Product information

Information about other products is available at: www.ibl-america.com

TSH mouse ELISA

RUO

REF IB79180

Σ 96

Immuno-Biological Laboratories, Inc. (IBL-America)
8201 Central Ave. NE, Suite P, Minneapolis, Minnesota 55432, USA
Phone: +1 (763) - 780-2955 Fax.: +1 (763) - 780-2988
Email: ibl@ibl-america.com Web: www.ibl-america.com

CONTENTS

1 INTRODUCTION 3
2 PRINCIPLE 3
3 WARNINGS AND PRECAUTIONS 3
4 REAGENTS 4
5 SAMPLE COLLECTION AND PREPARATION 5
6 ASSAY PROCEDURE 5
7 EXPECTED NORMAL VALUES 7
8 QUALITY CONTROL 7
9 PERFORMANCE CHARACTERISTICS 8
10 LIMITATIONS OF PROCEDURE 9
11 LEGAL ASPECTS 9
12 REVISION HISTORY OF INSTRUCTION FOR USE 10
13 REFERENCES 10
14 SHORT INSTRUCTION 11

1 INTRODUCTION

1.1 Intended Use

The **IBL-America TSH mouse ELISA** is an enzyme immunoassay for the quantitative measurement of TSH in mouse serum and EDTA plasma. **For Research Use Only. Not for use in diagnostic procedures.** This kit is intended for single use only.

1.2 Description of the analyte

Thyroid-stimulating hormone (also known as thyrotropin or TSH) is a glycoprotein produced by the anterior pituitary gland. Through its action on the thyroid gland, it plays a major role in maintaining normal circulating levels of the iodothyronines, T4 and T3. The production and secretion of TSH is controlled on the side by negative feedback from circulating T4 and T3, and on the other side by the hypothalamic thyrotropin-releasing hormone (TRH).
The TSH molecule is composed of two non-identical subunits, α and β, that are bound together in a noncovalent manner. Within a species, the TSH α subunit is structurally identical to the α subunits of related glycoprotein hormones (LH, FSH). The β subunits of the related hormones are structurally hormone-specific and therefore determine their unique biological activities.
Mouse models are widely accepted and indispensable for studying thyroid-stimulating hormone (TSH) regulation within the hypothalamic-pituitary-thyroid axis, owing to the high conservation of TSH signaling and feedback mechanisms between mice and humans. Genetic and disease-oriented mouse models have been essential for elucidating both fundamental TSH physiology and TSH-driven disorders (1–3).

2 PRINCIPLE

The **TSH mouse ELISA** is a solid phase enzyme-linked immunosorbent assay (ELISA) in the microtiter plate format, designed for the quantitative measurement of TSH in mouse serum and EDTA plasma. The microtiter plate is coated with a monoclonal antibody directed against TSH β subunit. Calibrators and samples are pipetted in the coated wells and incubated with the enzyme conjugate (horseradish peroxidase-labeled TSH antibody).
During 18-24 hours incubation at 2-8°C sandwich complexes consisting of the two antibodies and the mouse TSH are formed.
Unbound components are removed by a washing step. Subsequently, the chromogenic substrate TMB (3,3',5,5'-tetramethyl-benzidine), is added to all wells. During a 30 minutes incubation, the substrate is converted to a colored end product (blue) by the bound enzyme. Enzyme reaction is stopped by dispensing hydrochloric acid as stop solution (change from blue to yellow). The intensity of the color formed is proportional to the concentration of TSH in the sample. The Optical Density (OD) of the color solution is measured with a microtiter plate reader at 450 nm.
A calibrator curve is constructed by plotting OD values against concentrations of calibrators, and concentrations of unknown samples are determined using this calibrator curve.

3 WARNINGS AND PRECAUTIONS

1. For Research Use Only (RUO). Not for use in diagnostic or therapeutic procedures. This product is intended solely for use by qualified and trained laboratory personnel. Users must be proficient in immunochemical assay techniques (ELISA) and experienced in handling potentially infectious or hazardous laboratory reagents.
2. All blood components and biological materials should be handled as potentially hazardous in use and for disposal. Follow universal precautions when handling and disposing of infectious agents.
3. All human source material used in the preparation of the reagents has been tested and found negative for antibody to HIV 1&2, HbsAg, and HCV. No test method however can offer complete assurance that HIV, HBV, HCV or other infectious agents are absent. Therefore, the reagents must be handled in the same manner as potentially infectious material.
4. Before starting the assay, read the instructions for use (IFU) completely and carefully. Use the valid version of the IFU provided with the kit. Be sure that everything is understood.
5. The microtiter plate contains break apart strips. Unused wells must be stored at 2-8°C in the sealed foil pouch and used in the frame provided.
6. Pipetting of samples and reagents must be done as quickly as possible and in the same sequence for each step.
7. 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.

