Instructions for use

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Modified Gliadin Peptide IgA ELISA

Enzyme immunoassay for the qualitative and quantitative determination of IgA antibodies against MPG in human serum or plasma (EDTA, citrate, heparin).

REF **RE75741**

Σ **12x8**

2°C 8°C

EU: IVD CE

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Always there for you

1. OVERVIEW

1.1. Introduction and background

Celiac disease (CD; synonyme: gluten-sensitive enteropathy) is caused by a hypersensitive reaction of genetically predisposed individuals to ingested gluten (1). Gluten is a set of proteins present in many kinds of cereal grain, e.g. wheat, oats, barley and rye. CD affects the upper small intestine: its morphological manifestation, the more or less complete atrophy of the villi of the mucous membrane, leads to malabsorption problems, e.g. chronic vitamin deficiency (2). However, the symptoms are variable or sometimes even absent (3).

It has been known for many years that elevated levels of gliadin-specific antibodies occur in the sera of celiac patients (4, 5, 6). Gliadin is a component of gluten and constitutes a predominant antigen. It is fragmented in the small intestine and the resulting peptides are deamidated by the enzyme tissue transglutaminase (tTG) which itself has been identified as the major CD autoantigen (7).

Recently, it has been shown that certain deamidated gliadin peptides are powerful immunogens and that antibodies directed at these peptides exhibit a better diagnostic accuracy for CD, as compared to antibodies directed at crude gliadin (8). At the same time, gliadin-specific antibodies (resp. antibodies against deamidated gliadin peptides) are considered more sensitive than tTG-directed autoantibodies when diagnosing CD in very young children (9).

The present enzyme-linked immunosorbent assay (ELISA) is intended for the quantitative or qualitative determination of IgA antibodies directed against a modified (deamidated) gliadin peptide (MGP) in human serum or plasma (cf. section 7). The immobilised antigen is a highly purified, synthetic peptide derivative. The test is fast (incubation time 30 / 30 / 30 minutes) and flexible (divisible solid phase, ready-to-use reagents). Six calibrators allow quantitative measurements; a negative and a positive control check the assay performance.

1.2 Intended Purpose

MGP IgA ELISA is an enzyme-linked immunosorbent assay (ELISA) intended for the quantitative or qualitative determination of IgA class antibodies directed against a modified (deamidated) gliadin peptide (MGP) in human serum or plasma samples.

Its function is the aid to diagnosis of gluten-sensitive enteropathies like celiac disease and dermatitis herpetiformis.

This product is intended for manual professional in vitro diagnostic use only.

2. WARNINGS AND PRECAUTIONS

The test kit is intended for in vitro diagnostic use only; not for internal or external use in humans or animals. It must be executed by trained professional staff.

The kit has been tested for transport stability and can be shipped unrefrigerated for up to 3 days. Store at 2 - 8°C on arrival. In case of doubt, contact your local distributor or the manufacturer.

Do not use reagents beyond their expiration dates. Adherence to the protocol is strongly recommended.

The Sample Diluent, calibrators and controls contain Na-azide as antimicrobial agent. The wash buffer contains bromonitrodioxane and the conjugate methylisothiazolone / bromonitrodioxane as preservative. The substrate contains 3, 3', 5, 5'-tetramethylbenzidine (TMB) and hydrogen peroxide (H_2O_2). The stop solution, 0,2 M sulfuric acid (H_2SO_4), is acidic and corrosive.

The above mentioned reagents may be toxic if ingested. Follow routine precautions for handling hazardous chemicals. Avoid all body contact, wear gloves and eye protection. If one of the reagents comes into contact with skin or mucous membrane, wash thoroughly with water. Never pipette by mouth. Dispose in a manner complying with local/national regulations.

Na-Azide may react with lead and copper plumbing to form explosive metal azides. On disposal, flush with a large amount of water to prevent azide build-up.

The calibrators and controls contain components of human origin. They were tested for human immunodeficiency virus (HIV)-Ag, hepatitis B surface (HBs)-Ag and antibodies against HIV 1/2 and hepatitis C virus (HCV) and showed negative results; either in an FDA-approved or a CE-compliant test, according to European Directive 98/79/EC.

However, no test can guarantee that material of human origin is not actually infectious. The preparations should therefore be treated as potentially infectious and disposed of accordingly, as should the samples (and residues thereof); according to CDC (Center of Disease Control, Atlanta, USA) or other local / national guidelines on laboratory safety and decontamination.

