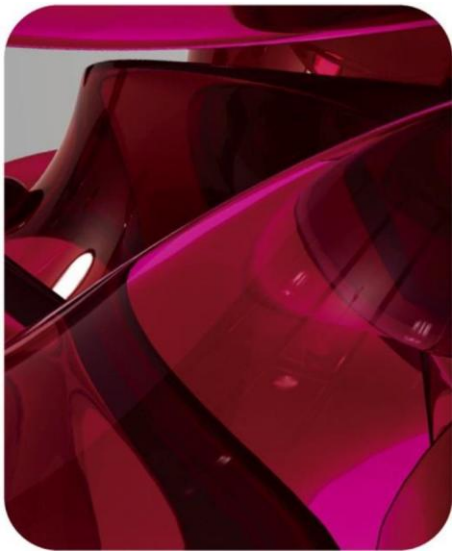
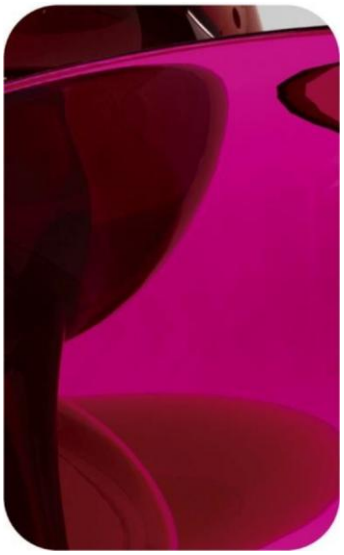
AESKU.DIAGNOSTICS

THE DIAGNOSTIC TOOL THAT WORKS







AESKUBLOTS®

THE DIAGNOSTIC TOOL THAT WORKS

INSTRUCTION MANUAL

***AESKUBLOTS®* ANA-17 Pro**

Ref 4001

CE

Instruction Manual

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1 Intended Use

***AESKUBLOTS*® ANA-17 Pro** is a membrane based enzyme immunoassay for qualitative detection of IgG antibodies against dsDNA, nucleosomes, histones, Sm, PCNA, Rib-P0, SS-A/Ro60kD, SS-A/Ro52kD, SS-B/La, CENP-B, SCL-70, U1-snRNP, AMA M2, Jo-1, Pm-Scl, Mi-2 and Ku in human serum. Antigens are located as parallel lines at exactly defined positions on a nitrocellulose membrane.

The assay is a tool in differential diagnosis of systemic rheumatic diseases.

The test-kit is for professional use only in laboratories.

2 Clinical Application and Principle of the Test

Anti-nuclear antibodies (ANAs) are an important tool for the differential diagnosis of systemic rheumatic diseases. The detection of autoantibodies in the Line Immunoassay (LIA) with corresponding specific antigens allows a simple and reliable differentiation of ANAs by their specificity. ANAs are especially found in active and inactive systemic lupus erythematosus (SLE), mixed connective tissue diseases (MCTDs), scleroderma, Sjögren's syndrome, primary biliary cirrhosis (PBC) and polymyositis. According to their relevance for the single autoimmune diseases, 17 antigens are arranged on an ***AESKUBLOTS*® ANA-17 Pro** test strip (SLE, Sjögren's syndrome, CREST-syndrome, scleroderma, MCTD, PBC and myositis).

Antibodies against:

- Nucleosomes are directed against epitopes of the histone complex (nucleosome). In addition, anti-dsDNA and anti-histone antibodies can recognize epitopes of the nucleosome. In comparison to anti-dsDNA antibodies, anti-nucleosome antibodies are more sensitive and can provide a useful addition to the diagnosis of SLE (Chabre et al. 1995; Bruns et.al. 2000). Furthermore, they have pathogenetic significance in lupus nephritis (Van Bruggen et al. 1996; Amoura et al. 1999).
- dsDNA are regarded as being specific for SLE and have been observed in approximately 50-80 % of the patients.
- Histones are common in SLE patients. However, they also occur in other connective tissue diseases. Antibodies to histones in the absence of other autoantibodies (especially anti-dsDNA) are a characteristic marker for drug-induced lupus erythematosus (Rubin 1999).
- Sm (Smith antigen) as well as antibodies against double stranded DNA (dsDNA) are highly specific for SLE and thus are included in diagnostic and classification criteria for SLE.
- U1-snRNP are pathognomonic for MCTD but do also occur in SLE. A high titer of antibodies against this antigen is typical for the sharp's syndrome.
- SS-A (Ro; soluble cytoplasmic and/or nuclear ribonucleoproteins of 52 kDa and 60 kDa) and antibodies against SS-B (La; 48 kDa protein associated with RNA-

polymerase III) are mainly found in high titers for primary and secondary Sjögren's syndrome but also in SLE, congenital heart block and neonatal lupus.