Immuno-Biological Laboratories, Inc. (IBL-America)
8201 Central Ave. NE, Suite P, Minneapolis, Minnesota 55432, USA
Phone: +1 (763) - 780-2955 Fax.: +1 (763) - 780-2988
Email: ibl@ibl-america.com Web: www.ibl-america.com

8. Mix the contents of the microtiter plate wells thoroughly to ensure good test results. Do not reuse wells.
9. Do not let wells dry during assay; add reagents immediately after completing the washing steps.
10. Allow the reagents to reach room temperature (18-25°C) before starting the test. Temperature will affect the OD readings of the assay.
11. Never pipet by mouth and avoid contact of reagents and samples with skin and mucous membranes.
12. Do not smoke, eat, drink or apply cosmetics in areas where samples or kit reagents are handled.
13. Wear disposable gloves when handling samples and reagents. Microbial contamination of reagents or samples may give false results.
14. Handling should be done in accordance with the procedures defined by an appropriate national biohazard safety guideline or regulation.
15. Do not use reagents beyond expiry date as shown on the kit labels.
16. All indicated volumes have to be performed according to the protocol. Optimal test results are only obtained when using calibrated pipettes and microtiter plate readers.
17. Do not mix or use components from kits with different lot numbers. Do not exchange wells of different microtiter 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 lead to slightly different results.
18. Avoid contact with Stop Solution. It may cause skin irritation and burns.
19. Some reagents contain CMIT and MIT as preservatives. In case of contact with eyes or skin, flush immediately with water.
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 please refer to Safety Data Sheets. Safety Data Sheets for this product are available upon request directly from IBL-America or at www.ibl-america.com.
22. If product information, including labeling, is incorrect or inaccurate, please contact the kit manufacturer or supplier.

4 REAGENTS

4.1 Reagents provided

1. **SORB MT Microtiter Plate**, 12x8 (break apart) strips, 96 wells, ready to use; wells coated with monoclonal anti-TSH antibody.
2. **SAM DIL Calibrator/Sample Diluent**, 1 vial, 1.0 ml, brownish, ready to use.
3. **CAL LYO Master Calibrator**, 1 vial, 5 ng, lyophilized, in buffered matrix containing highly purified TSH; for reconstitution see “4.4 Reagent preparation”.
4. **ENZ CONJ Enzyme Conjugate**, 1 vial, 11.0 ml, red, ready to use; horseradish peroxidase-labeled TSH antibody.
5. **SUB TMB Substrate Solution**, 1 vial, 22 ml, clear, ready to use; Tetramethylbenzidine (TMB).
6. **STOP SOLN Stop Solution**, 1 vial, 7.0 ml, clear, ready to use; contains 2 N hydrochlorid acid. Avoid contact with the stop solution. It may cause skin irritations and burns.
7. **WASH SOLN 10x Wash Solution**, 1 vial, 50 ml (**10x** concentrated), clear; see „Reagent preparation“.
8. **Adhesive Cover**

4.2 Material required but not provided

- Centrifuge
- Microtiter plate reader capable for endpoint measurements at 450 nm
- Vortex mixer
- Manual or automatic equipment for microtiter plate washing
- Calibrated variable precision micropipettes (10 µl, 50 µl, 100 µl, 200 µl, 300 µl, and 500 µl) and multi-dispenser or multichannel pipettes with disposable pipette tips
- Absorbent paper
- Distilled or deionized water
- Tubes for preparation of calibrator solution series
- Timer
- Semi logarithmic graph paper or software for data reduction

4.3 Storage conditions

When stored at 2-8°C unopened reagents will be stable until expiration date. Do not use reagents beyond this date. Opened reagents must be stored at 2-8°C. After first opening the reagents are stable for 30 days if used and stored properly. Keep away from heat and direct sunlight.
Microtiter plate wells must be stored at 2-8°C. Take care that the foil bag is sealed tightly.
Store Master Calibrator at 2-8°C for seven days or at < -20°C (in aliquots) for 30 days after reconstitution.

4.4 Reagent preparation

Allow reagents and required number of wells to reach room temperature (18-25°C) before starting the test.

