AESKULISA **ASCA-A**

Protocol 30-30-30 REF30-7507US

Instruction manual

Contents

1. Intended Use

AESKULISA ASCA-A is a solid phase enzyme immunoassay (ELISA) employing purified mannan for the semi-quantitative and qualitative detection of IgA anti-Saccharomyces cerevisiae antibodies (ASCA) in human serum. ASCA recognize specifically mannan, a component of the outer cell wall of yeast.

The AESKULISA ASCA A kit should not be used as a screening test for ASCA, since some Crohn's disease patients do not have ASCA IgA antibodies. The AESKULISA ASCA A kit should be used to compliment, but not to replace or to substitute for ASCA IgG antibody testing.

The assay is an aid in the diagnosis of Crohn`s disease and should be used in conjunction with other serological tests and clinical findings.

2. Clinical Application and Principle of the Assay

Crohn‘s disease is one of the two major Inflammatory Bowel Diseases (IBD). IBD is an umbrella term, that covers both primary disorders causing inflammation or ulceration in the small and large intestine, Crohn‘s disease and ulcerative colitis. Crohn‘s disease affects both, the small bowel and the colon, unlike ulcerative colitis which is restricted to the colon only. The etiology is not revealed yet, although a genetic and infectious background for the disease is under discussion.[1-3,5] Colonoscopy and ileoscopy are the established tools of diagnosis, no serology was available so far. Though Crohn‘s disease and ulcerative colitis share several symptoms the course of the diseases, its complications and its management are different, especially when it comes down to surgery.[4] Consequently the differental diagnosis of both diseases is crucial prior to treatment. However, about 5-10% of the patients can not be distinguished clearly by existing available diagnostic methodologies and are referred to as indeterminate colitis.[6,7]

ASCA have been found to be specific markers for Crohn`s disease. They have been reported for these patients with a frequency of up to 68%.[9] The identification of the target antigen mannan, a mannose-rich carbohydrate antigen of the outer cell wall of yeast, enabled the detection of ASCA by enzyme immunoassay.[8]

Principle of the test

Serum samples diluted 1:101 are incubated in the microplates coated with the specific antigen. Patient‘s antibodies, if present in the specimen, bind to the antigen. The unbound fraction is washed off in the next step. Afterwards anti-human immunoglobulins conjugated to horseradish peroxidase (conjugate) are incubated and react with the antigen-antibody complex of the samples in the microplates. Unbound conjugate is washed off in the next step. Addition of TMB-substrate generates an enzymatic colorimetric (blue) reaction, which is stopped by diluted acid (color changes to yellow). The rate of color formation from the chromogen is a function of the amount of conjugate bound to the antigen-antibody complex and this is proportional to the initial concentration of the respective antibodies in the patient sample.

3. Kit Contents

To be reconstituted:

5x Sample Buffer	1 vial, 20 ml - 5x concentrated (capped white: yellow solution) Containing: Tris, NaCl, BSA, sodium azide < 0.1% (preservative)
50x Wash Buffer	1 vial, 20 ml - 50x concentrated (capped white: green solution) Containing: Tris, NaCl, Tween-20, sodium azide < 0.1% (preservative)

Ready to use:

Negative Control	1 vial, 1.5 ml (capped green: yellow solution) Containing: PBS, BSA, Human serum (diluted), sodium azide < 0,1% (preservative)
Positive Control	1 vial, 1.5 ml (capped red: yellow solution) Containing: PBS, BSA, Human serum (diluted), sodium azide < 0,1% (preservative)
Cut-off Control	1 vial, 1.5 ml (capped blue: yellow solution) Containing: PBS, BSA, Human serum (diluted), Sodium Azide < 0,1% (preservative)
Calibrators	6 vials, 1.5 ml each 0, 3, 10, 30, 100, 300 U/ml (color increasing with concentration: yellow solutions) Containing: PBS, BSA, Human serum (diluted), sodium azide < 0,1% (preservative)
Conjugate	1 vial,15 ml IgA (capped red: red solution) Containing: PBS, BSA, goat - anti-human immunoglobulins conjugated to horseradish peroxidase
TMB Substrate	1 vial, 15 ml (capped black) Containing: Stabilized TMB/H_2O_2
Stop Solution	1 vial, 15 ml (capped white: colorless solution) Containing: 1M Hydrochloric Acid
Microtiterplate	12x8 well strips with breakaway microwells Coated with purified Mannan

Material required but not provided:

Microtiter plate reader 450 nm reading filter and optional 620 nm reference filter (600-690 nm). Glass ware (cylinder 100-1000ml), test tubes for dilutions. Vortex mixer, precision pipettes (10, 100, 200, 500, 1000 µl) or adjustable multipipette (100-1000µl). Microplate washing device (300 µl repeating or multi-channel pipette or automated system), adsorbent 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 the microplate at 2-8°C/35-46°F, in their original containers. Once prepared, reconstituted solutions are stable for 1 month at 4°C/39°F, at least. ***Reagents and the microplate shall be used within the expiry date indicated on each component, only. Avoid intense exposure of TMB solution to light. Store microplates in designated foil, including the desiccant, and seal tightly.***