- Scl-70 are directed against DNA-topoisomerase I. They are highly specific for systemic scleroderma and are indicative of a severe course of the disease.
- CENP-B (80 kDa centromere protein B) are typical for the CREST-syndrome (69 % of CREST patients), which is a more protracted type of systemic sclerosis.
- Jo-1 are directed against histidyl-tRNA-synthetase (a cytoplasmic protein involved in protein biosynthesis) and are found in 20-40 % of patients with polymyositis and dermatomyositis.
- ribosomal P-proteins are directed against several phosphoproteins of the large ribosomal subunit. They occur in patients with systemic lupus erythematosus (Elkon et al. 1985) and in lupus patients with cerebral involvement (Bonfa et al. 1987).
- AMA M2 react with the proteins of the ketoacid-dehydrogenase complex of mitochondria. They occur in 95 % of PBC patients in high titers. Their evidence is crucial for the diagnosis of PBC and for separation from other cholestatic liver diseases.
- Ku mostly react with the p80 subunit respectively a conformational epitope on the p70/p80 heterodimer of the DNA-dependent protein kinase. They also bind other proteins with sequencehomology to p70/p80 (e.g. NFIV, TREF, EBP-80, E1BF and Ku-2). They occur in 5-25 % of polymyositis and scleroderma overlap-syndrome patients and 1-7 % of myositis patients. They also occur in of patients with primary pulmonary hypertension (approximately 20 %), with SLE (5-10 %), with primary Sjögren's syndrome (20 %) and occasionally with other connective tissue diseases (Cooley et al. 1999).
- Mi-2 occur in 15-20 % of dermatomyositis patients. They have a high diagnostic specify. 95 % of patients with Mi-2 antibodies suffer from dermatomyositis. However, they occur rarely in polymyositis patients, so they are important for differential diagnosis (Roux et al. 1998; Targoff 2000). The Mi-2-antigen is part of a nuclear multiproteincomplex, which may be involved on the regulation of the cellular proliferation cycle.
- Pm-Scl are found in 24 % of Pm-Scl overlap-syndrome patients and in 3-10 % of scleroderma and polymyositis patients.
- PCNA are specific for SLE. The antigen is a protein with a molecular weight of 36 kDa, which is an auxiliary protein of DNA polymerase delta. It supports DNA synthesis and DNA repair mechanisms.

Principle of the test

The antigens are applied as lines on a nitrocellulose membrane. The membrane is blocked to prevent unspecific reactions. Membrane-strips with specific antigens at exactly defined positions are incubated in serum samples diluted 1:101. Patient's antibodies, if present in the specimen, bind to the antigen. The unbound fraction is washed off in the following step. Afterwards, anti-human immunoglobulins conjugated to horseradish peroxidase (conjugate) are incubated and react with the antigen-antibody complex of the samples. Unbound conjugate is washed off in the following step. After the addition of the TMB-substrate it is converted by an enzymatic reaction to a blue precipitate. The reaction is stopped by distilled water.

