







AESKUSLIDES® THE DIAGNOSTIC TOOL THAT WORKS

INSTRUCTION MANUAL ENGLISH



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ANCA

Standard Ref.	Description	Tests
54.100	ANCA Ethanol (12 wells)	120
54.101	ANCA Formalin (12 wells)	120
54.050	ANCA Ethanol (6 wells)	60
54.051	ANCA Formalin (6 wells)	60



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ANCA

Ref.	Description	Tests	
54.100	ANCA Ethanol (12 wells)	120	
54.101	ANCA Formalin (12 wells)	120	Including demo references:
54.050	ANCA Ethanol (6 wells)	60	xxx.Demo
54.051	ANCA Formalin (6 wells)	60	

1.INTENDED USE

AESKUSLIDES ANCA is an indirect immunofluorescence assay to detect anti-neutrophil cytoplasmic autoantibodies (ANCA) in human serum.

The assay is a tool for the differential diagnosis of ANCA-associated vasculitides (AAV) such as granulomatosis with polyangiitis (Wegener's)¹, microscopic polyangiitis and Churg-Strauss syndrome.

2.CLINICAL APPLICATION

The acronym ANCA (Anti-neutrophil cytoplasmic autoantibodies) describes a group of antibodies directed against different components of neutrophilic granulocytes and monocytes. For the detection of ANCAs, indirect immunofluorescence test on ethanol-fixed neutrophils has been the established method so far. It became apparent that some ANCAs create a cytoplasmic fluorescence pattern (thus called C-ANCAs) while others create a perinuclear pattern (the P-ANCAs) on ethanol fixed neutrophils. As both patterns may cover multiple antigens, immunofluorescence does not suffice for a satisfying differential diagnosis of vasculitis; thus each immunofluorescence test (IFT) should be verified with specific ELISA tests^{2,3}.

Some ANCAs give rise to an atypical fluorescence patter (the A-ANCA) which can be technically difficult to differentiate from a pattern generated by anti-nuclear antibodies (ANA) on ethanol fixed neutrophils. In order to help differentiating these, neutrophils which were fixed with formalin are employed. ANCAs which give rise to a P-ANCA/A-ANCA staining in ethanol fixed neutrophils will show a cytoplasmic pattern when formalin fixed neutrophils are used as a substrate. In the case that the staining pattern becomes negative, a testing for ANAs with Hep2 cells should be carried out.⁴

¹ Falk RJ, Gross WL, Guillevin L, Hoffman GS, Jayne DR, Jennette JC et al. Granulomatosis with Polyangiitis (Wegener's): An alternative name for Wegener's Granulomatosis. Arthritis Rheum 2011; 63: 863-864.

² Savige J, Gillis D, Benson E, Davies D, Esnault V, Falk RJ et al. International Consensus Statement on Testing and Reporting of Antineutrophil Cytoplasmic Antibodies (ANCA). Am J Clin Pathol 1999; 111: 507-513.

³ Savige J, Dimech W, Fritzler M, Goeken J, Hagen EC, Jennette JC et al. Addendum to the International Consensus Statement on testing and reporting of antineutrophil cytoplasmic antibodies. Quality control guidelines, comments, and recommendations for testing in other autoimmune diseases. Am J Clin Pathol 2003; 120: 312-318.

⁴ Csernok E, Holle JU. Twenty-eight years with antineutrophil cytoplasmic antibodies (ANCA): how to test for ANCA – evidence-based immunology? Autoimmun Highlights 2010; 1: 39-43.



