



EA MLA Signatory
Český institut pro akreditaci, o.p.s.
Olšanská 54/3, 130 00 Praha 3

issues

according to section 16 of Act No. 22/1997 Coll., on technical requirements for products, as amended

CERTIFICATE OF ACCREDITATION

No. 33/2018

Laboratoře Mikrochem a.s.
with registered office Nezvalova 984/2, Hodolany, 779 00 Olomouc, Company Registration
No. 60777907

to the Medical laboratory No. 8062
Mikrochem Laboratories

Scope of accreditation:

Laboratory diagnostics in the field of medical microbiology, allergology, and clinical immunology and primary sampling to the extent as specified in the appendix to this Certificate.

This Certificate of Accreditation is a proof of Accreditation issued on the basis of assessment of fulfillment of the accreditation criteria in accordance with

ČSN EN ISO 15189:2013

In its activities performed within the scope and for the period of validity of this Certificate, the Body is entitled to refer to this Certificate, provided that the accreditation is not suspended and the Body meets the specified accreditation requirements in accordance with the relevant regulations applicable to the activity of an accredited Conformity Assessment Body.

This Certificate of Accreditation replaces, to the full extent, Certificate No.: 613/2016 of 26. 10. 2016, or any administrative acts building upon it.

The Certificate of Accreditation is valid until: **26. 10. 2021**

Prague: 25. 1. 2018



Jiří Růžička
Director
Czech Accreditation Institute
Public Service Company

Accredited entity according to ČSN EN ISO 15189:2013:

Laboratoře Mikrochem a.s.
Mikrochem Laboratories
Nezvalova 984/2, Hodolany, 779 00 Olomouc

Medical laboratory locations:

- | | |
|---------------------------------|---|
| 1. Olomouc | Nezvalova 984/2, 779 00 Olomouc |
| 2. Přerov | Čechova 8, 750 02 Přerov |
| 3. Šumperk | Nerudova 34, 787 01 Šumperk |
| 4. Valašské Meziříčí | Vsetínská 854, 757 01 Valašské Meziříčí |
| 5. Šumperk Sampling Site | Dr. E. Beneše 2871/5, 787 01 Šumperk |

1. Olomouc

Examinations:

Ordinal number	Examination procedure name	Examination procedure identification	Examined object
802 - Medical microbiology			
1.	Quantitative examination of urine by culture method (manually and on an automatic analyzer)	SOP 01/1	Urine
2.	Examination of rectal swab by culture, microscopic and biochemical method	SOP 02/1	Rectal swab
3.	Examination of material from upper respiratory tract by culture method	SOP 03/1	Nasal, tonsillar, nasopharyngeal, and laryngeal swab
4.	Examination of material from lower respiratory tract by culture and microscopy	SOP 04/1	Sputum, endotracheal aspirate, extracted material, flush, BAL
5.	Examination of material from urogenital tract including <i>Neisseria gonorrhoeae</i> , <i>Ureaplasma spp.</i> and <i>Mycoplasma hominis</i> by culture method	SOP 05/1	Vulval, vaginal, cervical, urethral, and rectal swab
6.	Examination of clinical material by culture and microscopy	SOP 06/1	Swabs and smears of eyes, ears, mucous membrane and skin lesions, pieces of organs, pus, punctate and other materials, cannulas, drains, catheters, etc.

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Ordinal number	Examination procedure name	Examination procedure identification	Examined object
7.	Determination of sensitivity of microorganisms to antibiotics by disk diffusion test	SOP 07	Isolated bacterial cultures
8.	Identification of microorganisms by microscopic method, simple identification tests, biochemical tests and by agglutination	SOP 08	Isolated bacterial cultures
9.	Quantitative determination of DNA CMV by real-time PCR method	SOP 13	Incoagulable human blood with EDTA anticoagulant, CSF, urine, bronchoalveolar lavage, amniotic fluid
10.	Determination of antibodies to Tick-borne Encephalitis virus (IgM, IgG) by ELISA method (manually and on an automatic analyzer)	SOP 14	Serum
11.	Reserved		
12.	Determination of antibodies to CMV (IgM, IgG) by ELISA method (manually and on an automatic analyzer)	SOP 16	Serum
13.	Determination of antibodies to <i>Borrelia afzelii</i> (IgM, IgG), <i>Borrelia garinii</i> (IgM, IgG), <i>Borrelia burgdorferi</i> sensu lato (IgM, IgG) by Western blot method	SOP 17	Serum, punctate
14.	Determination of non-specific and specific antibodies to <i>Treponema pallidum</i> by agglutination (TPHA, RRR)	SOP 18	Serum
15.-17.	Reserved		