3 Kit Contents

TO BE RECONSTITUTED				
Item	Quantity	Cap color	Solution color	Description / Contents
Blocking Reagent	3 x for 10 ml concentrate each	white	N/A	Non-fat dry milk powder for preparation of 3 x 10 ml sample buffer
Wash Buffer (20x)	1 x 50 ml	white	colorless	20x concentrated for preparation of 1 L Tris buffer, pH 6.9 ± 0.2
READY TO USE				
Item	Quantity	Cap color	Solution color	Description / Contents
Conjugate, IgG	1 x 10 ml	blue	colorless	Anti-human immunoglobulin G (IgG) conjugated to horseradish peroxidase
TMB Substrate	1 x 10 ml	black	colorless	Stabilized TMB/H_2O_2
Membrane strips	24 strips	color coding: orange	N/A	Coated antigens see Intended use
tweezers, reference template, scoring sheet, adhesive strips (double-sides, white)	1 pc. each	N/A	N/A	N/A
incubation tray	3 pcs.	N/A	N/A	N/A
Labels for sample buffer	3 pcs.	N/A	N/A	N/A
MATERIALS REQUIRED, BUT NOT PROVIDED				
rocking platform, cylinder 1000 ml, pipette or cylinder for 10 ml, precision pipettes (10, 1000 µl), absorbent or filter paper. Our tests are designed to be used with purified water according to the definition of the United States Pharmacopeia (USP 26 - NF 21) and the European Pharmacopeia (Eur.Ph. 4th ed.).				

4 Storage and Shelf Life

Store all reagents and membrane-strips at 2-8 °C/35.6-46.4 °F in their original containers. Once prepared, reconstituted wash buffer as well as opened strips, conjugate and TMB are stable at 2-8 °C/35.6-46.4 °F for six weeks. Reconstituted blocking reagent is stable at 2-8 °C/35.6-46.4 °F for 3 weeks. Reagents and strips shall be used within the expiry date indicated on each respective component. Don’t use components after the expiry dates. Avoid intense exposure of TMB solution to the light.

5 Precautions of Use and General Introductions

5.1 Health hazard data

This product is for IN VITRO DIAGNOSTIC use only. Thus, only staff trained and specially advised in methods of in vitro diagnostics may perform the kit.

All kit components are classified according to Regulation (EC) No. 1272/2008 [CLP]. See the Materials and Safety Document (MSDS) for more information on ingredients.

Substances listed on the so-called "Candidate List of Substances of very High Concern (SVHCV) for authorization" of the European Chemicals Agency (ECHA) are not intentional components of this product. It is therefore not to be expected that these substances are contained in amounts ≥ 0.1 % in the product.

Reagents should be stored safely and be inaccessible to children.

In particular, the mixture does not contain any substances in concentrations ≥ 0.1 % to be classified as PBT or vPvB.

Patient samples should be considered potentially infectious and handled according to national laws. Patient samples and other potentially infectious material should be decontaminated after the test run.

5.2 General directions for use

To differentiate between the various ***AESKUBLOTS***® tests available, a color coding is applied above the reference line of the strips:

Color coding	***AESKUBLOTS***®
red	ANA-17 comp
orange	ANA-17 Pro
brown	Liver Pro
purple	Vasculitis Pro
black	Gastro Pro
green	Borrelia-G and Borrelia-M

In case that the product information, including the labeling, is incorrect please contact the manufacturer or the supplier of the test kit.

Blocking Reagent and wash buffer may be interchanged between lots and test kits. All other components are specific for each test kit and are not to be interchanged. Do not exchange reagent components between autoimmunity and borrelia diagnostic tests!

For handling of conjugate do not use polystyrene vessels.

Allow all components to reach room temperature (20-32 °C/68-89.6 °F) before use, mix well and follow the recommended incubation scheme for an optimum performance of the test.

Never expose components to higher temperature than 37 °C/ 98.6 °F.

Always pipette substrate solution with brand new tips only. Protect this reagent from light. Never pipette conjugate with tips priorly used with other reagents.

The intensity of the band color does not necessarily correlate with antibody titers obtained by other reference methodologies.

Samples from apparent normal blood donors may contain autoantibodies.

If the patient sample contains elevated levels of immune complexes or other immunoglobulin aggregates, false positive results by non-specific binding cannot be ruled out.

A definite clinical diagnosis should not only be based on the results of the performed test. The diagnosis should be made by a physician after all clinical and laboratory findings have been evaluated. The diagnosis is to be verified using different diagnostic methods.

6 Sample Collection, Handling and Storage

Use preferentially freshly collected serum samples. Blood withdrawal must follow national requirements. Do not use icteric, lipemic, hemolyzed or bacterially contaminated samples. Sera with particles should be cleared by low speed centrifugation (< 1000 x g). Blood samples should be collected in clean, dry and empty tubes.