5. Precautions of Use

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. Although this product is not considered particularly toxic or dangerous in conditions of normal use, refer to the following for maximum safety :

Recommendations and precautions

This kit contains potentially hazardous components. Though kit reagents are not classified being irritant to eyes and skin we recommend to avoid contact with eyes and skin and wear disposable gloves.
WARNING! Calibrators, Controls and Buffers contain sodium azide (NaN_3) as a preservative . NaN_3 may be toxic if ingested or adsorbed by skin or eyes. NaN_3 may react with lead and copper plumbing to form highly explosive metal azides. On disposal, flush with a large volume of water to prevent azide build-up. Please refer to decontamination procedures as outlined by CDC or other local/national guidelines.
Do not smoke, eat or drink when manipulating the kit. Do not pipette by mouth.
All human source material used for some reagents of this kit (controls, standards e.g.) has been tested by FDA approved methods and found negative for HbsAg, Hepatitis C and HIV 1. However, no test can guarantee the absence of viral agents in such material completely. Thus handle kit controls, standards and patient samples as if capable of transmitting infectious diseases and according to national requirements.

5.2 General directions for use

Do not mix or substitute reagents or microplates from different lot numbers. This may lead to variations in the results.

Allow all components to reach room temperature (20-26°C/64-78.8°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 used with other reagents prior.

Limitations

A definite clinical diagnosis should not be based on the results of the performed test only, but should be made by the physician after all clinical and laboratory findings have been evaluated.

The diagnosis is to be verified using different diagnostic methods.
A negative result does not rule out the presence of Crohn's disease. A positive result does only indicate the presence of antibodies to *S.cervisiae* and does not necessarily indicate the presence of Crohn's disease.
The assay performance characteristics have not been established for matrices other than serum.
The assay performance has not been established for pediatric Crohn's disease and Ulcerative colitis patients.
The presence of immune complexes or other immune aggregates in the patient sample may cause an increased level of non-specific binding and produce false negatievs in this assay.
A negative ASCA antibody result does not rule out the presence of ASCA antobodies because the antibody concentration may be below the limit of detection of this assay.
This test may be used to complement but not substitute for ASCA IgG antibody screening. ASCA A results should not be reported without the corresponding IgG results.

6. Sample Collection, Handling and Storage

Use preferentially freshly collected serum samples. Blood withdrawal must follow national requirements. Do not use icteric, lipemic, hemolysed 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 immediately, respectively stored tightly closed at 2-8°C/35-46°F up to three days, or frozen at -20°C/-4°F for longer periods.

7. Assay Procedure

7.1 Preparations prior to pipetting

Dilute concentrated reagents:

Dilute the concentrated sample buffer 1:5 with distilled water (e.g. 20 ml plus 80 ml).
Dilute the concentrated wash buffer 1:50 with distilled water (e.g. 20 ml plus 980 ml).

Samples

Dilute serum samples 1:101 with sample buffer (1x)
e.g. 1000 µl sample buffer (1x) + 10 µl serum. Mix well !

Washing

Prepare 20 ml of diluted wash buffer (1x) per 8 wells or 200 ml for 96 wells
e.g. 4 ml concentrate plus 196 ml distilled water.

Automated washing:

Consider excess volumes required for setting up the instrument and dead volume of robot pipette.

Manual washing:

Discard liquid from wells by inverting the plate. Knock the microwell frame with wells downside vigorously on clean adsorbent paper. Pipette 300 µl of diluted wash buffer into each well, wait for 20 seconds. Repeat the whole procedure twice again.

Microplates

Calculate the number of wells required for the test. Remove unused wells from the frame, replace and store in the provided plastic bag, together with desiccant, seal tightly (2-8°C/35-46°F).

7.2 Work flow

For pipetting scheme see Annex A, for the test procedure see Annex B
We recommend pipetting samples and calibrators in duplicate.

- Pipette 100 µl of each patient‘s diluted serum into the designated microwells.
- Pipette 100 µl calibrators OR cut-off control and negative and positive controls into the designated wells.
- Incubate for 30 minutes at room temperature (20-26°C/64-78.8°F).
- Wash 3x with 300 µl washing buffer (diluted 1:50).
- Pipette 100 µl conjugate into each well.
- Incubate for 30 minutes at room temperature (20-26°C/64-78.8°F).
- Wash 3x with 300 µl washing buffer (diluted 1:50).
- Pipette 100 µl TMB substrate into each well.
- Incubate for 30 minutes at room temperature (20-26°C/64-78.8°F).
- Pipette 100 µl stop solution into each well, using the same order as pipetting the substrate.
- Incubate 5 minutes minimum.
- Agitate plate carefully for 5 sec.
- Read absorbance at 450 nm (optionally 450/620 nm) within 30 minutes.