3. PRINCIPLE OF THE TEST

The wells of the solid phase are coated with MGP. On this surface, the following immunological reactions take place:

1st reaction: MGP-specific antibodies present in the sample bind to the immobilised antigen, forming the antigen-antibody complex. Then, non-bound sample components are washed away from the solid phase.

2nd reaction: A second antibody, directed at human IgA antibodies and conjugated with horse-radish peroxidase (HRP), is added. This conjugate binds to the complex. Then, excess conjugate is washed away from the solid phase.

3rd reaction: The enzyme-labelled complex converts a colourless substrate into a blue product. The degree of colour development reflects the concentration of IgA antibodies against MGP in the sample.

4. CONTENTS OF THE KIT

a. **MTP** **Microtiter Plate**, coated with MGP and hermetically packed in a foil laminate pouch together with a desiccant bag. The plate consists of 12 strips, each of which can be broken into 8 individual wells.

b. **ENZCONJ IgA** **Enzyme Conjugate IgA**, 14 mL, ready-to-use, yellow coloured. Buffered solution containing stabilising protein, methylisothiazolone and bromonitrodioxane.

c. **CAL A–F** **Calibrator A-F**, 2,0 mL each, 0 - 3,0 - 8,0 - 18 - 45 and 100 U MGP IgA / mL, ready-to-use, gradually blue coloured. Contain TBS, BSA, Tween and Na-azide.

d. **CONTROL+** & **CONTROL -** **Positive and Negative Control**, 2,0 mL each, ready-to-use, green and red coloured, respectively. Contain TBS, BSA, Tween and Na-azide.

e. **SAMPLEDIL** **Sample Diluent**, 100 mL, ready-to-use, orange coloured. Contains Tris-buffered saline (TBS), bovine serum albumin (BSA), Tween and Na-azide.

f. **TMB SUBS** **TMB Substrate Solution**, 14 mL, ready-to-use, colourless. Contains a buffered solution of TMB and H_2O_2. Contained in a vial impermeable to light.

g. **WASHBUF** **CONC** **Wash Buffer**, 100 mL, 10x-concentrate, blue coloured. Contains TBS, Tween and bromonitrodioxane.

h. **STOP** **TMB Stop Solution** (0,2 M H_2SO_4), 14 mL, colourless, ready-to-use. Caution: sulfuric acid is corrosive.

i. Instructions for Use

j. Lot-specific certificate of analysis

5. MATERIALS REQUIRED BUT NOT SUPPLIED

a. Deionised or distilled water

b. Graduated cylinder, 1000 mL

c. Tubes for sample dilution (transfer tubes in the microwell plate format recommended)

d. Pipettes for 10, 100 and 1000 µL (1- and 8-channel pipettes recommended)

e. Microwell plate washer (optional)

f. Microwell plate photometer fitted with a 450 nm filter

g. ELISA evaluation program (recommended)

6. STORAGE OF THE KIT

Store kit at 2 - 8°C, do not freeze. It is stable up to the expiry date stated on the label of the box. Do not use kit beyond its expiry date.

7. REAGENT AND SAMPLE PREPARATION / SPECIMEN REQUIREMENTS

Do not exchange or pool corresponding components from different kits, due to possibly different shipping or storage conditions. If the kit is to be used for several tests, only the currently needed amount of reagents should be withdrawn. It is **crucially important** that no cross-contamination between the reagents occurs. Use only clean pipettes and do **not pour back** residues into the original flasks.

a. The solid phase must reach room temperature before opening the pouch. Remove the supernumerary microwells from the frame and immediately put them back into the pouch, together with the desiccant bag. Reseal the pouch hermetically and keep it refrigerated for future use.

b. Dilute the wash buffer 10x-concentrate (100 mL, blue) with 900 mL deionised water. Mix thoroughly. The diluted buffer is stable for several weeks if stored refrigerated (2 - 8°C).

c. Preparation of the samples: handle patient specimens as potentially infectious agents. Besides serum, EDTA-, citrate- or heparin-treated plasma is suitable sample material as well.

   Specimen requirements: highly lipemic, haemolysed or microbially contaminated samples may cause erroneous results and should be avoided.

   Prepare samples using normal laboratory techniques. Turbid samples must first be clarified (centrifuged). The clarified or clear samples are mixed and then diluted 1/100, e.g. 10 µL serum or plasma + 990 µL Sample Diluent. Also mix the dilution.