After separation, the serum samples should be used during the first 8 h. Alternatively, the samples should be stored in tightly closed vials at 2-8 °C/35.6-46.4 °F for up to 48 h, or frozen at -20 °C/-4 °F for longer periods. Avoid freezing and thawing samples repeatedly. (Thomas: Labor und Diagnose; CLSI Guideline GP44-A4) Do not use thermally inactivated samples (56 °C/132.8 °F).

7 Assay Procedure

7.1 Preparations prior to starting

Confirm that no salt crystals have been formed in the concentrate. If this happened, dissolve the crystals by slightly warming, room temperature should be enough, the concentrate.

Dilute concentrated wash buffer 1:20 with distilled water (e.g. 50 ml plus 950 ml).

For preparation of sample buffer: add 10 ml wash buffer to one bottle Blocking Reagent and mix well.

7.2 Test Steps

Important notes:

Follow exactly this protocol. Make sure that the two components mentioned in the protocol are added to the tray in steps 2, 6, 9.

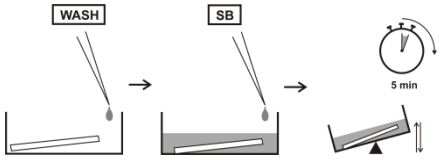
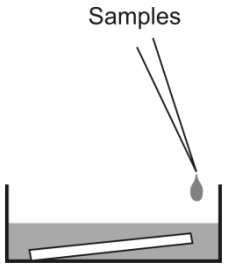
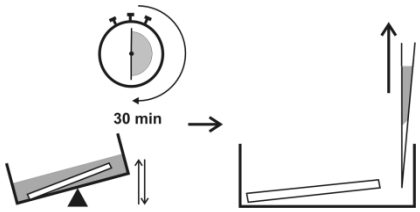
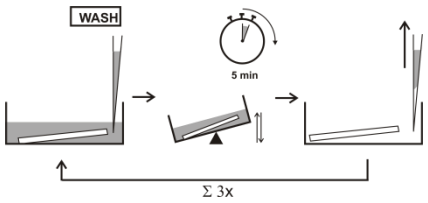
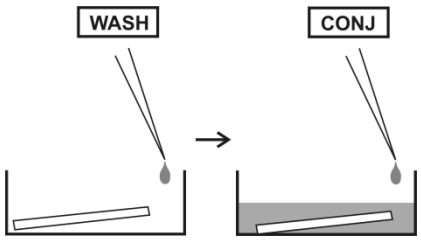
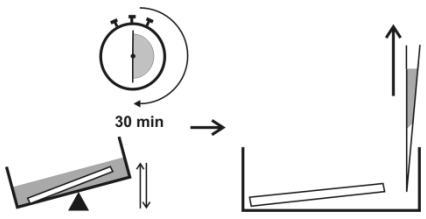
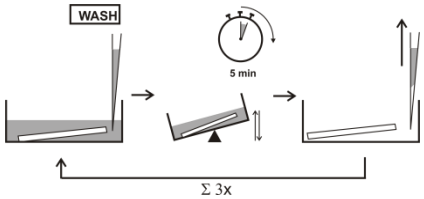
Do not let strips dry out during incubation steps.

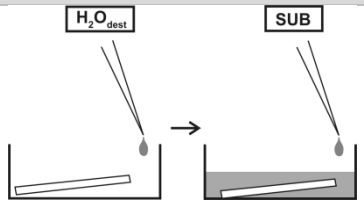
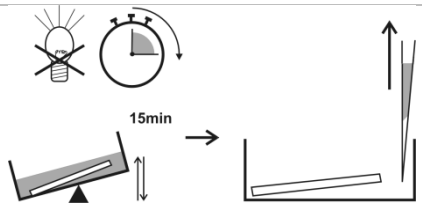
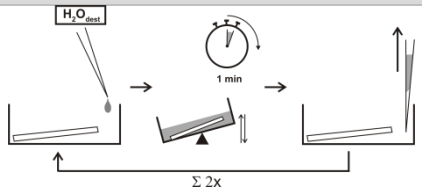
Do not touch strips with fingers, use tweezers.

Remove diluted samples completely after incubation of strips to avoid carry over.