7.3 Quality Control

- Perform calibrators and controls with each batch of samples to ensure that all reagents and procedures perform properly.
- In order for the test to be considered valid all of the following criteria below must all be met. If any of these critera are not met, the test should be considered invalid and the assay repeated:

  Calibrator F, Calibrator A, Positive Control, Negative Control and Cut-Off Control should react according to the values specified in the quality control certificate.
- The user should refer to NCCLS document C24-A for additional guidance on appropriate QC practices.

7.4 Expected Values

The cut-off was established and validated with more than 75 healthy donors of mean age of 42.2 years (Range 22-66 years) and 74% of them are female whereas 26% are male.
Each laboratory should establish its own normal range based upon its own techniques, controls, equipment and patient population according to their own established procedures.
The incidence of ASCA antibodies in other populations is summarized in the table below. A literature analysis[10 - 13] revealed the following data:

Disease	# Tested	positive ASCA-A (#)	positive ASCA-A (%)
Crohns Disease	492	194	39.4
Celiac Disease	37	11	29.7
Ulcerative colitis	394	31	7.9
Autoimmune-Liverdiseases	215	39	18.1
Healthy Donors	344	14	4.1

8. Semi-quantitative and Qualitative Interpretation

For **semi-quantitative interpretation** establish the standard curve by plotting the **optical density (OD) of each calibrator (y-axis)** with respect to the corresponding concentration values in **U/ml (x-axis)**. For best results we recommend log/lin coordinates and 4-Parameter Fit. From the OD of each sample, read the corresponding antibody concentrations expressed in **U/ml.**

Normal Range	Positive Results
≤ 15 U/ml	**> 15 U/ml**

Example of a standard curve

We recommend pipetting calibrators in parallel for each run.

Calibrators IgA	*OD 450/620 nm*	*CV % (Variation)*
0 U/ml	0.032	2.8
3 U/ml	0.152	2.6
10 U/ml	0.281	1.2
30 U/ml	0.646	2.4
100 U/ml	1.214	1.7
300 U/ml	2.104	1.6

Example of calculation

Patient	Replicate (OD)	Mean (OD)	Result (U/ml)
P 01	0.904/0.937	0.921	58.3
P 02	0.564/0.551	0.558	25.9

For lot specific data, see enclosed quality control certificate. Medical laboratories might perform an in-house Quality Control by using own controls and/or internal pooled sera. ***Do not use this example for interpreting patients results!***

For **qualitative interpretation** read the optical density of the cut-off control and the patient samples. Compare patient´s OD with the OD of the cut-off control. All samples which are higher than cut-off are considered positive.

Negative:	**OD patient < OD $_{\text{cut-off}}$**
Positive:	**OD patient > OD $_{\text{cut-off}}$**

9. Technical Data

Sample material:	serum
Sample volume:	10 µl of sample diluted 1:101 with 1x sample buffer
Total incubation time:	90 minutes at room temperature (20-26°C/64-78.8°F)
Calibration range:	0-300 U/ml
Analytical sensitivity:	1.0 U/ml
Storage:	at 2-8°C/35-46°F use original vials, only
Number of determinations:	96 tests

10. Performance Data

10.1 Analytical sensitivity

Testing sample buffer 40 times on AESKULISA ASCA A (REF7507US) gave an analytical sensitivity of 1.0 U/ml.

10.2 Clinical Studies

The microplates are coated with purified ***mannan from S. cerevisiae.*** 264 sera suffering from Crohns disease, Ulcerative Colitis and several other diseases have been tested on the AESKULISA ASCA A and another ASCA test. The result as a comparison to the predicate device are shown in the table below. (the data has been aquired with the AESKULISA ASCA A (REF7507US)).

Disease	# Tested	positive AESKU (#)	positive AESKU (%)
Crohns Disease	100	59	59.0
Ulceraive Colitis	55	9	16.4
Healthy Donors	50	0	0.0
Celiac Disease	30	2	6.7
Systemic Lupus Erythematosus	10	2	20.0
Wegeners Granulomatosis	2	0	0.0
Sjögrens Syndrome	4	2	50.0
Reactive Arthritis	11	1	9.1
Mixed Connective Tissue disease	1	0	0.0
Chronic Arthritis	1	0	0.0

