Instructions for use

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U1-RNP-Ab ELISA

Enzyme immunoassay for the qualitative and quantitative determination of IgG antibodies against U1-RNP in human serum or plasma (EDTA, citrate, heparin).

REF **RE75211**

Σ **12x8**

2°C 8°C

EU: IVD CE

IBL International GmbH
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Always there for you

1. Introduction and background

Uracil-rich, small nuclear RNAs (U-snRNA) are physiologically complexed with proteins to ribonucleoprotein particles (U-snRNP) which are involved in the splicing process of pre-mRNA. Different complexes (U1-U6) can be distinguished according to the participating RNA; their protein components are in part common, in part different. For example, U1-snRNA is complexed with the so-called Sm-proteins which are also present in other U-snRNPs, and with the U1-specific proteins A, C and 68kDa.

Autoantibodies directed against these three U1-specific proteins are considered as diagnostic marker for mixed connective tissue disease (MCTD; synonym: Sharp syndrome) (1, 2, 3). MCTD is a well defined overlap syndrome characterized by typical clinical manifestations, distinct autoantibodies and specific HLA constellation, i.e. DR2 and DR4 (4). U1-RNP specific antibodies are also associated with Systemic Lupus Erythematosus (SLE) but occur with distinctly lower prevalence (about 35%) and mostly in combination with further antinuclear autoantibodies (ANA) (4). Nowadays, proteins A, C and 68kDa are regarded as the actual RNP antigen, rather than the complete U1-RNP.

The present enzyme-linked immuno sorbent assay (ELISA) is intended for the quantitative or qualitative determination of IgG antibodies directed against U1-RNP in human serum or plasma (cf. section 7). The antigen preparation is a balanced mixture of the human proteins A, C and 68kDa (thus avoiding the disturbing influence of Sm antigens); all of them recombinant and highly purified preparations. 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.

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 personnel staff.

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 Diseae 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 U1-RNP antigens, as described above. On this surface, the following immunological reactions take place:

1st reaction: U1-RNP-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 IgG 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 U1-RNP IgG in the sample.

4. Contents of the kit

a. **MTP** 1 Microtiter Plate, coated with U1-RNP-specific antigens 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 IgG** Enzyme Conjugate IgG, 14 mL, ready-to-use, red coloured. Buffered solution containing stabilising protein, methylisothiazolone and bromonitrodioxane.

c. **CAL A–F** 6 Calibrators, 2,0 mL each, 0 - 0,60 - 2,0 - 6,0 - 20 and 60 U U1-RNP IgG / mL, ready-to-use, gradually blue coloured. Contain TBS, BSA, Tween and Na-azide.

d. **CONTROL -** & **CONTROL +** Negative and Positive 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. Directions 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. 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 buffer. 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. For longer storage, -20°C or lower temperatures are recommended. 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, red); 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.

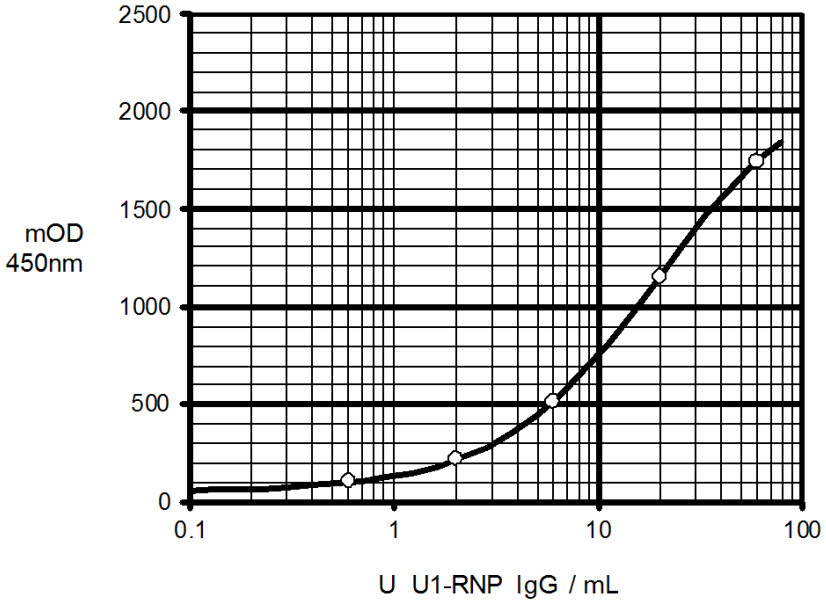
g. Rapidly (preferably using an 8-channel pipette) dispense the stop solution (14 mL, ready-to-use, colourless. Caution: corrosive!); 100 µL per well. Use the same sequence as for the substrate. The colour changes from blue to yellow. Agitate the plate, preferably on an orbital shaker, for about 10 seconds.