Continuously shake strips during incubation steps.

Give sample buffer, conjugate and substrate together with the wash buffer to one side of the incubation tray. Do not allow to flow over the strips.

Step	*Description*
1.	Ensure the preparations, from step 7.1 above, have been carried out prior to test begin.
2.	 Put strip in correct orientation into incubation tray (reference line and color coding upwards). Put 700 µl wash buffer and 300 µl sample buffer in the incubation tray. Moisten strip with the solution and incubate for 5 minutes with agitation.
CONTROLS & SAMPLES	
3.	 Pipette 10 µl serum sample into the designated incubation trays with sample buffer.
4.	 Incubate for 30 minutes at 20-32 °C/68-89.6 °F with agitation. After that remove sample completely.
5.	 Wash 3 times for 5 minutes with 1.5 ml wash buffer by agitation. Remove wash buffer after every washing step.
CONJUGATE	
6.	 Pipette 700 µl wash buffer and 300 µl conjugate into each incubation tray with strip.
7.	 Incubate for 30 minutes at 20-32 °C/68-89.6 °F with agitation. Remove conjugate.
8.	 Wash 3 times for 5 minutes with 1.5 ml wash buffer by agitation. Remove wash buffer after every washing step.

SUBSTRATE		
9.		Pipette 700 µl dH_2O and 300 µl substrate into each incubation tray with strip.
10.		Incubate for 15 minutes at 20-32 °C/68-89.6 °F with agitation, protected from intense light. Remove substrate.
STOP		
11.		Pipette 2 ml dH_2O into each incubation tray with strip. Incubate 1 minute with agitation. Remove dH_2O. Repeat this step one time.
12.	Remove strip of the incubation tray. Dry strip between filter paper	
13.	Analyze results within 24 h.	

***AESKUBLOTS*® ANA-17 Pro** is also intended to be automatically processed and evaluated on the ***HELIA*® Automated Blot System**.

Reagent preparation for ***HELIA*® Automated Blot System**: Dilute one part wash buffer concentrate (WASH) with 19 parts ultrapure water (e.g. 50 ml wash buffer concentrate and 950 ml ultrapure water) to obtain a ready-to-use wash buffer. All other reagents are ready to use when processed in ***HELIA*® Automated Blot System**. For detailed handling of the test on ***HELIA*® Automated Blot System** refer to the instruction manual of the ***HELIA*® Automated Blot System**.

8 Qualitative Interpretation

In case that the values of the controls do not meet the criteria, the test is invalid and has to be repeated. We recommend retesting samples that are borderline.

The following technical issues should as well be checked: expiry date of (prepared) reagents, storage conditions, pipettes, equipment, incubation conditions and washing methods.

If the samples tested show aberrant values or any kind of deviation or if the validation criteria are not met because of reasons outside the operator's responsibility, please contact the manufacturer or the supplier of the test kit.

Medical laboratories might perform an in-house quality control by using their own controls and/or internal pooled sera, as stated in national regulations.

8.1 Manual Analysis

Test results can be considered valid, if:

- Functional control is visible
- Cut-off control is visible
- Color intensity of Cut-off control is weaker than color intensity of functional control

Fix dried strips onto scoring sheet aligned with reference line. Align reference template with the strips reference line. Interpret results only in reference to Cut-off control of each strip.

Each test kit contains a color copy with all bands provable in the test.

The analysis is carried out by means of comparing the color intensities of the bands with color intensity of the Cut-off control. The test is equivocal if the intensities do not significant differ. If the color is more intense, the test result is positive, if the color intensity is weaker, the test is negative.

The results can be recorded on the scoring sheet.

8.2 Software-supported evaluation

The analysis of the strips can be carried out by means of using AESKU.SCAN Software. Please refer to the instructions for use of AESKU.SCAN.

Test results can be considered valid, if:

- Functional control is visible
- Cut-off control is visible
- Color intensity of Cut-off control is weaker than color intensity of functional control

AESKU.SCAN 2.0:

Fix dried strips onto scoring sheet (printable) aligned with reference line. Align reference template with the strips reference line.

Evaluate strips according to the instructions for use of AESKU.SCAN 2.0 software.