10.3 Comparison Studies

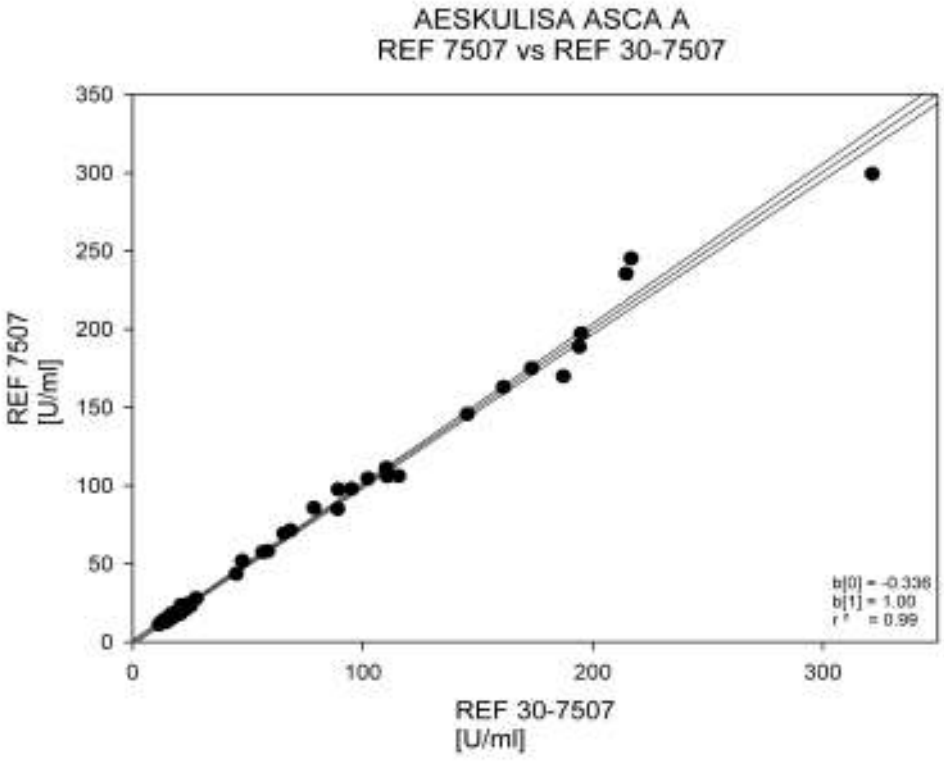
		AESKULISA ASCA A		
		positive	negative	
other ASCA A assay	positive	55	19	74
	negative	20	170	190
		75	189	264

positive agreement: 74.3 % (55/74)
negative agreement: 89.5 % (170/190)
total agreement: 85.2 % (225/264)

Be advised that the agreement revers to the comparison of the AESKULISA ASCA A results to that of another ASCA A kit. There was no attempt to correlate the assay results with the disease presence or absence. No judgement can be made on the comparisons accuracy to predict disease.

The AESKULISA ASCA A exists in two protocols: REF 7507US (30-15-15 minutes incubation time) and REF 30-7507 (30-30-30 minutes incubation time) you hold in your hand now. The comparison of these tests was assessed with 78 sera tested on both kits REF 7507US (30-15-15 protocol) and REF 30-7507US (30-30-30 protocol). A linear regression analysis of the two products showed that the two products are equivalent. Included in these sera are more than 37 sera close to the cut-off (range 10-20 U/ml).

Y = b[0] + b[1]X	**value**	**range (CI95%)**
b[0]	**-0.336**	**-2.00 / 1.33**
b[1]	**1.00**	**0.98 / 1.02**
r^2	**0.99**	



10.4 Linearity

Chosen sera have been tested with this kit and found to dilute linearly. However, due to the heterogeneous nature of human autoantibodies there might be samples that do not follow this rule. (the data has been aquired by the 30-15-15 protocol (REF7507US))

Sample No.	Dilution Factor	measured concentration (U/ml)	expected concentration (U/ml)	Recovery (%)
1	1 / 100	124.4	125.0	99.5
	1 / 200	63.6	62.5	101.7
	1 / 400	33.4	31.3	106.9
	1 / 800	16.0	15.6	102.4
2	1 / 100	289.5	295.0	98.1
	1 / 200	154.7	147.5	104.9
	1 / 400	70.6	73.8	95.8
	1 / 800	33.7	36.9	91.3

10.5 Precision

To determine the precision of the assay, the variability (intra and inter-assay) was assessed by examining its reproducibility on three serum samples selected to represent a range over the standard curve. (n=18) (the data has been aquired with the AESKULISA ASCA A (REF7507US))

Intra-Assay			Inter-Assay		
Sample No.	Mean (U/ml)	CV (%)	Sample No.	Mean (U/ml)	CV (%)
1	18.2	5.6	1	23.1	4.8
2	52.5	5.1	2	48.5	4.7
3	112.7	2.9	3	115.6	3.7

10.6 Calibration

Due to the lack of international reference calibration *AESKULISA* ASCA-A is calibrated in arbitrary units (U/ml).