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 U1-RNP IgG 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:

$\text{absorbance}_{\text{borderline}}$ = $\text{absorbance}_{\text{positive control}}$ x 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 mOD

factor = 0,35

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

In order to gain an impression of how positive a particular sample is for U1-RNP IgG, one may calculate the ratio, according to the formula:

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

Example:

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

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

ratio = 1480 mOD / 438 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 U1-RNP IgG / mL sample	qualitative evaluation ratio
normal (negative) range	< 3,2	< 0,84
cut-off	4,0	1,00
equivocal range	3,2 - 5,0	0,84 - 1,20
positive range	> 5,0	> 1,20

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 IgG antibodies to U1-RNP. Hence, MCTD is not very likely. Due to the relatively low sensitivity of the parameter regarding SLE, a negative anti-U1-RNP result cannot rule out this disease. It should be noted that in SLE patients the titer of IgG autoantibodies may decrease in response to B cell depleting therapy (5).

A positive result should be interpreted primarily as indication of MCTD. However, the test should be positive on at least two occasions, separated by several weeks. A suspicion of SLE is supported but should be verified by measurement of e.g. dsDNA and Sm autoantibodies.

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.

11. Performance characteristics

11.1. Standardisation

The test is standardised with a purified serum preparation containing IgG antibodies specifically directed at U1-RNP. 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 IgG antibodies directed against U1-RNP. It has been validated (among other parameters) by means of the commercially available human reference sera of the "Center of Disease Control" (CDC, Atlanta, USA). The following results are typical:

serum	1	2	3	4	5	6	7	8	9	10
CDC-result	ds-DNA	SS-B /La	--	U1-RNP	Sm	--	SS-A /Ro	--	Scl-70	Jo-1
immune-fluorescence	homo-gen / rim	speck-led	speck-led	--	--	nuc-leolar	--	centro-mere	--	--
ELISA (U/mL)	2,6	0,6	>60	40	57	3,2	0,9	0,6	0,8	0,6

11.3. Detection limit (analytical sensitivity)

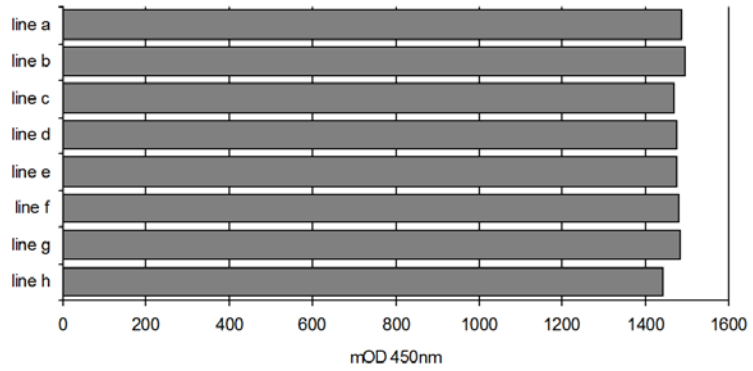
The detection limit is defined as that concentration of analyte that corresponds to the mean absorbance of Sample Diluent plus 3-fold standard deviation (s). It was determined as < 0,5 U U1-RNP IgG per mL sample (n = 24).

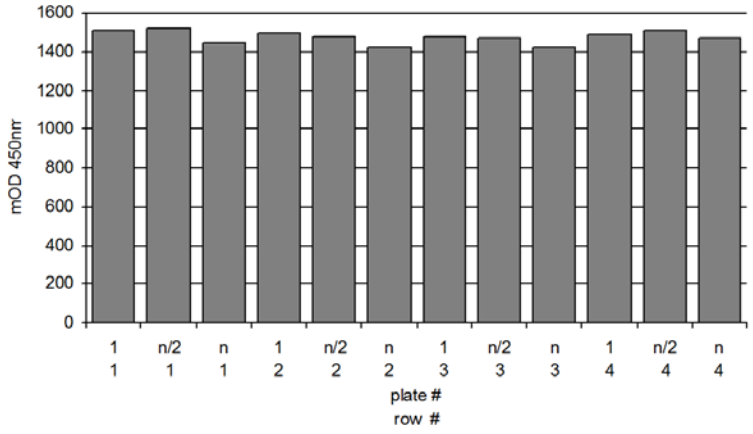
Recommended measuring range: 0,5 - 60 U U1-RNP IgG per mL sample

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 a 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. 1701P) of such an analysis.