Qualitative result analysis is carried out by means of comparing the color intensities of the individual antigens with the color intensity of the Cut-off control.

AESKU.SCAN 3.0:

Put strips within the incubation tray into the reader.

Evaluate strips according to the instructions for use of AESKU.SCAN 3.0 software.

Qualitative result analysis is carried out by means of comparing the color intensities of the individual antigens with the color intensity of the Cut-off control.

HELIA® Automated Blot System:

Using a ***HELIA*® Automated Blot System**, the results are analyzed automatically. The results can be determined in Index-values.

The following interpretation according to the signal intensity is suggested:

Result Interpretation	Symbol	Index	Color
Negative	-	0.0 - <0.8	Colorless
Equivocal	+/-	≥0.8 - <1.15	Blue
Weak positive	+	≥1.15 - <2.5	Yellow
Positive	++	≥2.5 - <4.0	Red
Strong positive	+++	≥ 4.0	Dark red

9 Technical Data

Sample material:	serum
Sample volume:	10 µl of sample
Total incubation time:	112 minutes at 20-32 °C/68-89.6 °F
Storage:	at 2-8 °C/35.6-46.4 °F; use original vials only.
Number of determinations:	24 tests

10 Performance Data

10.1 Normal Range Study

Expected values for ***AESKUBLOTS*®** **ANA-17 Pro** were analyzed with a panel of 120 sera from healthy donors.

All assays were performed fully automated according to the current IFUs.

***AESKUBLOTS*® ANA-17 Pro – Normal Range - Report**										
Antigen	**Number of samples**	**Positive samples**		**Equivocal samples**		**Negative samples**		**Min [Index]**	**Max [Index]**	**Mean [Index]**
		n	**[%]**	**n**	**[%]**	**n**	**[%]**			
dsDNA	120	0	0.00	4	3.33	116	96.67	0.00	1.10	0.25
Nucleosomes	120	0	0.00	3	2.50	117	97.50	0.00	0.90	0.21
Histones	120	0	0.00	5	4.17	115	95.83	0.10	0.90	0.29
Sm	120	0	0.00	0	0.00	120	100.00	0.00	0.60	0.11
PCNA	120	0	0.00	0	0.00	120	100.00	0.00	0.70	0.08
Rib-P0	120	1	0.83	1	0.83	118	98.33	0.00	1.40	0.12
SS-A/Ro60	120	0	0.00	0	0.00	120	100.00	0.00	0.50	0.13
SS-A/Ro52	120	0	0.00	0	0.00	120	100.00	0.00	0.50	0.08
SS-B/La	120	0	0.00	0	0.00	120	100.00	0.00	0.30	0.08
CENP-B	120	0	0.00	1	0.83	119	99.17	0.00	1.10	0.06
Scl 70	120	0	0.00	0	0.00	120	100.00	0.00	0.70	0.07
U1-snRNP	120	0	0.00	1	0.83	119	99.17	0.00	0.90	0.08
AMA-M2	120	0	0.00	1	0.83	119	99.17	0.00	0.80	0.14
Jo-1	120	0	0.00	0	0.00	120	100.00	0.00	0.40	0.05
PM-Scl	120	1	0.83	0	0.00	119	99.17	0.00	1.30	0.10
Mi-2	120	0	0.00	0	0.00	120	100.00	0.00	0.60	0.11
Ku	120	1	0.83	1	0.83	118	98.33	0.00	1.20	0.11

With ***AESKUBLOTS*®** **ANA-17 Pro** there were some equivocal results and some positive results. Most frequently equivocal and positive results showed the antigens dsDNA, Nucleosomes and Histones. Lowest Index-value measured was 0.0, highest Index-value measured was 1.4 (Rib-P0).

We also recommend in the IFU in chapter 8: “Quantitative and qualitative interpretation” that each laboratory should establish its own normal range.

10.2 Precision

Intra-Assay Precision

To determine the within-lab / intra-assay variances five different sera (S1-S5) have been tested for 20 times on ***AESKUBLOTS***® **ANA-17 Pro**. The positive- and negative agreement were calculated from these test values (n=20).