   For rapid dispensing during the assay procedure, preparation of the calibrators, controls and samples in microwell transfer tubes is recommended. This allows the operation of an 8-channel pipette during the assay procedure.

   If samples are not assayed immediately, they should be stored at 2 - 8°C and assayed within 3 days. Repeated freezing and thawing of samples should be avoided. Thawed samples must be mixed prior to diluting.

8. ASSAY PROCEDURE

Before starting the assay, all components of the kit must have reached room temperature (23 ± 3°C).

To achieve best results, i.e. the maximum ratio between specific and background signal, **careful washing** is essential (steps a, c and e). It is **crucially important to remove the wash solution completely.** For that purpose, tap the plate firmly on several layers of absorbent tissue. Automated washers must be verified according to results obtained by manual washing.

a. Immediately prior to use, wash the solid phase once: fill wells with 350 µL wash buffer each, let soak for about 10 seconds in the wells and remove.

b. Dispense the calibrators (2,0 mL each, ready-to-use, gradually blue), controls (2,0 mL each, ready-to-use, green and red) and the diluted samples rapidly into the microwells; 100 µL per well. Duplicate measurements are recommended.

   Incubate the plate for 30 minutes at room temperature (23 ± 3°C).

c. Wash the wells 4 times as in step a.

d. Rapidly (preferably using an 8-channel pipette) dispense the conjugate (14 mL, ready-to-use, yellow); 100 µL per well. Incubate the plate as in step b.

e. Repeat wash step c.

f. Rapidly (preferably using an 8-channel pipette) dispense the substrate solution (14 mL, ready-to-use, colourless, black vial); 100 µL per well. Incubate the plate as in step b. As the substrate is photosensitive, avoid intense light exposure (e.g. direct sunlight) during incubation.

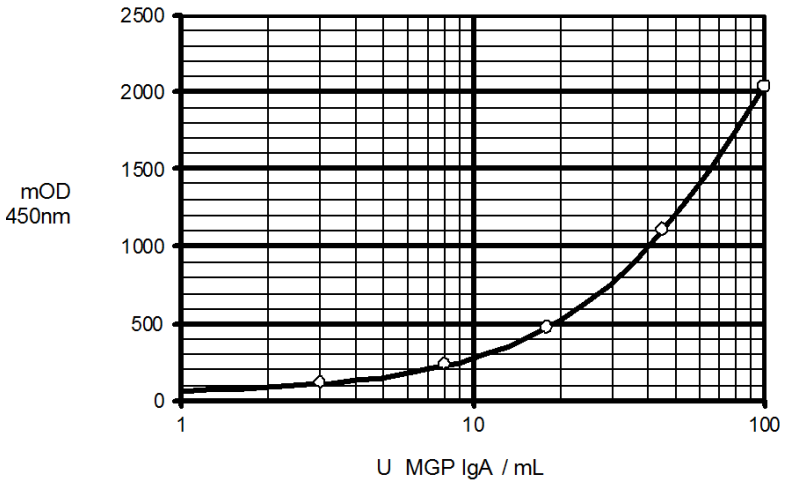
g. Rapidly (preferably using an 8-channel pipette) dispense the stop solution (14 mL, ready-to-use, colourless. Caution: corrosive!); 100 µL per well. Use the same sequence as for the substrate. The colour changes from blue to yellow. Agitate the plate, preferably on an orbital shaker, for about 10 seconds.

h. Immediately read the absorbance in the microwell plate photometer at 450 nm.

Refrigerate the remainder of the reagents (2 - 8°C) if they are to be used again.

9. EVALUATION AND QUALITY CONTROL

Quantitative evaluation: the data obtained are quantitatively evaluated with the standard curve, as shown below. However, the depicted curve can only serve as a model. It can not substitute the measurement of the calibrators, together with the controls and actual samples. The curve has been constructed with a conventional ELISA evaluation program, using a 4-parameter function. The Spline approximation is also appropriate.



If no computer-supported evaluation is possible, the standard curve may be drawn by hand. It allows transformation of the absorbance value of a sample into its concentration, i.e. into U MGP IgA per mL sample.

Qualitative evaluation: the test may also be evaluated in a qualitative manner. This requires measurement of the positive control only. Nevertheless, measurement and examination of the negative control is recommended (see below: quality control).