Calibrators:
Reconstitute lyophilized mouse TSH **Master Calibrator** **CAL** **LYO** with **0.5 ml dist. water** 30 min. before use (final concentration 10 ng/ml). Prepare a 1:2 dilution series with **Calibrator/Sample Diluent** **SAM** **DIL** to get calibrators with 10, 5.0, 2.5, 1.25 and 0.625 ng/ml as follows.
Label four tubes: CAL4 (5.0 ng/ml), CAL3 (2.5 ng/ml), CAL2 (1.25 ng/ml) and CAL1 (0.625 ng/ml). Pipet **50 µl** of the **Calibrator/Sample Diluent** **SAM** **DIL** into all tubes. Pipet **50 µl** of the **reconstituted Master Calibrator** **CAL** **LYO** into tube CAL4 (5.0 ng/ml) and mix thoroughly. Successively repeat this process to complete the 2-fold dilution series. The reconstituted Master Calibrator will serve as the highest Calibrator CAL5 (10 ng/ml). Use the Calibrator/Sample Diluent as the Zero Calibrator CAL0.

Wash Solution:
Dilute 50 ml of 10x concentrated **Wash Solution** **WASH** **SOLN** **10x** with 450 ml deionized water to a final volume of 500 ml. The diluted Wash Solution **WASH** **SOLN** **1x** is stable for at least 12 weeks at room temperature. Precipitates may form when stored at 2-8°C, which should dissolve again by swirling at room temperature. The Wash Solution should only be used when the precipitates have completely dissolved.

4.5 Disposal of the kits

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

4.6 Damaged test kits

In case of any severe damage of the test kit or components, IBL-America has to be informed written, 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 SAMPLE COLLECTION AND PREPARATION

For determination of mouse TSH, serum and EDTA plasma are the preferred sample matrices. The procedure calls for 10 µl sample per well. The samples may be stored refrigerated at 2-8°C for one week, or up to 6 months frozen at -20°C. To avoid repeated thawing and freezing the samples should be aliquoted.
Samples expected to contain mouse TSH concentrations higher than the highest Calibrator (10 ng/ml) should be diluted with the **Calibrator/Sample Diluent** **SAM** **DIL** before assaying. The additional dilution step has to be taken into account for the calculation of the results.
Do not use hemolytic, icteric, or lipemic samples. Samples containing sodium azide should not be used in the assay.

6 ASSAY PROCEDURE

6.1 General remarks

- Do not interchange components of different lots.
- All reagents and samples must be allowed to come to room temperature (18-25°C) before use. All reagents must be mixed without foaming.
- Once the test has been started, all steps should be completed without interruption.

Immuno-Biological Laboratories, Inc. (IBL-America)
8201 Central Ave. NE, Suite P, Minneapolis, Minnesota 55432, USA
Phone: +1 (763) - 780-2955 Fax.: +1 (763) - 780-2988
Email: ibl@ibl-america.com Web: www.ibl-america.com

- Use new disposal plastic pipette tips for each calibrator, control, or sample to avoid cross contamination.
- Optical Density is a function of 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 equally elapsed time for each pipetting step without interruption.
- As a general rule the enzymatic reaction is linearly proportional to time and temperature.
- Respect the incubation times as stated in these Instructions for Use.
- Duplicate determination of calibrators, controls, and samples is recommended to identify potential pipetting errors.
- Mircotiter plate washing is important. Improperly washed wells will give erroneous results. It is recommended to use a multi-dispenser or multichannel pipette, or an automatic microtiter plate washing system. Do not allow the wells to dry between incubations. Do not scratch coated wells during washing and aspiration. Wash and fill all reagents with care. While washing, check that all wells are filled precisely with Wash Solution, and that there are no residues in the wells.
- A calibrator curve must be established for every run.
- For internal quality control we suggest using **Mouse Control Set coded IBDEV88MC**. For more information, please contact IBL-America.

6.2 Assay procedure

1. Prepare a sufficient number of Microtiter Plate wells to accommodate Calibrators, Controls and samples in duplicates.
2. Preparation of Calibrators: Label four tubes: CAL4 (5.0 ng/ml), CAL3 (2.5 ng/ml), CAL2 (1.25 ng/ml) and CAL1 (0.625 ng/ml). Pipet **50 µl** of the **Calibrator/Sample Diluent** **SAM** **DIL** into all tubes. Pipet **50 µl** of the **reconstituted Master Calibrator** **CAL** **LYO** into tube CAL4 (5.0 ng/ml) and mix thoroughly. Successively repeat this process to complete the 2-fold dilution series. The reconstituted Master Calibrator will serve as the highest Calibrator CAL5 (10 ng/ml). Use the Calibrator/Sample Diluent as the Zero Calibrator CAL0.

