Incubate 60 min** at **37°C** in a waterbath.
⚠	The supernatants of the respective samples can be stored at 2 - 8 °C for one day. For longer storage up to one week freeze at -20°C. Avoid repeated thawing and freezing.
4.	Vortex. Withdraw **100 µL** for the acylation step of the Histamine ELISA and pipette into the respective **glass tubes.**
5.	Pipette **50 µL** of each **Plasma Standard** with **50 µL Release Buffer** into the respective **glass tubes.**
6.	Pipette **50 µL** of each **Plasma Control** with **50 µL Release Buffer** into the respective **glass tubes.**
7.	Pipette **100 µL** of **Indicator Buffer** into each tube. Vortex.
8.	Pipette **20 µL** of **Acylation Reagent** into each tube. Vortex each tube immediately after pipetting.
9.	Cover tubes. **Incubate 30 min** at **RT (18-25°C).**
10.	Pipette **750 µL** of diluted **Assay Buffer** into each tube. Vortex.

10.3.2. Alternative version Acylation in 96-deep well Acylation Plate.

⚠	The 96-deep well Acylation Plate cannot be reused. Use only once!

The following procedure must be performed in two variants:

Plasma

1.	Pipette **100 µL** of each **Plasma Standard**, **Plasma Control** and **patient plasma** into the respective wells of the 96-deep well Acylation Plate.
2.	Pipette **100 µL** of **Indicator Buffer** into each well. Briefly mix contents by gently shaking the plate.
3.	Pipette **20 µL** of **Acylation Reagent** into each well. Briefly mix contents by gently shaking the plate.
4.	Cover plate with adhesive foil.. **Incubate 30 min** at **RT (18-25°C).**
5.	Pipette **750 µL** of diluted **Assay Buffer** into each well.
6.	**Mix the acylated standards, controls and samples with a 8-Channel Micropipettor** and transfer it to the Microtiter Plate (see TEST PROCEDURE).

Urine, Cell Culture Supernatants

1.	Pipette **50 µL** of each **Urine/Cell Culture Standard**, **Urine/Cell Culture Control** and **patient urine / cell culture sample** into the respective wells of the 96-deep well Acylation Plate.
2.	Pipette **50 µL** of **Indicator Buffer** into each well. Briefly mix contents by gently shaking the plate. If the indicator becomes colorless, the pH of the solution is too low and the sample contains too much acid. In that case add another 50 µL of Indicator Buffer until the solution remains reddish.
3.	Pipette **10 µL** of **Acylation Reagent** into each well Briefly mix contents by gently shaking the plate.
4.	Cover plate with adhesive foil. **Incubate 30 min** at **RT (18-25°C).**
5.	Pipette **2000 µL** of diluted **Assay Buffer** into each well.
6.	**Mix the acylated standards, controls and samples with a 8-Channel Micropipettor** and transfer it to the Microtiter Plate (see TEST PROCEDURE).

11. TEST PROCEDURE

1.	Pipette **50 µL** of each acylated **Standard,** acylated **Control and** acylated **patient sample** into the respective wells of the Microtiter Plate.
2.	Pipette **50 µL** of freshly prepared **Enzyme Conjugate** into each well.
3.	Pipette **50 µL** of **Histamine Antiserum** into each well.
4.	Cover plate with adhesive foil. **Incubate 3 h** at **RT (18-25°C)** on an orbital shaker (500 rpm).
5.	Remove adhesive foil. Discard incubation solution. Wash plate **4 x** with **250 µL** diluted **Wash Buffer**. Remove excess solution by tapping the inverted plate on a paper towel.
6.	For adding of Substrate and Stop Solution use, if available, an 8-channel Micropipettor. Pipetting should be carried out in the same time intervals for Substrate and Stop Solution. Use positive displacement and avoid formation of air bubbles.
7.	Pipette **100 µL TMB Substrate Solution** into each well.
8.	**Plasma: Incubate 40 min** at **RT (18-25°C)** on an orbital shaker (500 rpm). **Urine/Cell Culture Supernatants: Incubate 20 min** at **RT (18-25°C)** on an orbital shaker (500 rpm).
9.	Stop the substrate reaction by adding **100 µL** of **TMB Stop Solution** into each well. Briefly mix contents by gently shaking the plate.
10.	**Measure** optical density with a photometer at **450 nm** (Reference-wavelength: 600-650 nm) within **15 min** after pipetting of the Stop Solution.