In qualitative test evaluation, the absorbance of the samples is compared with the borderline absorbance (= cut-off). It is determined according to the following formula:

$\text{absorbance}_{\text{borderline}} = \text{absorbance}_{\text{positive control}} \times \text{factor}$

The factor depends on the kit lot and is quoted in the lot-specific certificate of analysis which is included with each test kit. Example:

$\text{absorbance}_{\text{positive control}} = 1250 \text{ mOD}$

$\text{factor} = 0{,}35$

$\text{absorbance}_{\text{borderline}} = 1250 \text{ mOD} \times 0{,}35 = 438 \text{ mOD}$

In order to gain an impression of how positive a particular sample is for MGP IgA, one may calculate the ratio, according to the formula:

$\text{ratio} = \text{absorbance}_{\text{sample}} / \text{absorbance}_{\text{borderline}}$

Example:

$\text{absorbance}_{\text{borderline}} = 438 \text{ mOD}$

$\text{absorbance}_{\text{sample}} = 1480 \text{ mOD}$

$\text{ratio} = 1480 \text{ mOD} / 438 \text{ mOD} = 3{,}4$

Quality control: the positive and negative control check the assay performance. Their authorised values and acceptable ranges, respectively, are quoted in the lot-specific certificate of analysis. Values of the controls must fall within the indicated ranges; otherwise, the results of the assay are invalidated.

10. INTERPRETATION OF RESULTS / LIMITATIONS OF THE PROCEDURE

Based on the measurement of a blood donor and a positive collective of sera (see below), we suggest for the assessment of patient sera:

	quantitative evaluation U MGP IgA / mL sample	qualitative evaluation ratio
normal (negative) range	< 6,7	< 0,86
cut-off	8,0	1,00
equivocal range	6,7 - 9,6	0,86 - 1,17
positive range	> 9,6	> 1,17

These specifications are given as an indication only; in order to check their accuracy, each analysis should include parallel samples of normal sera.

A negative test result indicates that the patient does not have an elevated level of IgA antibodies to MGP. It does not preclude the possibility of an IgA deficiency (10). Babies and children might not yet have developped an appropriate IgA-antibody level. In these cases, or if clinical signs of CD are observed, IgG antibodies directed at MGP and/or tTG should be determined.

A positive result should be considered as an indication for CD. For confirmation, IgA antibodies against tTG may be examined.

Specimens exhibiting results within the borderline range quoted above should be considered as equivocal and reported as such. It is recommended that a second sample be collected two weeks later and run in parallel with the first sample to document a possible change of antibody titer.

As with any serological test, the results should be interpreted in the light of the patient's symptoms and other diagnostic criteria. In more detail, the definitive diagnosis of celiac disease requires at least the following 3 criteria:

a. serological test: tTG IgA antibodies in the patients serum;

b. histological test: biopsy and histologic evaluation according to the Oberhuber-Marsh classification;

c. nutritional test: remission (of symptomes and of serological findings) on a gluten-free diet. Hence, during diagnosis period, blood samples should be taken several times of a patient and monitored (11 - 14).

In case one of these criteria is not met, the attending physician shall refer to official guidelines to decide on the follow up steps to take for diagnosis and treatment (15 - 18).

11. PERFORMANCE CHARACTERISTICS

11.1. Standardisation

The test is standardised with a purified serum preparation containing IgA antibodies specifically directed at MGP. This preparation is calibrated against a set of gradually positive sera, solely reserved for this purpose. The degree of sample reactivity is measured in arbitrary units (U/mL) since no international standard is available.

11.2. Analytical specificity

The test allows the specific determination of human IgA antibodies directed against MGP.

Interference with anticoagulants (EDTA, Citrat, Heparin) in samples has been tested and no interference effects have been observed.

11.3. Detection limit (analytical sensitivity)

The detection limit is defined as that concentration of analyte that corresponds to the mean absorbance of Sample Diluent plus 3-fold standard deviation (s).
It was determined as < 1 U MGP IgA per mL sample (n = 24).