	1	2	3	4	5	6	7	8	9	10	11	12
A	CAL0	CAL4	P1	P..								
B	CAL0	CAL4	P1	P..								
C	CAL1	CAL5	P2									
D	CAL1	CAL5	P2									
E	CAL2	CO1	P3									
F	CAL2	CO1	P3									
G	CAL3	CO2	P4									
H	CAL3	CO2	P4									

CAL0-5: Calibrator 0-5, CO1/CO2: Mouse Control Set, P1-P..: samples

3. Dispense **10 µl** of each **Calibrator** **CAL** **0** **-** **5**, **Control** **CONTROL** **1** **-** **2** and **samples** in duplicates with new disposable tips into appropriate **Microtiter Plate** **SORB** **MT** wells.
4. Add **100 µl** of **Enzyme Conjugate** **ENZ** **CONJ** into each well.
5. Mix for 10 seconds, cover the **Microtiter Plate** with the **Adhesive Cover** and incubate for **18-24 hours** at 2-8°C.
6. Peel off the **Adhesive Cover**, discard the content of the wells and wash **4 times** with **300 µl** diluted **1x Wash Solution** **WASH** **SOLN** **1x** (see chapter 4.4) at room temperature (18-25°C). Remove as much Wash Solution as possible by beating the Microtiter Plate carefully on absorbent paper.
   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** **SUB** **TMB** to each well.
8. Incubate without shaking for **30 minutes** at room temperature in the dark.
9. Stop reaction by adding **50 µl** of **Stop Solution** **STOP** **SOLN** to each well and mix carefully.
10. Determine the OD of each well at **450 nm**. It is recommended to read the wells within 15 minutes.

6.3 Calculation of results

1. Calculate the average Optical Density (OD) values for each set of calibrators, controls, and samples.
2. The obtained ODs of the calibrators (y-axis, linear) are plotted against their concentration (x-axis, logarithmic) either on semi-logarithmic paper or using an automated method.
3. Using the mean OD value for each sample determine the corresponding concentration from the calibrator curve.
4. Automated method: The results in this Instructions for Use have been calculated automatically using a 4 PL (4 Parameter Logistics) curve fit. 4 Parameter Logistics is the preferred calculation method. Other data reduction functions may give different results.
5. The concentration of the samples can be read directly from this calibrator curve. Samples with concentrations higher than that of the highest calibrator have to be further diluted and reassayed. For the calculation of the concentrations this dilution factor has to be taken into account.

6.3.1 Example of typical Calibrator Curve

Following data are intended for illustration only and must not be used to calculate results from another run.

Calibrator		Optical Density
Calibrator 0	(0 ng/ml)	0.076
Calibrator 1	(0.625 ng/ml)	0.256
Calibrator 2	(1.25 ng/ml)	0.446
Calibrator 3	(2.5 ng/ml)	0.874
Calibrator 4	(5.0 ng/ml)	1.703
Calibrator 5	(10 ng/ml)	3.026

7 EXPECTED NORMAL VALUES

In order to determine the normal range of serum and EDTA plasma TSH in mouse, samples of female and male mice were collected and analyzed using the IBL-America TSH mouse ELISA.
Following ranges are calculated with the results of this study.

Mouse Strain	Sample Type	Gender	n =	Median (ng/ml)	Range (ng/ml)
BL6N	Serum	female	13	n. d.	n. d. - 0.32
		male	13	0.29	n. d. - 0.88
CD1	Serum	female	15	n. d.	n. d. - 0.41
		male	14	0.06	n. d. - 0.31

n. d.: not detectable

Twenty EDTA plasma in total were tested for both strains and genders and found from non-detectable to 0.04 ng/ml.

It is recommended that each laboratory establishes its own normal range since TSH levels can vary due to handling, mouse strain, and sampling techniques.

8 QUALITY CONTROL

Good laboratory practice requires that controls are run with each calibrator curve. A statistically significant number of controls should be assayed to assure proper performance. The use of control samples is advised to assure the day-to-day validity of results. The corresponding results of the external **Mouse Control Set** coded **IBDEV88MC** are stated in its Instructions for Use respectively on the QC datasheet (Certificate of Analysis) included in the TSH mouse ELISA.
If the results of the assay do not meet the established acceptable ranges of control materials, results should be considered invalid. In this case, check the following technical areas: Pipetting and timing devices, microtiter plate reader, 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 IBL-America directly.