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Myeloperoxidase (MPO) has been identified as the major P-ANCA antigen (MPO-ANCA). However, other cellular components like Lactoferrin, Cathepsin G, Lysozyme and Elastase also cause a perinuclear staining and are therefore included into the group of P-ANCAs. However, they are not specifically associated with AAVs and may play a role in the differential diagnosis to other non-vasculitis diseases.⁵

In contrast, Proteinase 3 is the major target antigen of the C-ANCAs (PR3-ANCA).⁶ Another antigen that may produce a C-ANCA is the BPI (bactericidal/permeability-increasing protein).⁷

ANCAs are found frequently in patients with microscopic polyangiitis (60% MPO-ANCA, 30% PR3-ANCA) and in patients with Churg-Strauss syndrome (30% MPO-ANCA, 30% PR3-ANCA).⁸ Autoantibodies to PR3 are a specific serological marker for granulomatosis with polyangiitis (Wegener's).Here, 50% (localized disease) to 95% (generalized disease) show PR3-ANCAs.⁹

Antibodies against the other antigens relevant in ANCAs such as Lactoferrin, Cathepsin G, Elastase and BPI were associated with a wide variety of diseases. However, a clear clinical relevance is still being investigated.⁵ In the case of anti-Elastase antibodies, a correlation with cocaine-induced midline destructive lesions (CIMDL) has been shown.¹⁰

Antigen Characterization: human neutrophils (granulocytes) fixed either with ethanol or formalin

Cross – reactivity: As described in the clinical application section, the presence of ANAs can give fluorescence patterns which can be confused for a P-ANCA/A-ANCA. Otherwise no cross-reactivity is present.

The detection of antibodies is based on the principle of indirect immunofluorescence assay (IIFA). Glass microscope slides are coated with tissue sections or cells (HEp-2 cells (ANA), Granulocytes (ANCA) or *Crithidia luciliae* (nDNA)). If the patient's serum contains specific antibodies they will bind during the first incubation. After removing unbound material by washing steps, bound antibodies are detected by Fluorescein conjugated anti-human immunoglobulins during the second incubation. A specific green fluorescent staining of antigen-antibody-complex can be visualized with the aid of a fluorescent microscope.

⁵ Wiik A, Stummann L, Kjeldsen L, Borregaard N, Ullman S, Jacobsen S et al. The diversity of perinuclear antineutrophil cytoplasmic antibodies (pANCA) antigens. Clin Exp Immunol 1995; 101 Suppl 1: 15-17.

⁶ Gross WL, Csernok E, Helmchen U. Antineutrophil cytoplasmic autoantibodies, autoantigens, and systemic vasculitis. APMIS 1995; 103: 81-97.

⁷ Zhao MH, Jones SJ, Lockwood CM. Bactericidal/permeability-increasing protein (BPI) is an important antigen for anti-neutrophil cytoplasmic autoantibodies (ANCA) in vasculitis. Clin Exp Immunol 1995; 99: 49-56.

⁸ Bosch X, Guilabert A, Font J. Antineutrophil cytoplasmic antibodies. Lancet 2006; 368: 404-418.

⁹ Holle JU, Csernok E, Gross WL. Wegener Granulomatosis. 2008; In: Diagnostic Criteria in autoimmune Diseases, Shoenfeld Y, Cervera R, and Gershwin ME, eds. Humana Press, pp. 99-102.

¹⁰ Wiesner O, Russell KA, Lee AS, Jenne DE, Trimarchi M, Gregorini G et al. Antineutrophil cytoplasmic antibodies reacting with human neutrophil elastase as a diagnostic marker for cocaine-induced midline destructive lesions but not autoimmune vasculitis. Arthritis Rheum 2004; 50: 2954-2965.



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3. KIT PROCEDURE

Please refer to Assay Procedure listed in Common Instructions, Section 11, for detailed instructions. The following details shall be used for the ANCA kits:

Counter staining time: 30 to 90 seconds

• Recommended Screening titer: 1:20

4. INTERPRETATION

Anti-neutrophil cytoplasmic antibodies (ANCA) are of major clinical importance in assessing patient's vascular disorders.

The appropriate end titer is that in which the patient serum shows a simple positive fluorescence. Weak fluorescence with titers between 1:20 and 1:80 or vagueness with respect to the clinical results should be checked by way of monitoring control. In such a case the samples should be collected about every 3 weeks and similarly tested.

1:20 25μL Serum + 475μL Samplebuffer 1:40 20μL Serum + 780μL Samplebuffer (respectively 1:2 of the "1:20"-Dilution) 1:80 10μL Serum + 790μL Samplebuffer (respectively 1:2 of the "1:40"-Dilution) 1:160 10μL Serum + 1590μL Samplebuffer (respectively 1:2 of the "1:80"-Dilution) a.s.o.