Calculation of agreements	
Percent positive agreement [%]	98.6
Percent negative agreement [%]	100.0
Percent overall agreement [%]	99.6

Inter-Assay Precision

To determine the inter-assay / day to day variances five different sera (S1-S5) over the whole range have been tested 8 times per run, in a total of 5 runs on 5 different days (n=40). For day 1 the results from the within-lab / intra-assay variances are used (n=20). The positive- and negative agreement were calculated from these test values.

Calculation of agreements	
Percent positive agreement [%]	99.8
Percent negative agreement [%]	100.0
Percent overall agreement [%]	99.9

Lot-to-Lot Precision

To determine the Lot-to-Lot Precision, five different sera (S1-S5) over the whole range have been tested 8 times on 3 Lots (n=24). Lot 1 is taken from Run 1 of the Inter Assay data. The positive- and negative agreement were calculated across the test values of the three different Lots.

Calculation of agreements	
Percent positive agreement [%]	99.1
Percent negative agreement [%]	100.0
Percent overall agreement [%]	99.8

10.3 Relative Sensitivity and Specificity

In order to determine the positive agreement (relative sensitivity*), 115 sera from IIF antibody-positive patients were tested in ***AESKUBLOTS***® **ANA-17 Pro.** For determination of the negative agreement (relative specificity*), 50 sera from blood donors were analyzed.

Positive agreement	99.1 % (114/115)
Negative agreement	98.0 % (49/50)
Total agreement	98.8 % (163/165)

10.4 Competitor comparison internal study, Diagnostic Sensitivity and Specificity

A clinical study with different serum samples from patients with SLE, systemic sclerosis, myositis, Sjogren`s syndrome, PBC, MCTD and healthy controls were analyzed with the ***AESKUBLOTS*® ANA-17 Pro.** Furthermore these samples were measured with a competitor Westernblot or in comparison to the ***AESKUBLOTS*® ANA-17 comp**. All assays were performed according to the current IFUs. After that the results were compared to determine the diagnostic sensitivity and specificity of the assay.

Antigen	Sensitivity	Specificity healthy controls	Specificity non-SLE
dsDNA	75.0 %	97.6 %	100.0 %
Nucleosomes	100.0 %	97.6 %	97.6 %
Histone	n.a.*	96.2 %	100.0 %
SmD1	n.a.*	100.0 %	100.0 %
PCNA	n.a.*	100.0 %	100.0 %
Rib-P0	100.0 %	100.0 %	100.0 %
SS-a/Ro60 kD	100.0 %	100.0 %	96.4 %
SS-a/Ro52 kD	100.0 %	100.0 %	n.a.*
SS-B/La	n.a.*	100.0 %	100.0 %
CENP-B	100.0 %	100.0 %	95.6 %
Scl-70	n.a.*	100.0 %	100.0 %
U1-sn RNP	n.a.*	100.0 %	100.0 %
AMA-M2	100.0 %	100.0 %	100.0 %
Jo-1	n.a.*	100.0 %	100.0 %
PM-Scl	n.a.*	100.0 %	96.7 %
Mi-2	n.a.*	100.0 %	n.a.*
Ku	n.a.*	97.6 %	n.a.*

*could not be determined

The sensitivities and specificities for the ***AESKUBLOTS*® ANA-17 Pro** show very good results. In some cases, no sensitivities could be calculated for individual parameters because no positive samples were present in the measured panel. Here, further samples are to be investigated in the future.

11 Disposal

Please observe the relevant statutory requirements!