Immuno-Biological Laboratories, Inc. (IBL-America)
8201 Central Ave. NE, Suite P, Minneapolis, Minnesota 55432, USA
Phone: +1 (763) - 780-2955 Fax.: +1 (763) - 780-2988
Email: ibl@ibl-america.com Web: www.ibl-america.com

9 PERFORMANCE CHARACTERISTICS

9.1 Reproducibility

9.1.1 Intra-Assay

The intra-assay variation was determined by 20 replicate measurements of three samples within one run.

	Sample 1	Sample 2	Sample 3
Mean (ng/ml)	1.27	2.56	4.77
SD (ng/ml)	0.04	0.07	0.12
CV (%)	3.3	2.9	2.5
n =	20	20	20

9.1.2 Inter-Assay

The inter-assay variation was determined by duplicate measurements of three samples in at least ten different runs.

	Sample 1	Sample 2	Sample 3
Mean (ng/ml)	1.22	2.48	4.68
SD (ng/ml)	0.04	0.10	0.16
CV (%)	3.3	3.9	3.4
n =	10	11	11

9.2 Recovery

Recovery was determined by adding increasing amounts of the analyte to three different samples containing different amounts of endogenous analyte. Each sample (non-spiked and spiked) was measured by the IBL-America TSH mouse ELISA. The percentage recoveries were determined by comparing observed and expected results of the samples.

Sample	Spiking	Observed Concentration (ng/ml)	Expected Concentration (ng/ml)	Recovery %
1	native	n. d.	-	-
	1 ng/ml	1.08	1.00	108
	2 ng/ml	2.17	2.00	108
	4 ng/ml	4.68	4.00	117
2	native	n. d.	-	-
	1 ng/ml	1.02	1.00	102
	2 ng/ml	2.18	2.00	109
	4 ng/ml	4.35	4.00	109
3	native	n. d.	-	-
	1 ng/ml	1.15	1.00	115
	2 ng/ml	2.50	2.00	125
	4 ng/ml	4.98	4.00	124

n. d.: not detectable

9.3 Linearity

Three samples were assayed both undiluted and diluted with Zero Calibrator. The percentage linearities were determined by comparing observed and expected results of the samples.

Sample	Dilution	Observed Concentration (ng/ml)	Expected Concentration (ng/ml)	Linearity %
1	native	5.63	-	-
	1 : 2	3.12	2.81	111
	1 : 4	1.70	1.41	121
	1 : 8	0.89	0.70	127
2	native	5.94	-	-
	1 : 2	2.87	2.97	96
	1 : 4	1.44	1.49	97
	1 : 8	0.83	0.74	111
3	native	6.36	-	-
	1 : 2	3.42	3.18	108
	1 : 4	1.72	1.59	108
	1 : 8	0.85	0.79	107

10 LIMITATIONS OF PROCEDURE

Reliable and reproducible results will be obtained when the assay procedure is performed with a complete understanding of the instructions for use and with adherence to GLP (Good Laboratory Practice). Any improper handling of samples or modification of this test might influence the results.

10.1 Interfering Substances

- Until now no substances (drugs) are known influencing the measurement of mouse TSH in serum or EDTA plasma.
- Hemolytic, icteric, or lipemic samples can cause false results.
- Samples containing sodium azide must not be used in the assay.
- Non-specific interferences with this in vitro immunoassay cannot be excluded. If implausible results are suspected, they should be considered invalid and verified by further testing.

10.2 High Dose Hook Effect

Up to a tested concentration of 1000 ng/ml TSH no High Dose Hook Effect could be observed for the TSH mouse ELISA.

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 a sufficient number of controls within the test procedure 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 regarding results please contact IBL-America.

11.2 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 results and validity of the overall test. Such modification and/or exchanges invalidate any claim for replacement.
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.

Immuno-Biological Laboratories, Inc. (IBL-America)
8201 Central Ave. NE, Suite P, Minneapolis, Minnesota 55432, USA
Phone: +1 (763) - 780-2955 Fax.: +1 (763) - 780-2988
Email: ibl@ibl-america.com Web: www.ibl-america.com

12 REVISION HISTORY OF INSTRUCTION FOR USE

Version 1 - no former version available

13 REFERENCES

1. Ortiga-Carvalho TM, Chiamolera MI, Pazos-Moura CC, Wondisford FE. Hypothalamus-Pituitary-Thyroid Axis. Compr Physiol. 2016 Jul 1;6(3):1387–428. doi:10.1002/J.2040-4603.2016.TB00708.X

2. Wondisford FE. Evaluating the hypothalamic-pituitary-thyroid (HPT) axis in mice. In: Methods in Molecular Biology. Humana Press Inc.; 2018. p. 155–61. doi:10.1007/978-1-4939-7902-8_13 PubMed PMID: 29892823.