The classical C-ANCA pattern showing granular homogenous cytoplasmic staining with minimal staining of the nuclear area.

P-ANCA pattern showing sharply delineated perinuclear staining (ethanol-fixed neutrophils) or C-ANCA cytoplasmic pattern (formalin-fixed-neutrophils).



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5. SPECIFIC PERFORMANCE CHARACTERISTICS

254 frozen samples were tested on AESKUSLIDE ANCA Ethanol and AESKUSLIDES ANCA Formalin and were compared to reagents from another company. The samples had been stored for several years and represented patients being evaluated for vasculitis disease. Comparison of the two kits was done to demonstrate comparability between two independent manufacturers ANCA systems including consistency of pattern.

Clinical samples represented a full spectrum of autoimmune diseases

5.1 Results:

ANCA Ethanol	predicate			
AESKUSLIDES	С	р	neg	Total
С	93		2	95
р		37	2	39
neg	2		118	120
Total	95	37	122	254

positive agreement is 98.5% ((93+37 / 132)) negative agreement is 96.7% (118/122) total agreement is 97.6% ((130+118)/254)

ANCA Formalin	predicate		
AESKUSLIDES	c neg Total		
С	130	6	136
neg		118	118
Total	130	124	254

positive agreement is 100% (130 / 130) negative agreement is 95.1% (118/124) total agreement is 97.6% ((130+118)/254)

5.2 Reproducibility and Precission

Three different LOTS of AESKUSLIDES for ANCA Ethanol and ANCA Formalin each were tested with 10 serum samples (4 MPO and PR3 positive and 2 negative) which cover the complete set of patterns. These samples were diluted from 1:40 up to 1:5120 and each dilution analysed by two independet readers on all three LOTS. Acceptance criteria was a deviation of +/-1 fluoresence intensity. The acceptance criteria were met for all samples, all dilutions, all LOTS and all independent readers.

More detailed data upon request



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6. DATA INTERPRETATION SHEET

ANCA

Date:	Lot.:	Fixation
Slide No.:	Operator:	ethanol: formalin:

Well No.	ID	Dilution factor	F.I.	nucleoplasm	cytoplasm	autoantibodies	remarks
1							
2							
3							
4							
5							
6							
7							
8							
9							
10							
11							
12							



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7. STANDARD KIT CONTENTS

7.1 STANDARD KITS

		(DES each kit)		CONJUGATE (1x)		POSITIVE CONTROL (1x 0.5ml)	
Kit Ref.	Kit Description	Ref.	Wells	Coated with	Ref.	Quantity	Description	Ref.	Description
54.100	ANCA Ethanol	s54.100	12	human neutrophils	C54.100	4 ml	IgG Capped blue: slightly blue coloured solution. Containing: BSA, Tween,	PC54.100	ANCA pattern control C-ANCA Capped red: colourless solution. Containing: Human serum (diluted), sodium azide <0.1% (preservative)
54.100	(12 wells)	\$54.100	12	(ethanol fixation)	C54.100	4 mi	Fluorescein (FITC) labelled Anti- human Antibody	PC54.101	ANCA pattern control P-ANCA Capped red: colourless solution. Containing: Human serum (diluted), sodium azide <0.1% (preservative)
	ANCA Formalin	s54.101 1	human neutrophils (formalin fixation)	human neutrophils			IgG Capped blue: slightly blue coloured solution.	PC54.100	ANCA pattern control C-ANCA Capped red: colourless solution. Containing: Human serum (diluted), sodium azide <0.1% (preservative)
54.101	(12 wells)			C54.101	4 ml	Containing: BSA, Tween, Fluorescein (FITC) labelled Anti- human Antibody	PC54.101	ANCA pattern control P-ANCA Capped red: colourless solution. Containing: Human serum (diluted), sodium azide <0.1% (preservative)	
-40-0	ANCA Ethanol	CA Ethanol	Ethanol 54.050	human neutrophils	S C54.050 2 ml Containing: BSA, Tween,		coloured solution.	PC54.100	ANCA pattern control C-ANCA Capped red: colourless solution. Containing: Human serum (diluted), sodium azide <0.1% (preservative)
54.050	(6 wells)	s54.050	6	(ethanol fixation)		PC54.101	ANCA pattern control P-ANCA Capped red: colourless solution. Containing: Human serum (diluted), sodium azide <0.1% (preservative)		
-40-	ANCA Formalin	F4.051		human neutrophils	GE4.054	2 1	IgG Capped blue: slightly blue coloured solution.	PC54.100	ANCA pattern control C-ANCA Capped red: colourless solution. Containing: Human serum (diluted), sodium azide <0.1% (preservative)
54.051	(6 wells)	s54.051	6	(formalin fixation)	C54.051	2 ml	Containing: BSA, Tween, Fluorescein (FITC) labelled Anti- human Antibody	PC54.101	ANCA pattern control P-ANCA Capped red: colourless solution. Containing: Human serum (diluted), sodium azide <0.1% (preservative)