11. Literature

1. **Seibold F, Stich O, Hufnagel R, Kamil S, Scheurlen M (2001).**
   Anti-Saccharomyces cerevisiae antibodies in inflammatory bowel disease: a family study.
   Scand J Gastroenterol 36: 196-201.
2. **Sendid B, Colombel JF, Jacquinot PM et al. (1996).**
   Specific antibody response to pligomannosidic epitopes in Crohn`s disease.
   Clin Diagn Lab Immunol 3: 219-226.
3. **Giaffer MH, Clark A, Holdsworth CD (1992).**
   Antibodies to Saccharomyces cerevisiae in patients with Crohn`s disease and their possible pathogenic importance.
   Gut 33: 1071-1075.
4. **Bernstein CN, Blanchard JC, Rawsthorne P and Wadja A (1999).**
   Epidemiology of Crohn‘s disease in a central canadian province: a population-based study.
   Am. J. Epidemiol. 149(10): 916-924.
5. **Glas J, Torok HP, Vilsmaier F, Herbinger KH, Hoelscher M, Folwaczny C (2002)**
   Anti-saccharomyces cerevisiae antibodies in patients with inflammatory bowel disease and their first-degree relatives: potential clinical value.
   Digestion. 66(3):173-177.
6. **Peters M, Joossens S, Vermeire S, Vlietinck R, Bossuyt X, Rutgeerts P (2001)**
   Diagnostic value of Anti-Saccharomyces Cervisiae and antineutrophil cytoplasmatic autoanti bodies in inflamatory bowel disease.
   Am. J. Gastroenterol. 96: 730-734
7. **Sandborn WJ. (2004)**
   Serologic markers in inflammatory bowel disease: state of the art.
   Rev. Gastroenterol. Disord. 4(4):167-74
8. **Rutgeerts P and Vermeire S (1998)**
   Clinical value of the detection of antibodies in the serum for diagnosis and treatment of inflammatory bowel disease.
   Gastroenterol. 115: 1006-1022
9. **Klebl FH, Bataille F, Hofstädter F, Herfarth H, Schölmerich J, Rogler G (2004)**
   Optimising the diagnostic value of Anti-Saccharomyces Cerevisiae-antibodies (ASCA) in Crohn’s disease.
   Int. J. Colorectal Dis. 19: 319-24
10. **Lawrance IC, Murray K, Hall A, Sung JJ, Leong R. (2004)**
    A prospective comparative study of ASCA and pANCA in Chinese and Caucasian IBD patients.
    Am. J. Gastroenterol. 99: 2186-94
11. **Damoiseaux JG, Bouten B, Linders AM, Austen J, Roozendaal C, Russel MG, Forget PP, Tervaert JW. (2002)**
    Diagnostic value of anti-Saccharomyces cerevisiae and antineutrophil cytoplasmic antibodies for inflammatory bowel disease: high prevalence in patients with celiac disease.
    J. Clin. Immunol. 22: 281-87
12. **Muratori P, Muratori L, Guidi M, Maccariello S, Pappas G, Ferrari R, Gionchetti P, Campieri M, Bianchi FB. (2003)**
    Anti-Saccharomyces cerevisiae antibodies (ASCA) and autoimmune liver diseases.
    Clin.Exp.Immunol. 132: 473 - 476
13. **Sutton CL, Yang H, Li Z, Rotter JI, Targan SR, and Braun J. (2003)**
    Familial expression of anti-Saccharomyces cerevisiae mannan antibodies in affected and unaffected relatives of patients with Crohn‘s disease.
    Gut 46: 58 - 63.

ANNEX A: Pipetting scheme

We suggest pipetting calibrators, controls and samples as follows:
For **semi-quantitative interpretation** use calibrators to establisch a standard curve
For **qualitative interpretation** use cut-off control

ANHANG A: Pipettierschema

Wir empfehlen, die Kalibratoren, Kontrollen und Proben wie folgt zu pipettieren:
Zur **semi-quantitativen Auswertung** verwenden Sie die Kalibratoren zur Erstellung einer Standardkurve.
Zur **qualitativen Auswertung** verwenden Sie die Cut-off Kontrolle.

For **semi-quantitative interpretation** use calibrators to establish a standard curve