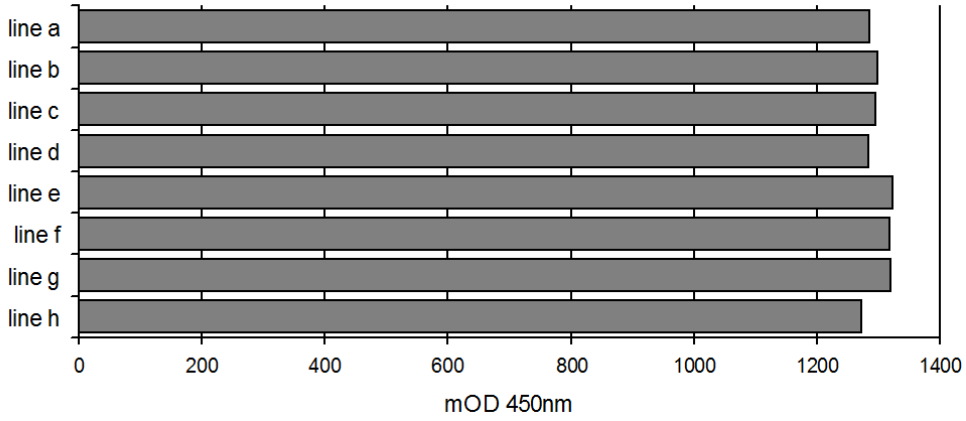
Recommended measuring range: 2 - 100 U MGP IgA per mL sample

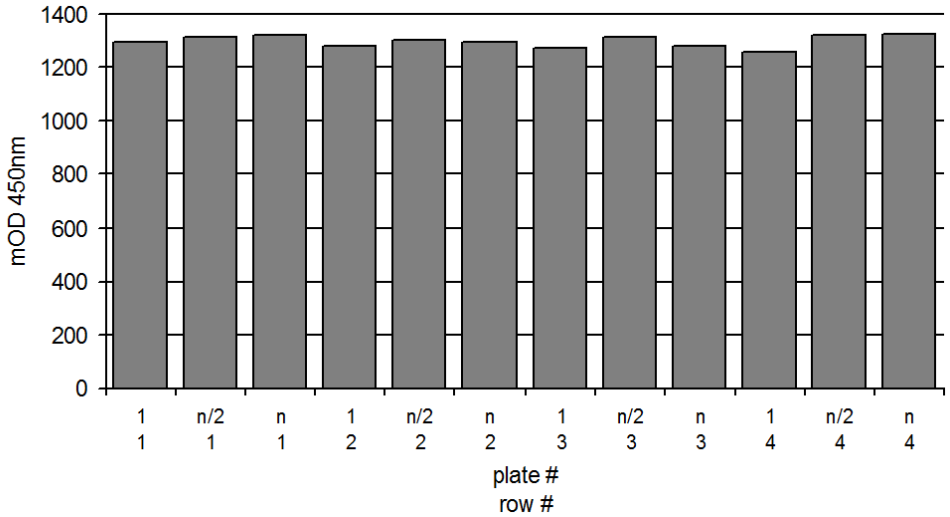
11.4. Homogeneity of the solid phase

Measurement of the solid phase homogeneity is a regular QC part of each production lot. This is determined by 288-fold measurement of an IgG-positive but non-saturating sample on 3 selected plates. Acceptance criterion: mOD-coefficient of variation (cv) over the plates < 8%.

The figure below shows a representative excerpt (solid phase lot no. 1306O) of such an analysis.

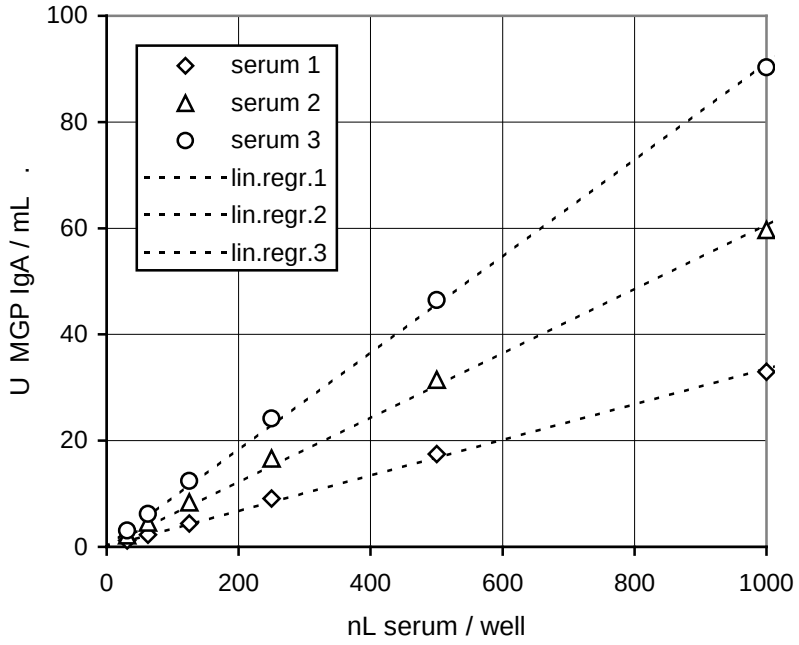
plate row	1 1	n/2 1	n 1	1 2	n/2 2	n 2	1 3	n/2 3	n 3	1 4	n/2 4	n 4	mean	cv %
line a	1292	1323	1309	1274	1293	1272	1266	1298	1257	1239	1270	1329	1285	2,1
line b	1307	1328	1315	1280	1292	1294	1284	1294	1293	1263	1312	1317	1298	1,4
line c	1309	1313	1310	1287	1311	1291	1267	1298	1275	1250	1320	1322	1296	1,7
line d	1271	1318	1312	1268	1290	1287	1252	1298	1253	1249	1311	1288	1283	1,9
line e	1324	1332	1344	1302	1311	1321	1303	1350	1315	1280	1348	1339	1322	1,6
line f	1309	1336	1329	1289	1307	1321	1285	1346	1316	1286	1346	1339	1317	1,7
line g	1317	1322	1347	1284	1332	1326	1291	1328	1323	1280	1362	1329	1320	1,9
line h	1268	1249	1300	1267	1290	1256	1253	1307	1224	1232	1287	1331	1272	2,5
mean	1300	1315	1321	1281	1303	1296	1275	1315	1282	1260	1320	1324	**1299**	
cv %	1,6	2,1	1,3	0,9	1,1	1,9	1,4	1,8	2,8	1,6	2,4	1,2		**2,3**