NOTE: The contents of the remaining components of the kits i.e. Common reagents (Neg. Ctrl, Mounting Medium etc.) are described below in section 8 COMMON REAGENTS CONTENTS.

7.2 DEMO KITS

For the content of the demo kits refer to the corresponding certificate of analysis.



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8. COMMON REAGENTS CONTENTS

a. Common Reagents

Ref.	Reagent		uantity Volume	Description	Ready to use
NCANCA	Negative Control	1x	0.5ml	Capped green: colourless solution. Containing: Human serum (diluted), sodium azide <0.1% (preservative)	YES
* EBIFA	Evans Blue 0.2%	1x	1.5ml	Capped white: Blue coloured solution Containing: PBS, Evans Blue. Dilute the Evans Blue 0.2% 1:3000 in 1x WBIFA	NO
MMIFA	Mounting Medium	1x	8ml	Validated for use with the HELMED® Capped white: colourless solution Containing: PBS, Glycerin.	YES
WBIFA	Washbuffer (10x)	1x	100ml	Capped white: colourless solution Dilute the concentrated buffer 1:10 in distilled water (e.g.: 100 ml + 900 ml). Containing: PBS, sodium azide (preservative).	NO
SBIFA	Samplebuffer (1x)	1x	70ml	Capped white: colourless solution for the dilution of patient sera Containing: BSA, PBS, sodium azide (preservative).	YES

Quantities are per kit. (*)must be ordered seperatly.

b. Materials required but not provided

- 1. Distilled water
- 2. Test tubes for sample dilution
- 3. Measuring flask
- 4. Volumetric pipette
- 5. Timer
- 6. Fluorescence microscope with FITC system, (490nm excitation filter, 510nm barrier filter)
- 7. Incubator tray
- 8. Staining dish
- 9. Pipetting tips
- 10. Cover slips (24x60 mm)
- 11. Squeeze wash bottle

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



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9. STORAGE AND SHELF LIFE

Store all reagents at 2°C-8°C/35-46°F, protected from intense light. The expiration date of each component is indicated on the respective label. Do not use reagents beyond the expiration date.

Store all reagents and the slides at 2-8°C/35-46°F, in their original containers. Once prepared, reconstituted solutions are stable for at least 1 week at 2-8°C/35-46°F. **Reagents and the slides shall be used within the expiry date indicated on each component, only.**

10. PRECAUTIONS OF USE

c. 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 intended 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 avoiding contact with eyes and skin and wearing disposable gloves.

All human source material used for some reagents of this kit (controls e.g.) has been tested by approved methods and found negative for HBsAg, Hepatitis C and HIV. However, no test can guarantee the absence of viral agents in such material completely. Thus handle kit controls and patient samples as if capable of transmitting infectious diseases and according to national requirements.

The kit contains material of animal origin (BSA, Immunoglobulin) as stated in the table of contents, handle according to national requirements.

d. General directions for use

- 1. Do not pipette by mouth. Do not smoke, eat or drink when manipulating the kit.
- 2. Do not mix or substitute reagents from different lot numbers. This may lead to variations in the results.
- 3. Keep all flasks sealed after use to avoid bacterial contamination.
- 4. Always pipette all solutions with new sterile pipetting tips.
- 5. Never expose components to higher temperature than 37°C / 98,6°F.
- 6. Never let the slide wells dry out during the whole procedure.
- 7. Never freeze the slides.