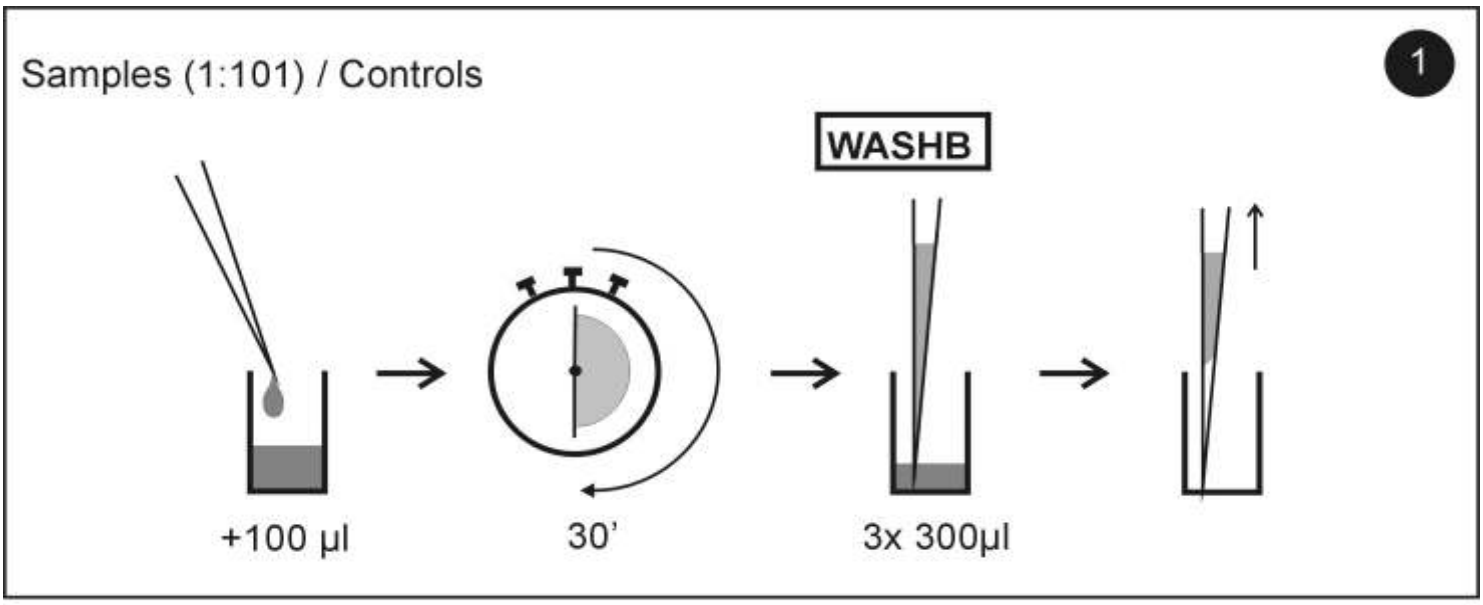
	1	2	3	4	5	
A	CalA	CalE	P1			
B	CalA	CalE	P1			
C	CalB	CalF	P2			
D	CalB	CalF	P2			
E	CalC	PC	P3			
F	CalC	PC	P3			
G	CalD	NC	...			
H	CalD	NC	...			

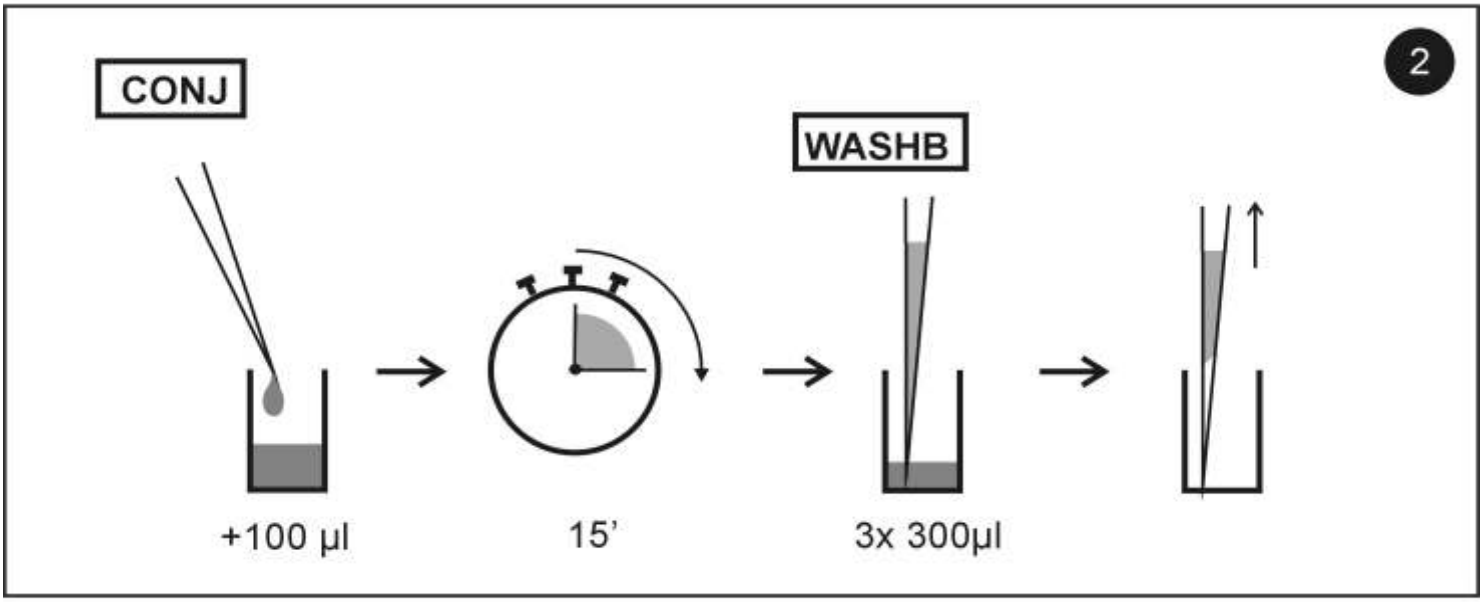
For **qualitative interpretation** use cut-off control