3. Eckstein A, Philipp S, Goertz G, Banga JP, Berchner-Pfannschmidt U. Lessons from mouse models of Graves' disease. Endocrine. Springer; 2020. p. 265–70. doi:10.1007/s12020-020-02311-7 PubMed PMID: 32399893.

14 SHORT INSTRUCTION

all sample sizes given in µl

Steps	CAL 0 - 5 (0-10 ng/ml)	CONTROL 1 - 2	Sample	Temperature (°C)
Pipet **CAL 0 - 5**	**10**	**-**	-	18-25
Pipet **CONTROL 1 - 2**	**-**	**10**	**-**	
Pipet **samples**	**-**	**-**	**10**	
Pipet **ENZ CONJ**	**100**			
Mix for 10 seconds				
Cover plate with **Adhesive Cover**				
Incubate for **18-24 h**				**2-8**
Decant Wash **4x** with **WASH SOLN 1x**	**300** (4 times)			18-25
Pipet **SUB TMB**	**200**			
Incubate without shaking for **30 min** in the **dark**				
Pipet **STOP SOLN**	**50**			
Read at **λ = 450 nm**				

Immuno-Biological Laboratories, Inc. (IBL-America)
8201 Central Ave. NE, Suite P, Minneapolis, Minnesota 55432, USA
Phone: +1 (763) - 780-2955 Fax.: +1 (763) - 780-2988
Email: ibl@ibl-america.com Web: www.ibl-america.com

SYMBOLS USED WITH IBL-AMERICA ASSAYS

Symbol	English	Deutsch	Française	Espanol	Italiano
CE	European Conformity	CE-Konformitäts-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	utilisation 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	Artikelnummer	Référence	Número de catálogo	No. di catalogo
LOT	Lot. No. / Batch code	Chargencode	No. de lot	Número de lote	Lotto no
Σ	Contains sufficient for <n> tests/	Ausreichend für <n> Prüfungen	Contenu suffisant pour "n" tests	Contenido suficiente para <n> ensayos	Contenuto sufficiente per "n" saggi
	Storage Temperature	Temperaturbegrenzung	Température de conservation	Temperatura de conservacion	Temperatura di conservazione
	Expiration Date	Verwendbar bis	Date limite d'utilisation	Fecha de caducidad	Data di scadenza
	Manufacturer	Hersteller	Fabricant	Fabricante	Fabbricante
V<x>	Version	Version	Version	Versión	Versione
	Single-use	Nicht wiederverwenden/ Nur zum Einmalgebrauch/ Nur einmal verwenden	À usage unique	Uso único	Uso una volta
	Distributor	Vertreiber	Distributeur	Distribuidor	Distributore

Symbol	Português	Hungarian	Polska	Bulgarian	
CE	Conformidade Europeia	Európai megfelelőség	Zgodność europejska	Европейско съответствие	
	Siga as instruções de uso	Kövesse a használati utasítá sokat	Postępuj zgodnie z instrukcją obsługi	Вижте инструкциите за употреба	
IVD	Dispositivo de diagnóstico in vitro	In vitro diagnosztikai eszköz	Urządzenie do diagnostyki in vitro	Уред за ин витро диагностика	
RUO	Apenas para fins de investigação	Kizárólag kutatási célokra	Tylko do użytku badawczego	Само за изследователска употреба	
REF	Número de artigo	Cikkszám	Numer artykułu	Каталожен номер	
LOT	Código do lote	Tételkód	Kod partii	Партиден номер / Код на партидата	
Σ	Suficiente para <n> exames	Elégséges <n> vizsgákhoz	Wystarczający dla <n> egzaminów	Съдържа достатъчно за <n> теста/	
	Temperatura de armazenamento	Tárolási hőmérséklet	Temperatura przechowywania	Температура на съхранение	
	Utilizável até	Használható addig, amíg	Użyteczny do	Срок на годност	
	Fabricante	Gyártó	Producent	производител	
V<x>	Versão	Verzió	Wersja	Версия	
	Utilização única	Egyszer használatos	Jednorazowe	За еднократна употреба	
	Distribuidor	Forgalmazó	Dystrybutor	Дистрибутор	