11.5. Linearity

In order to assess the dose-response relationship of the test, positive sera were measured in serial 2-fold dilution. Acceptance criterion: linear regression of 4 successive dilutions must yield a correlation factor > 0,98. A typical result is depicted below.



11.6. Precision

For the assessment of the test precision, the variability of results under the following conditions was determined: a. within 1 assay and between 3 assays, b. between 3 operators and c. between 2 kit lots.

a. Intra- and inter-assay variability (n = 24 and 72, respectively)

sample	mean U/mL	variability (cv, %) intra-assay	inter-assay
1	13,2	2,2	2,7
2	21,4	4,2	6,3
3	44,5	2,3	3,3

b. Operator to operator variability (n = 12)

sample	mean U/mL	variability (cv, %)
1	12,5	4,6
2	20,5	3,5
3	43,5	1,7

c. Variability between 2 kit lots (n = 6)

sample	mean U/mL	variability (cv, %)
1	12,4	5,3
2	22,2	10,4
3	44,3	3,5

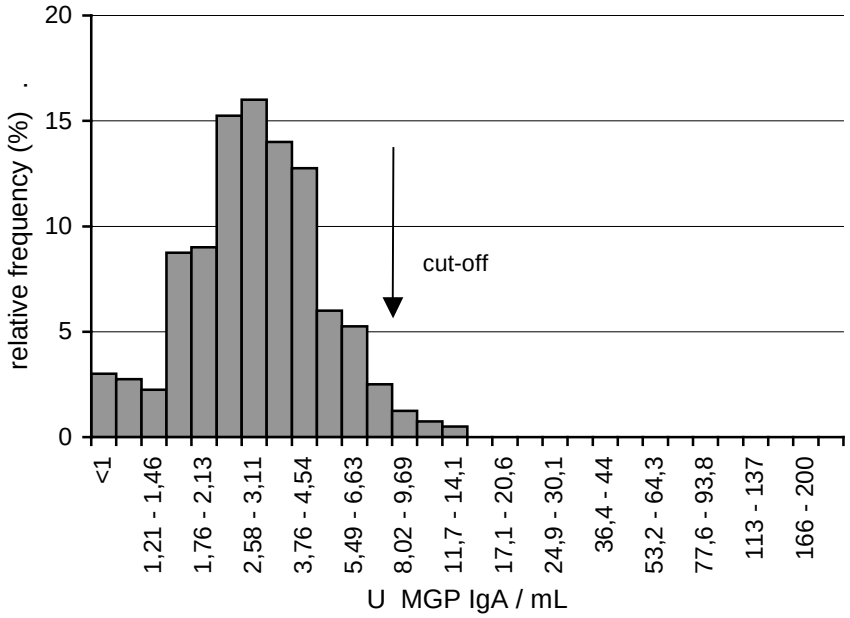
11.7. Frequency distribution of MGP IgA

This was analysed in a sera collective of blood donors, equally distributed by sex and age, and a sera collective of CD patients, defined by biopsy and/or positive anti-tTG IgA result according to a CE-compliant reference ELISA. The following distribution of the analyte was observed:

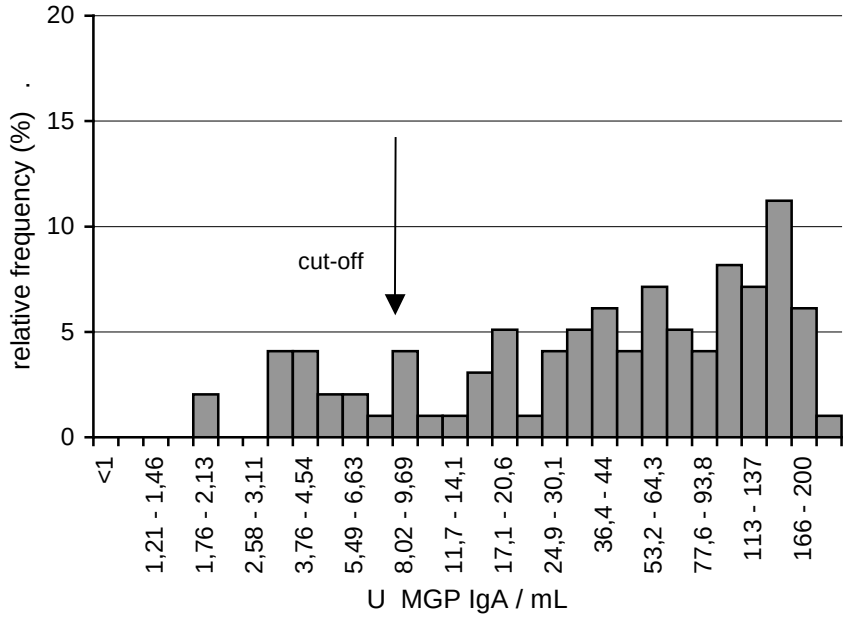
blood donor sera			positive sera		
n:	400		n:	98	
mean:	3,3	U/mL	mean:	69,2	U/mL
mean + s:	5,0	U/mL	mean - s:	10,2	U/mL
mean + 2s:	6,8	U/mL	mean - 2s:	< 0	U/mL
median:	2,8	U/mL	median:	52,7	U/mL
95th percentile:	6,5	U/mL	5th percentile:	3,6	U/mL

ROC-analysis of these data was used to determine the cut-off as 8,0 U/mL (10). Based on the data presented here, the diagnostic specificity and sensitivity of the ELISA was calculated to 97,5 and 84,7 %, respectively. These values apply for the measured sera only; other collectives may yield different results.

blood donor sera



positive sera



12. DECLARATION

IBL International GmbH guarantees that the product delivered has been thoroughly tested to ensure that its properties specified herein are fulfilled. No further warranties are given.

The performance data presented here were obtained using the procedure indicated. Any modification in the procedure may affect the results in which case IBL disclaims all warranties whether expressed, implied or statutory. Moreover, IBL accepts no liability for any damage, whether direct, indirect or consequential, which results from inappropriate use or storage of the product.

13. REFERENCES

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14. SUMMARY FLOW CHART

a. Dilute the samples 1/100 in Sample Diluent (100 mL, ready-to-use, orange) and mix.

b. Dilute the wash buffer 10x-concentrate (100 mL, blue) with water and mix.

c. Wash the wells once with 350 µL wash buffer each. Dispense 100 µL of the calibrators (2,0 mL each, ready-to-use, gradually blue) and controls (2,0 mL each, ready-to-use, green and red) and of the diluted samples into the wells of the solid phase. Duplicate measurements are recommended. Incubate for 30 minutes at room temperature (23 ± 3°C).

d. Wash the wells 4 times with 350 µL wash buffer each.

e. Dispense 100 µL of the conjugate (14 mL, ready-to-use, yellow) into the wells. Incubate as in step c.

f. Repeat washing step d.

g. Dispense 100 µL of the substrate solution (14 mL, ready-to-use, black vial) per well. Incubate as in step c. Then, add 100 µL stop solution (14 mL, ready-to-use, colourless) per well and agitate the plate briefly.

h. Immediately measure the absorbance at 450 nm.

i. Quantitative evaluation: determine the standard curve and, using this curve, transform the absorbance of the samples into their respective antibody concentration (U/mL).

j. Qualitative evaluation: determine the borderline absorbance by multiplying the absorbance of the positive control with the factor shown in the certificate of analysis. Then, calculate the ratio of the samples by dividing their absorbance by the borderline absorbance.