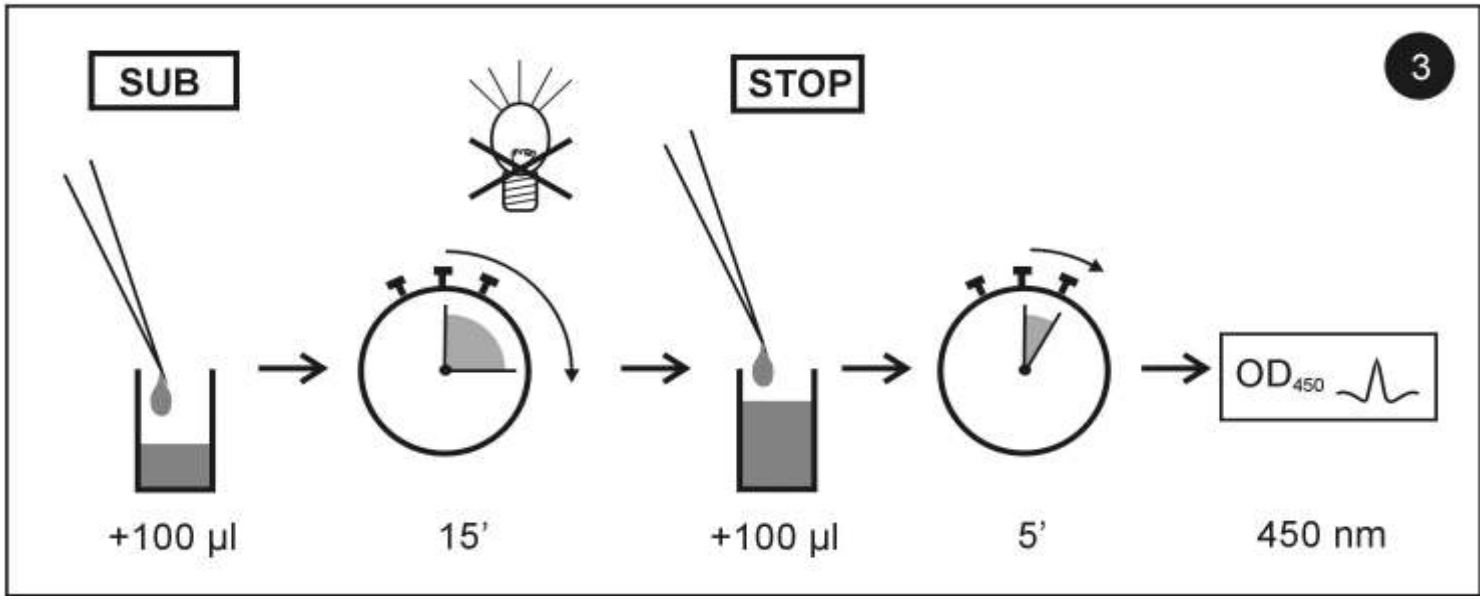
	1	2	3	4	5	
A	NC	P2				
B	NC	P2				
C	CC	P3				
D	CC	P3				
E	PC	...				
F	PC	...				
G	P1	...				
H	P1	...				

CalA: calibrator A, CalB: calibrator B, CalC: calibrator C, CalD: calibrator D, CalE: calibrator E, CalF: calibrator F
PC: positive control
NC: negative control
CC: Cut-off control
P1: patient 1
P2: patient 2
P3: patient 3

Annex B: Test Procedure/ Testablauf/ Procedura del test/ Διαδικασία δοκιμασίας/ Procedimiento del test







Assay/Test: _____ Incubation / Inkub. : 1._____min Date/ Datum:_____

Temperature/Temperatur:_____ °F _____ °C 2._____min

Signature/Unterschrift:._____

Name:_____ 3._____min

	1	2	3	4	5	6	7	8	9	10	11	12
A												
B												
C												
D												
E												
F												
G												
H												