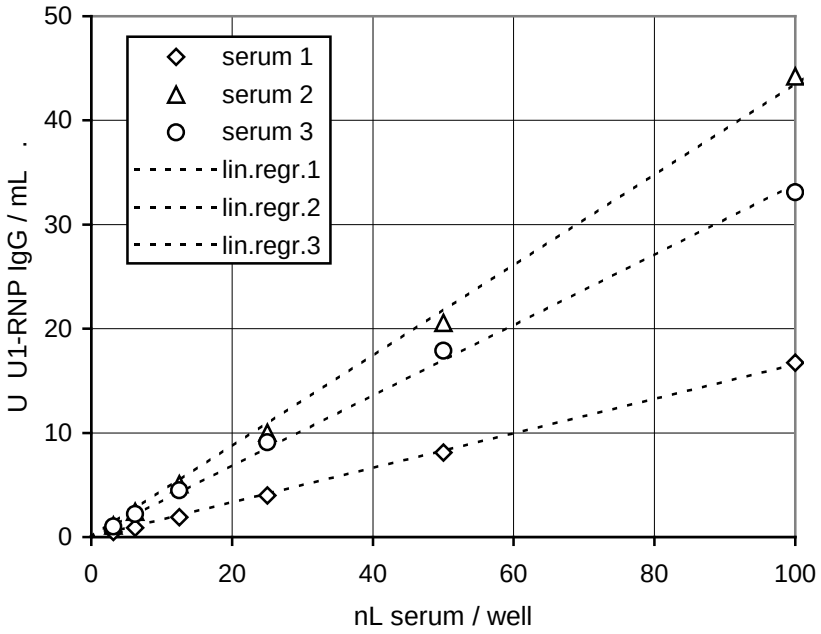
plate row	1 1	n/2 1	n 1	1 2	n/2 2	n 2	1 3	n/2 3	n 3	1 4	n/2 4	n 4	mean	cv %
line a	1501	1521	1457	1503	1482	1449	1472	1487	1424	1495	1526	1520	1486	2,1
line b	1555	1555	1450	1528	1503	1425	1468	1496	1425	1523	1521	1497	1496	3,0
line c	1483	1514	1437	1502	1483	1412	1460	1463	1398	1507	1505	1441	1467	2,6
line d	1509	1504	1443	1505	1482	1425	1479	1484	1431	1475	1519	1474	1478	2,1
line e	1513	1520	1419	1446	1487	1427	1502	1474	1441	1484	1521	1485	1477	2,4
line f	1546	1508	1444	1514	1476	1417	1488	1485	1408	1489	1537	1464	1481	2,9
line g	1531	1530	1475	1485	1482	1438	1485	1471	1426	1491	1511	1477	1484	2,1
line h	1481	1473	1455	1453	1443	1395	1444	1416	1402	1434	1464	1438	1442	1,9
mean	1515	1516	1448	1492	1480	1424	1475	1472	1419	1487	1513	1475	**1476**	
cv %	1,8	1,5	1,1	1,9	1,1	1,1	1,2	1,7	1,1	1,7	1,5	1,9		**2,6**





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	6,0	2,3	2,5
2	13	3,9	4,7
3	30	3,2	3,4

b. Operator to operator variability (n = 12)