Each laboratory should establish its own in house controls upon its own techniques, controls, equipment and patient population according to its established procedures.

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.

In case that the values of the controls do not meet the criteria the test is invalid and has to be repeated. The following technical issues should be proven: Expiration dates of (prepared) reagents, storage conditions, pipettes, devices, photometer, incubation conditions and washing methods. If the items tested show aberrant values or any kind of deviation or that the validation criteria are not met without a justified cause please contact our local representative.



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11. SAMPLE COLLECTION, HANDLING AND STORAGE

Preparation of samples: use preferentially freshly collected serum samples. Blood withdrawal must follow national requirements. Collect blood samples aseptically.

Lipemic, icteric, hemolysed or microbially contaminated specimens may cause interference.

Sera with particles should be cleared by low speed centrifugation ($<1000 \times g$). Blood samples should be collected in clean, dry and empty tubes. After separation, the serum samples should be used during the first 8h, respectively stored tightly closed at 2-8°C/35-46°F up to 48h, or frozen at -20°C/-4°F for longer periods. Avoid repeated freezing and thawing.

12. ASSAY PROCEDURE

e. Preparation prior to pipetting

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.

- 1. Preparation of the Wash Buffer: Dilute the concentrated buffer 1:10 with distilled water.
- 2. Dilution of samples: Dilute patient sera (for screening titer refer to *Kit Procedure* section above according to the product reference that you are using) with 1x Samplebuffer. These vary between HEp-2, nDNA, rLKS, EMA etc. kits.
- 3. Controls are ready to use.
- 4. Prepare a protocol: Data interpretation sheets are available in the *Kit Procedure* section according to the product reference that you are using.



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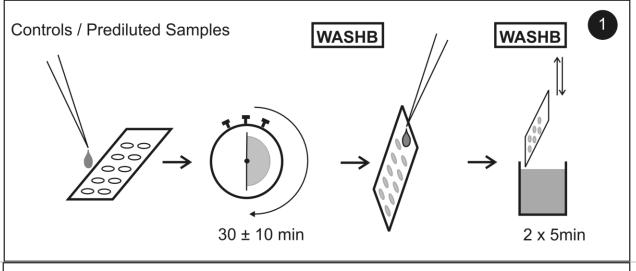
f. Test Procedure