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IVD	♦ Diagnosi in vitro ♦ Pour diagnostic in vitro ♦ In Vitro Diagnostikum ♦ Para uso Diagnóstico in vitro	♦ For in vitro diagnostic use ♦ Para uso diagnóstico in vitro ♦ In Vitro Διαγνωστικό μέσο
REF	♦ Numero d'ordine ♦ Référence Catalogue ♦ Bestellnummer ♦ Número de catálogo	♦ Cataloge number ♦ Numéro de catálogo ♦ Αριθμός παραγγελίας
LOT	♦ Descrizione lotto ♦ Lot ♦ Chargen Bezeichnung ♦ Lote	♦ Lot ♦ Lote ♦ Χαρακτηρισμός παρτίδας
CE	♦ Conformità europea ♦ Déclaration CE de Conformité ♦ Europäische Konformität ♦ Déclaracão CE de Conformidade	♦ EC Declaration of Conformity ♦ Declaración CE de Conformidad ♦ Ευρωπαϊκή συμφωνία
96	♦ 96 determinazioni ♦ 96 tests ♦ 96 Bestimmungen ♦ 96 Testes	♦ 96 tests ♦ 96 pruebas ♦ 96 προσδιορισμοί
i	♦ Rispettare le istruzioni per l'uso ♦ Voir les instructions d'utilisation ♦ Gebrauchsanweisung beachten ♦ Ver as instrucões de uso	♦ See instructions for use ♦ Ver las instrucciones de uso ♦ Λάβετε υπόψη τις οδηγίες χρήσης
	♦ Da utilizzarsi entro ♦ Utilise avant le ♦ Verwendbar bis ♦ Utilizar antes de	♦ Use by ♦ Utilizar antes de ♦ Χρήση μέχρι
+2°C +8°C	♦ Conservare a 2-8°C ♦ Conserver à 2-8°C ♦ Lagerung bei 2-8°C ♦ Conservar entre 2-8°C	♦ Store at 2-8°C (35-46°F) ♦ Conservar a 2-8°C ♦ Φυλάσσεται στους 2-8°C
	♦ Prodotto da ♦ Fabriqué par ♦ Hergestellt von ♦ Fabricado por	♦ Manufactured by ♦ Fabricado por ♦ Κατασκευάζεται από
CO-CAL	♦ Calibratore cut-off ♦ Etalon Seuil ♦ Grenzwert Kalibrator ♦ Calibrador de cut-off	♦ Cut off Calibrator ♦ Calibrador de cut-off ♦ Οριακός ορός Αντιδραστήριο βαθμονόμησης
CON +	♦ Controllo positivo ♦ Contrôle Positif ♦ Positiv Kontrolle ♦ Controlo positivo	♦ Positive Control ♦ Control Positivo ♦ Θετικός ορός ελέγχου
CON -	♦ Controllo negativo ♦ Contrôle Négatif ♦ Negativ Kontrolle ♦ Controlo negativo	♦ Negative Control ♦ Control Negativo ♦ Αρνητικός ορός ελέγχου
CAL	♦ Calibratore ♦ Etalon ♦ Kalibrator ♦ Calibrador	♦ Calibrator ♦ Calibrador ♦ Αντιδραστήριο βαθμονόμησης
RC	♦ Recupero ♦ Corrélation ♦ Wiederfindung ♦ Recuperacão	♦ Recovery ♦ Recuperado ♦ Ανάκτηση
CONJ	♦ Coniugato ♦ Conjugé ♦ Konjugat ♦ Conjugado	♦ Conjugate ♦ Conjugado ♦ Σύζευγμα
MP	♦ Micropiastra rivestita ♦ Microplaque sensibilisée ♦ Beschichtete Mikrotiterplatte ♦ Microplaca revestida	♦ Coated microtiter plate ♦ Microplaca sensibilizada ♦ Επικαλυμμένη μικροπλάκα
PINP	♦ Piastra ad aghi rivestita ♦ Pinplate sensibilisée ♦ Beschichtete Pinplatte ♦ Pinplate revestida	♦ Coated pinplate ♦ Pinplate sensibilizada ♦ Επικαλυμμένη πλάκα Pin
WASHB 50x	♦ Tampone di lavaggio ♦ Tampon de Lavage ♦ Waschpuffer ♦ Solucão de lavagem	♦ Wash buffer ♦ Solución de lavado ♦ Ρυθμιστικό διάλυμα πλύσης
SUB	♦ Tampone substrato ♦ Substrat ♦ Substratpuffer ♦ Substrato	♦ Substrate buffer ♦ Tampón sustrato ♦ Ρυθμιστικό διάλυμα υποστρώματος
STOP	♦ Reagente bloccante ♦ Solution d'Arrêt ♦ Stopreagenz ♦ Solucão de paragem	♦ Stop solution ♦ Solución de parada ♦ Αντιδραστήριο διακοπής αντίδρασης
SB 5x	♦ Tampone campione ♦ Tampon Echantillons ♦ Probenpuffer ♦ Diluente de amostra	♦ Sample buffer ♦ Tampón Muestras ♦ Ρυθμιστικό διάλυμα δειγμάτων

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