12. QUALITY CONTROL

The test results are only valid if the test has been performed following the instructions. Moreover the user must strictly adhere to the rules of GLP (Good Laboratory Practice) or comparable standards/laws. User and/or laboratory must have a validated system to get diagnosis according to GLP. All kit controls must be found within the acceptable ranges as stated on the labels and the QC certificate. If the criteria are not met, the run is not valid and should be repeated. Each laboratory should use known samples as further controls. It is recommended to participate at appropriate quality assessment trials.

In case of any deviation the following technical issues should be proven: Expiration dates of (prepared) reagents, storage conditions, pipettes, devices, incubation conditions and washing methods.

13. CALCULATION OF RESULTS

The obtained OD of the standards (y-axis, linear) are plotted against their concentration (x-axis, logarithmic) either on semi-logarithmic graph paper or using an automated method. A good fit is provided with cubic spline, 4 Parameter Logistics or Logit-Log.

For the calculation of the standard curve, apply each signal of the standards (one obvious outlier of duplicates might be omitted and the more plausible single value might be used).

The concentration of the samples can be read directly from the standard curve.

In case of diluted samples the values have to be multiplied with the corresponding dilution factor.

Samples showing concentrations above the highest standard have to be diluted as described in PRE-TEST SETUP INSTRUCTIONS and reassayed.

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

Conversion:

Histamine (ng/mL) x 8.997 = nmol/L

Typical Calibration Curve Plasma

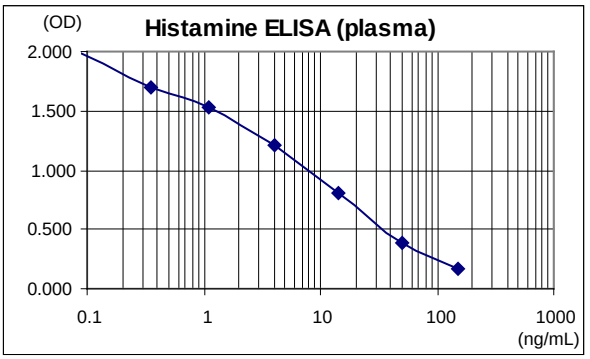
(Example. Do not use for calculation!)

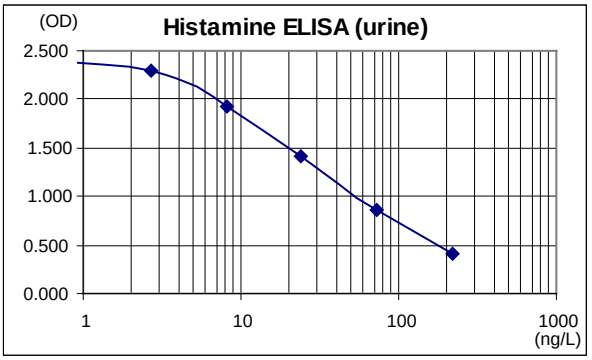
Standard	Histamine (ng/mL)	OD_{Mean}	OD/OD_{max} (%)
A	0.0	2.122	100
B	0.35	1.705	80.3
C	1.1	1.534	72.3
D	4.0	1.209	57.0
E	14	0.802	37.8
F	50	0.390	18.4
G	150	0.162	7.6

Typical Calibration Curve Urine

(Example. Do not use for calculation!)

Standard	Histamine (ng/mL)	OD_{Mean}	OD/OD_{max} (%)
A	0.0	2.476	100
B	2.7	2.298	92.8
C	8.1	1.931	78.0
D	24.3	1.413	57.0
E	73.0	0.851	34.3
F	219	0.402	16.2





14. EXPECTED VALUES

The results themselves should not be the only reason for any therapeutical consequences. They have to be correlated to other clinical observations and diagnostic tests.

Apparently healthy subjects show the following values: (95 % percentile)

Plasma	0.2 - 1.0 ng/mL
Urine	5 – 56 µg/d (24 h)
	8 – 53 µg/g Creatinine (spontaneous)
Whole Blood	< 60 ng/mL

It is recommended that each laboratory establishes its own range of normal values.