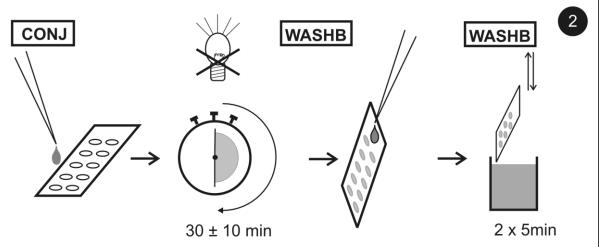
No.	Step description
110.	
1.	Remove required slide(s) from pouch(es) and mark them. Do not touch the wells. Do not allow the slides to dry out.
	Preparation of incubator tray : Place a small volume of deionized or distilled water in an incubator tray and place slide(s) on supports in the incubator tray.
	Incubate slide(s) 30 minutes \pm 10 minutes at room temperature in the moist incubator tray. Use consistent incubation times for the conjugate.
2.	First incubation : Pipette an adequate volume of each diluted serum and controls (ready to use) into the appropriate wells, avoid direct contact of pipette with slide surface.
	Make sure that each well is completely covered with a corresponding serum. It is important to use as much test material as necessary to cover the well completely. But avoid a running between the wells because this may cause incorrect results.
	Washing : After incubation remove slides from incubator tray and rinse briefly with wash buffer using a squeeze wash bottle. Do not squirt buffer directly on the wells.
3.	NOTE: To prevent cross contamination tilt slide first towards one row and, carefully run a stream of wash buffer along the midline of the slide, allowing the wash buffer to run off the lower edge of the slide. Then tilt the slide towards the other row, and repeat this procedure, allowing the wash buffer to run off what is now the lower edge of the slide. Wash slide(s) 10 minutes with wash buffer in a slide staining dish. Avoid direct contact of solid items with the substrate. For optimal results change the buffer solution once after 5 minutes.
	Lift slide(s) out of staining dish and carefully remove excess washing buffer.
	NOTE: It is important that slide wells do not dry out during the procedure as this may lead to damage to the substrate. Please do not blot or dry the slide in any manner or allow slide to sit without fluorescent antibody reagent for longer than a few seconds.
4.	Second incubation : After the washing procedure return slide immediately to incubator tray and cover each well with an adequate volume of FITC-conjugate and make sure that the well is covered completely.
	Incubate slide(s) 30 minutes ± 10 minutes at room temperature in the dark.
5.	Washing : After incubation remove slides from incubator tray and rinse briefly with wash buffer using a squeeze wash bottle. Do not squirt buffer directly on the wells. Wash slide(s) 10 minutes with wash buffer in a slide staining dish. For optimal results, change the buffer solution once after 5 minutes.
6.	*Optional counterstain: Dilute counterstain (Evans Blue) 1:3000 in Wash buffer and mix well. Tilt counterstain into the staining dish and incubate the slides in it. Refer to <i>Kit Procedure</i> section above according to the product reference that you are using for incubation time details. Evans Blue covers unspecific background fluorescence.
	Remove slide(s) after the incubation time and rinse briefly with washing buffer. Remove excess washing buffer. Please do not blot or dry the slide in any manner.
7.	Mounting Medium : Add an adequate volume of mounting medium along midline of each slide. Carefully place coverslip in position, avoiding air bubbles.
8.	Reading : Read slide(s) immediately at 400 - 800 x total magnification with a fluorescent microscope. (490 nm excitation filter, 510 nm barrier filter).

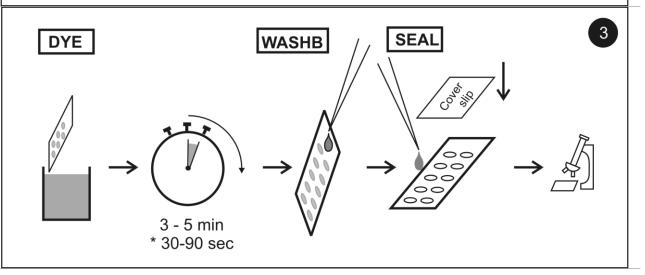


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g. Work flow









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13. TROUBLESHOOTING

ERROR	POSSIBLE CAUSES	SOLUTION
Low cell density	-Cell lysis following prolonged contact with deionised water -Buffer squirted directly on the substrate in the well	Follow the recommended wash procedure
	Proteolytic enzymes have attacked the substrate	Inactivate serum
	Serum dried in the well, fluorescence stronger at the edge	Always incubate in a humid environment
	Serum does not cover the test well	Apply an adequate volume of test material
Uneven fluorescence	Cross-reaction between the wells	Avoid running between the wells in the first incubation
	Marking the slide with a wax pencil produces a film on the slide	Use a standard (non-wax) pencil
	Microscope incorrectly adjusted	Check the adjustment of the UV-lamp
Diffuse	Slide incubated in refrigerator without cover	Seal slide with nail polish or paraffin wax
picture	I.F. Microscope is dirty. Possible scratches on the lense	Clean the microscope according to its instructions
	Conjugate and slides thawed and refrozen	Conjugate and slides stored at 2°C-8°C/35 -46°F.
	Controls diluted	Check instructions, use ready to use kit controls
Little or no fluorescence	-Bacterial contamination of the sera or conjugate -Microscope not adjusted -pH-value of Washing buffer too low (pH value 7.4 ± 0.2)	Check conditions
	FITC conjugate exposed to light	Store conjugate protected from the light
Background fluorescence	Incorrectly washedSlide dried outLipemic, hemolytic seraMicroscope error	- Check the washing instructions - Do not allow the slide to dry out - Use only fresh sera - Check correct filter / objective



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