Symbols / Symbole / Symboles / Símbolos / Simboli / Símbolos / Σύμβολα

REF	Cat.-No.: / Kat.-Nr.: / No.- Cat.: / Cat.-No.: / N.–Cat.: / N.º Cat.: / Αριθμός-Κατ.:
LOT	Lot-No.: / Chargen-Bez.: / No. Lot: / Lot-No.: / Lotto n.: / Lote N.º: / Αριθμός -Παραγωγή:
	Use by: / Verwendbar bis: / Utiliser à: / Usado por: / Da utilizzare entro:/ Usar até: / Χρησιμοποιείται από:
Σ	No. of Tests: / Kitgröße: / Nb. de Tests: / No. de Determ.: / Quantità dei tests: / N.º de Testes: / Αριθμός εξετάσεων:
CONC	Concentrate / Konzentrat / Concentré / Concentrar / Concentrato / Concentrado / Συμπύκνωμα
LYO	Lyophilized / Lyophilisat / Lyophilisé / Liofilizado / Liofilizzato / Liofilizado / Λυοφιλιασμένο
IVD	In Vitro Diagnostic Medical Device / In-vitro-Diagnostikum / Appareil Médical pour Diagnostics In Vitro / Dispositivo Médico para Diagnóstico In Vitro / Dispositivo Medico Diagnostico In vitro / Equipamento Médico de Diagnóstico In Vitro / Ιατρική συσκευή για In-Vitro Διάγνωση
BIO	Contains biological material of human origin / Enthält biologisches Material menschlichen Ursprungs / Contient une substance biologique d'origine humaine / Contiene material biológico de origen humano / Contiene materiale biologico di origine umana / Contém material biológico de origem humana / Περιέχει βιολογικό υλικό ανθρώπινης προέλευσης
BIO	Contains biological material of animal origin / Enthält biologisches Material tierischen Ursprungs / Contient une substance biologique d'origine animale / Contiene material biológico de origen animal / Contiene materiale biologico di origine animale / Contém material biológico de origem animal / Περιέχει βιολογικό υλικό ζωικής προέλευσης
UDI	Unique Device Identification / Eindeutige Gerätekennung / Identifiant de dispositif unique / Identificación única de producto / Identificatore univoco del dispositivo / Identificador de dispositivo único / Μοναδικός αναγνωριστικός κωδικός προϊόντος
	Read instructions before use / Arbeitsanleitung lesen / Lire la fiche technique avant emploi / Lea las instrucciones antes de usar / Leggere le istruzioni prima dell'uso / Ler as instruções antes de usar / 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 / Non esporre ai raggi solari / Manter longe do calor ou luz solar directa / 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: / Armazenar em: / Αποθήκευση στους:
2-8°C	Store at: 2 - 8°C / Lagern bei: 2 - 8°C / Stocker à: 2 - 8°C / Almacene a: 2 - 8°C / Armazenar a: 2 - 8°C / Conservare a: 2-8°C / Armazenar em: 2-8°C / Αποθήκευση στους: 2-8°C
	Manufacturer: / Hersteller: / Fabricant: / Productor: / Fabricante: / Fabbricante: / Παραγωγός:
	Distributor: / Distributor: / Distributeur: / Distributor: / Distributore: / Distribuidor: / Διανομέας:
	Caution! / Vorsicht! / Attention! / ¡Precaución! / Attenzione! / Cuidado! / 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. Per i simboli dei componenti del kit si veda COMPONENTI DEL KIT. Para símbolos dos componentes do kit ver MATERIAIS FORNECIDOS. Για τα σύμβολα των συστατικών του κιτ συμβουλευτείτε το ΠΑΡΕΧΟΜΕΝΑ ΥΛΙΚΑ.

Generic table, not all symbols are present in the product

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.

LIMITATION OF LIABILITY: IN ALL CIRCUMSTANCES THE EXTENT OF MANUFACTURER'S LIABILITY IS LIMITED TO THE PURCHASE PRICE OF THE KIT(S) IN QUESTION. IN NO EVENT SHALL MANUFACTURER BE LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL DAMAGES, INCLUDING DAMAGES FOR LOST PROFITS, LOST SALES, INJURY TO PERSON OR PROPERTY OR ANY OTHER INCIDENTAL OR CONSEQUENTIAL LOSS.

The labelling of hazardous substances is according to European directive.
For further country-specific classifications, please refer to the corresponding safety data sheet.

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