sample	mean U/mL	variability (cv, %)
1	5,9	1,5
2	13	3,7
3	29	3,0

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

sample	mean U/mL	variability (cv, %)
1	6,3	1,9
2	13	7,5
3	25	3,0

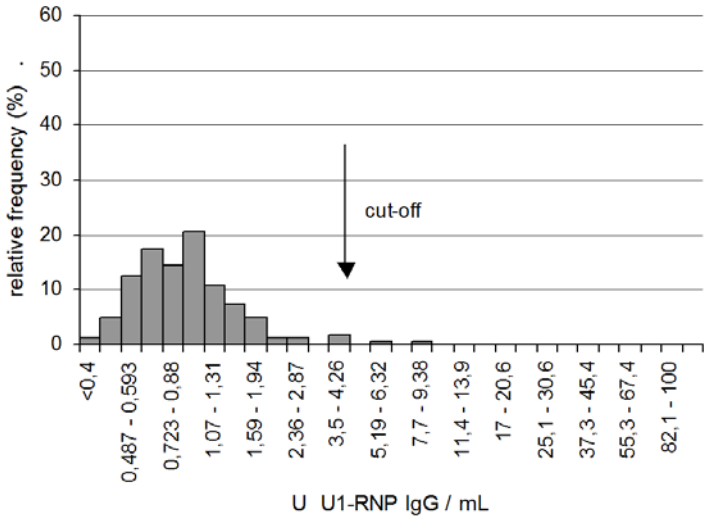
11.7. Frequency distribution of U1-RNP IgG

This was analysed in a sera collective of blood donors, equally distributed by sex and age, and a collective of sera found positive for U1-RNP autoantibodies according to a CE-compliant reference ELISA or that were clinically defined. The following distribution of the analyte was observed:

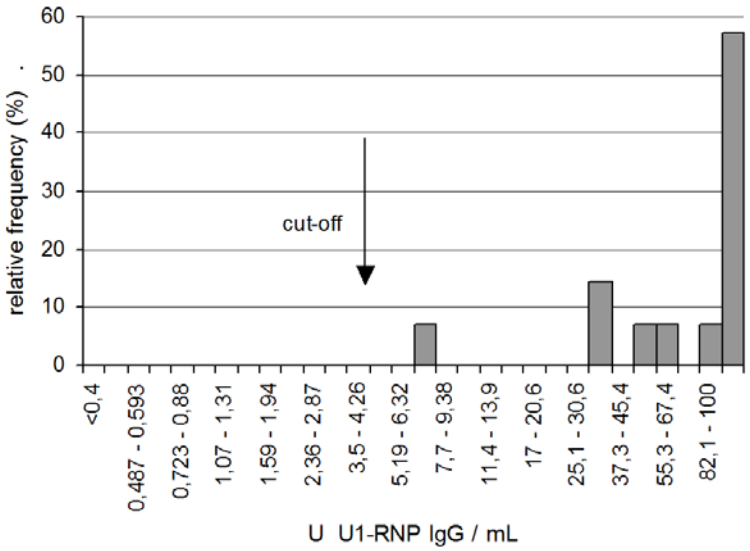
blood donor sera			positive sera		
n:	160		n:	14	
mean:	1,1	U/mL	mean:	240	U/mL
mean + s:	1,9	U/mL	mean - s:	< 0	U/mL
mean + 2s:	2,8	U/mL	mean - 2s:	< 0	U/mL
median:	0,9	U/mL	median:	170	U/mL
95th percentile:	2,1	U/mL	5th percentile:	25	U/mL

ROC-analysis of these data was used to determine the cut-off as 4,0 U/mL (6). The data presented here suggest a diagnostic specificity and sensitivity of the ELISA of about 99 and 100 %, respectively. These values apply for the measured sera only; other collectives may yield different results. In view of the low number of positive sera, particular caution is required when interpreting test sensitivity.

blood donor sera



positive sera



12. Warranty

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

1. Lerner, M. R., Steitz, J. A.: Antibodies to small nuclear RNAs complexed with proteins are produced by patients with systemic lupus erythematosus. Proc Natl Acad Sci USA 76 (1979), 5495 - 5499
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3. Combe, B., et al.: Clinical significance of anti-RNP and anti-Sm autoantibodies as determined by immunoblotting and immunoprecipitation in sera from patients with connective tissue diseases. Clin Exp Immunol 75 (1989), 18 - 24
4. Messinger, M.: Autoantikörper bei systemischen entzündlich-rheumatischen Erkrankungen (Kollagenosen). In: L. Thomas (ed.): Labor und Diagnose (2005), TH-Books-Verlags-Gesellschaft, Frankfurt/Main, 1139 – 1161
5. Persson, B., et al.: Disappearance and Reappearance of IgG, IgA and IgM Autoantibody Isotypes and Immune Complexes in Rituximab-Treated SLE Patients. Annals of the Rheumatic Diseases 72 (2013), A34
6. Sommer, R., and Eitelberger, F.: Wertigkeit der Gliadin-Antikörper im Serum zur Diagnose der Zöliakie. Wien Klin Wochenschr 104/4 (1992), 86 - 92

15. 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, red) 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 / 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.

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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