12 Literature

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13 Regulatory Symbols

IVD	¨ Diagnosi in vitro	¨ For in vitro diagnostic use
	¨ Pour diagnostic in vitro	¨ Para uso diagnóstico in vitro
	¨ In Vitro Diagnostikum	¨ In Vitro Διαγνωστικό μέσο
	¨ Para uso Diagnóstico in vitro	
REF	¨ Numero d'ordine	¨ Cataloge number
	¨ Référence Catalogue	¨ Numéro de catálogo
	¨ Bestellnummer	¨ Αριθμός παραγγελίας
	¨ Número de catálogo	
LOT	¨ Descrizione lotto	¨ Lot
	¨ Lot	¨ Lote
	¨ Chargen Bezeichnung	¨ Χαρακτηρισμός παρτίδας
	¨ Lote	
UDI	¨ Identificatore univoco del dispositivo	¨ Unique Device Identifier
	¨ Identifiant unique de l'appareil	¨ Identificador único del dispositivo
	¨ eindeutige Produktidentifizierung	¨ Μοναδικό αναγνωριστικό συσκευής
	¨ Identificador único do dispositivo	
CE	¨ Conformità europea	¨ EC Declaration of Conformity
	¨ Déclaration CE de Conformité	¨ Declaración CE de Conformidad
	¨ Europäische Konformität	¨ Ευρωπαϊκή συμφωνία
	¨ Déclaracão CE de Conformidade	
Σ 24	¨ 24 determinazioni	¨ 24 tests
	¨ 24 tests	¨ 24 pruebas
	¨ 24 Bestimmungen	¨ 24 προσδιορισμοί
	¨ 24 Testes	
eIFU WWW.AESKU.COM	¨ Rispettare le istruzioni elettroniche per l'uso	¨ See electronical instructions for use
	¨ Voir les instructions d'utilisation électronique	¨ Siga las instrucciones electrónicas de uso
	¨ Elektronische Gebrauchsanweisung beachten	¨ Ακολουθήστε τις ηλεκτρονικές οδηγίες χρήσης
	¨ Seguir as instruções electrónicas de utilização	
	¨ Da utilizzarsi entro	¨ Use by
	¨ Utilise avant le	¨ Utilizar antes de
	¨ Verwendbar bis	¨ Χρήση μέχρι
	¨ Utilizar antes de	
+2°C +8°C	¨ Conservare a 2-8°C (35.6-46.4°F)	¨ Store at 2-8°C (35.6-46.4°F)
	¨ Conserver à 2-8°C (35.6-46.4°F)	¨ Conservar a 2-8°C (35.6-46.4°F)
	¨ Lagerung bei 2-8°C (35.6-46.4°F)	¨ Φυλάσσεται στους 2-8°C (35.6-46.4°F)
	¨ Conservar entre 2-8°C (35.6-46.4°F)	
	¨ Prodotto da	¨ Manufactured by
	¨ Fabriqué par	¨ Fabricado por
	¨ Hergestellt von	¨ Κατασκευάζεται από
	¨ Fabricado por	
STRIP	¨ Strip di nitrocelluslosa rivestita	¨ Coated nitrocellulose strip
	¨ Strip de nitrocellulose couché	¨ Tira de nitrocelulosa recubierta
	¨ Nitrozellulosemembran-Streifen mit aufgebrachten Antigenen	¨ Επίστρωση λωρίδα νιτροκυτταρίνης
	¨ Tira de nitrocelulose revestido	
WASH 20x	¨ Tampone di lavaggio	¨ Wash buffer
	¨ Tampon de Lavage	¨ Solución de lavado
	¨ Waschpuffer	¨ Ρυθμιστικό διάλυμα πλύσης
	¨ Solucão de lavagem	
BLOCK-REAG	¨ Reagente bloccante	¨ Blocking Reagent
	¨ réactif de blocage	¨ Reactivo bloqueante
	¨ Blockier-Reagenz	¨ Αντιδραστήριο αποκλεισμού
	¨ Bloqueio de reagente	
RCNS 10ml	¨ Ricostituire con 10 mL	¨ Reconstitute with 10 mL
	¨ reconstituer avec 10 mL	¨ reconstituir con 10 mL
	¨ rekonstituiren mit 10 mL	¨ Ανασύσταση με 10 mL
	¨ reconstituir com 10 mL	
SB	¨ Tampone campione	¨ Sample buffer
	¨ Tampon Echantillons	¨ Tampón Muestras
	¨ Probenpuffer	¨ Ρυθμιστικό διάλυμα δειγμάτων
	¨ Diluente de amostra	
CONJ	¨ Coniugato	¨ Conjugate
	¨ Conjugé	¨ Conjugado
	¨ Konjugat	¨ Σύζευγμα
	¨ Conjugado	
SUB	¨ Tampone substrato	¨ Substrate buffer
	¨ Substrat	¨ Tampón sustrato
	¨ Substratpuffer	¨ Ρυθμιστικό διάλυμα υποστρώματος
	¨ Substrato	