15. LIMITATIONS OF THE PROCEDURE

Specimen collection and storage have a significant effect on the test results. See SPECIMEN COLLECTION AND STORAGE for details.

For cross-reactivities, see PERFORMANCE.

The following blood components do not have a significant effect (+/- 20% of expected) on the test results up to the below stated concentrations:

Hemoglobin	5 mg/mL
Bilirubin	1 mg/mL
Triglyceride	30 mg/mL

16. PERFORMANCE

Analytical Specificity (Cross Reactivity)	Substance	Cross Reactivity (%)	Cross-reactivity of other substances tested < 0.005 %	
	N-Acetyl-Histamine	0.34		
	3-Methyl-Histamine	0.09		
Analytical Sensitivity (Limit of Detection)	Plasma	0.02 ng/mL	Mean signal (Zero-Standard) - 2SD	
	Urine	1.3 ng/mL		
Precision		Range (ng/mL)	CV (%)	
Intra-Assay	Plasma	0.5 – 85	2.2 – 13.8	
	Urine	6.2 – 178	3.7 – 6.6	
Inter-Assay	Plasma	7.6 – 86	6.0 – 9.2	
	Urine	5.2 – 155	7.1 – 12.8	
Linearity		Range (ng/mL)	Serial dilution up to	Range (%)
	Plasma	16.5 – 129	1:8	100 - 112
	Urine	2.0 - 135	1:64	83 - 117
Recovery		Mean (%)	Range (%)	% Recovery after spiking
	Plasma	105	90 - 116	
	Urine	99	83 - 117	
Method Comparison Competitor Assay A	Plasma	IBL-Assay = 0.95 x A - 0.04		r = 0.99; n = 24
Method Comparison Competitor Assay A	Urine	IBL-Assay = 0.77 x A + 2.86		r = 0.88; n = 26
Method Comparison Competitor Assay B	Plasma	IBL-Assay = 0.56 x B + 0.01		r = 0.99; n = 20
Method Comparison Competitor Assay B	Urine	IBL-Assay = 0.68 x B + 11.3		r = 0.99; n = 24

17. PRODUCT LITERATURE REFERENCES

1. Miyazaki, D. Nakamura, T. Toda, M. Ono S. et al. Macrophage inflammatory protein-1α as a costimulatory signal for mast cell-mediated immediate hypersensitivity reactions. J. Clinical Investigation Vol. 115, No 2 Feb. (2005), 434-442. Address: University College London, UK.
2. Brown, Simon G A, Wiese Michael, Blackmann Konrad: Ant venom Immunotherapy: a double-blind, placebo-controlled, crossover trial. The Lancet, Vol 361, March 22 1001-1006 (2003) Address: Royal Hobart Hospital, Tasmania, Australia
3. Matsumoto, Jun and Matsuda Hajime: Mast-cell dependent histamine release after praziquantel treatment of Schistosoma Japonicum infection: implications for chemotherapy-related adverse effects. Parasitol Res 88; 888-893 (2002) Address: Dokkyo University of Medicine, Mibu, Japan
4. Matsumoto, Jun: Adverse effects of praziquantel treatment of Schistosoma japonicum infection: involvement of host anaphylactic reactions induced by parasite antigen release. International Journal for Parasitology 32, 461-471, (2002) Address: Dokkyo University of Medicine, Mibu, Japan
5. Ching-Hsiang Hsu, Kaw-Yan Chua, Mi-Hua Tao, Yih-Loong Lai, Heuy-Dong Wu, Shau-Ku Huang & Kue-Hsiung Hsieh (1996). Immunophrophylaxis of allergen- induced immunoglobulin E synthesis and airway hyperresponsiveness in vivo by genetic immunization. Nature Medicine, Volume 2, Number 5, May (1996): 540-544. Address: Kue-Hsiung Hsieh, Chang Gung Children's Hospital, Taiwan, Republic of China
6. Demoly P., Lebel B., et al "Predictive capacity of histamine release for the diagnosis of drug allergy". Allergy 54 (1999) 500-506.

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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