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Ordinal number	Examination procedure name	Examination procedure identification	Examined object
18.	Determination of IgA, IgG antibodies to <i>Chlamydia trachomatis</i> , IgM, IgA, IgG antibodies to <i>Chlamydia pneumoniae</i> by ELISA method (manually and on an automatic analyzer)	SOP 22	Serum
19.	Reserved		
20.	Determination of IgM, IgG antibodies to <i>Borrelia burgdorferi</i> sensu lato by ELISA method using an automatic analyzer	SOP 24	Serum, cerebrospinal fluid, punctate
21.	Determination of <i>Giardia intestinalis</i> , <i>Entamoeba histolytica</i> by ELISA method	SOP 26	Stool
22.	Determination of antibodies to <i>Toxoplasma gondii</i> by CFR (complement fixation reaction) method, (specific antibodies)	SOP 27	Serum
23.	Determination of antibodies to <i>Chlamydia sp.</i> , influenza virus A, B, adenoviruses, RS virus, CMV, HSV, VZV and Tick-borne Encephalitis virus by CFR (complement fixation reaction) method, (specific antibodies)	SOP 28	Serum
24.	Determination of IgA and IgG antibodies to <i>Helicobacter pylori</i> by ELISA method	SOP 29	Serum
25.- 28.	Reserved		



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Ordinal number	Examination procedure name	Examination procedure identification	Examined object
29.	Determination of IgE, IgA antibodies to <i>Toxoplasma gondii</i> by ELISA method	SOP 35	Serum
30.	Reserved		
31.	Determination of IgG antibodies to <i>Toxocara canis</i> by ELISA method	SOP 37	Serum
32.	Parasitological examination of stool by microscopy by Faust's flotation method	SOP 38	Stool
33.	Parasitological examination of stool by microscopy by Kato Thick Smear method	SOP 39	Stool
34.	Reserved		
35.	Examination for enterobiasis and taeniasis by Graham imprint method	SOP 41	Slide with lepex
36.- 38.	Reserved		
39.	Determination of hepatitis B virus antigens (HBsAg, HBeAg) and antibodies to hepatitis B virus antigens (anti -HBs, anti -Hbe, anti HBc, IgM anti-Hbc), confirmation of HBsAg antigen, antibodies to hepatitis A virus (IgM, IgG), antibodies to hepatitis C virus (anti-HCV) by chemiluminescence method (CMIA) on an automatic analyzer	SOP 48a	Serum



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Ordinal number	Examination procedure name	Examination procedure identification	Examined object
40.	Determination of IgM and IgG antibodies to <i>Toxoplasma gondii</i> by chemiluminescence method (CMIA) on an automatic analyzer	SOP 48b	Serum
41.	Determination of IgM and IgG antibodies to <i>Toxoplasma gondii</i> by chemiluminescence method (CMIA) on an automatic analyzer	SOP 48c	Serum
42.	Determination of HIV 1,2 Ag/Ab combo by chemiluminescence method (CMIA) on an automatic analyzer	SOP 48d	Serum
813 - Allergology and Immunology Laboratory			
1.	Determination of of anti-nuclear antibodies (ANA) anti-neutrophil cytoplasmic antibodies (ANCA), anti-double stranded DNA antibodies (ds DNA), anti-endomysial antibodies (EMA) by indirect immunofluorescence method	SOP 19	Serum
2.	Determination of proteins ASO, RF, CRP, IgG, IgA, IgM, C3, C4 by nephelometry and determination of total IgE by turbidimetry on an automatic analyzer	SOP 20	Serum
3.	Determination of CD3, CD4, CD8, CD19, CD16+56 cell surface markers by flow cytometry method	SOP 21	Serum



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Ordinal number	Examination procedure name	Examination procedure identification	Examined object
4.	Determination of autoantibodies to extractable nuclear antigens (ENA PROFIL), double stranded DNA (ds DNA) by ELISA method	SOP 23	Serum
5.	Determination of antibodies to gliadin, cow's milk and tissue transglutaminase by ELISA method	SOP 31	Serum

Primary sampling:

Ordinal number	Primary sampling procedure name	Primary sampling procedure identification	Primary sample
401.	Sampling of biological materials	SOP 42a	HCD swabs
402.	Sampling of biological materials	SOP 42b	Rectal swabs and lepex
403.	Venous blood sampling	SOP 43	Venous blood



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2. Přerov

Examinations:

Ordinal number	Examination procedure name	Examination procedure identification	Examined object
802 - Medical microbiology			
101.	Quantitative examination of urine by culture method	SOP 01/2	Urine
102.	Examination of rectal swab by culture, microscopic and biochemical method	SOP 02/2	Rectal swab
103.	Examination of material from upper respiratory tract by culture method	SOP 03/2	Nasal, tonsillar, nasopharyngeal, and laryngeal swab
104.	Examination of material from lower respiratory tract by culture and microscopy	SOP 04/2	Sputum, endotracheal aspirate, extracted material, flush, BAL
105.	Examination of material from urogenital tract including <i>Neisseria gonorrhoeae</i> , <i>Ureaplasma spp.</i> and <i>Mycoplasma hominis</i> by culture method	SOP 05/2	Vulval, vaginal, cervical, urethral, and rectal swab
106.	Examination of clinical material by culture and microscopy	SOP 06/2	Swabs and smears of eyes, ears, mucous membrane and skin lesions, pieces of organs, pus, punctate and other materials, cannulas, drains, catheters, etc.
107.	Determination of sensitivity of microorganisms to antibiotics by disk diffusion test	SOP 07	Isolated bacterial cultures
108.	Identification of microorganisms by microscopic method, simple identification tests, biochemical tests and by agglutination	SOP 08	Isolated bacterial cultures

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Ordinal number	Examination procedure name	Examination procedure identification	Examined object
109.	Detection of high risk human papillomavirus DNA by molecular hybridization of nucleic acids	SOP 11	Cervical swab and cervical biopsy
110.	Detection of <i>Chlamydia trachomatis</i> and <i>Neisseria gonorrhoeae</i> DNA by molecular hybridization of nucleic acids	SOP 12	Cervical, urethral and conjunctival sac swab
111.	Determination of hepatitis C virus antigen and antibodies by ELISA method	SOP 15	Serum
112.	Determination of non-specific and specific antibodies to <i>Treponema pallidum</i> by agglutination (TPHA, RRR)	SOP 18	Serum
113.	Reserved		
114.	Determination of HBs antigen and confirmation test for hepatitis B by ELISA method	SOP 44	Serum
115. - 200.	Reserved		

Primary sampling:

Ordinal number	Primary sampling procedure name	Primary sampling procedure identification	Primary sample
501.	Sampling of biological materials	SOP 42a	HCD swabs
502.	Sampling of biological materials	SOP 42b	Rectal swabs and leplex
503.	Venous blood sampling	SOP 43	Venous blood



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3. Šumperk

Examinations:

Ordinal number	Examination procedure name	Examination procedure identification	Examined object
802 - Medical microbiology			
201.	Quantitative examination of urine by culture method	SOP 01/3	Urine
202.	Examination of rectal swab by culture, microscopic and biochemical method	SOP 02/3	Rectal swab
203.	Examination of material from upper respiratory tract by culture method	SOP 03/3	Nasal, tonsillar, nasopharyngeal, and laryngeal swab
204.	Examination of material from lower respiratory tract by culture and microscopy	SOP 04/3	Sputum, endotracheal aspirate, extracted material, flush, BAL
205.	Examination of material from urogenital tract including <i>Neisseria gonorrhoeae</i> , <i>Ureaplasma spp.</i> and <i>Mycoplasma hominis</i> by culture method	SOP 05/3	Vulval, vaginal, cervical, urethral, and rectal swab
206.	Examination of clinical material by culture and microscopy	SOP 06/3	Swabs and smears of eyes, ears, mucous membrane and skin lesions, pieces of organs, pus, punctate and other materials, cannulas, drains, catheters, etc.
207.	Determination of sensitivity of microorganisms to antibiotics by disk diffusion test	SOP 07	Isolated bacterial cultures
208.	Identification of microorganisms by microscopic method, simple identification tests, biochemical tests and by agglutination	SOP 08	Isolated bacterial cultures



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Ordinal number	Examination procedure name	Examination procedure identification	Examined object
209.	Detection of mycobacteria in sputum and other clinical materials by microscopic and culture method	SOP 09	Induced sputum, BAL, stomach lavage, urine, cerebrospinal fluid, pleural exudate, punctates, smears and swabs from fistulae, pus processes and wounds, menstrual blood, stool, bioptic and section material, laryngeal swab
210.	Reserved		
211.	Determination of antibodies to <i>Borrelia afzelii</i> (IgM, IgG), <i>Borrelia garinii</i> (IgM, IgG), <i>Borrelia burgdorferi</i> sensu lato (IgM, IgG) by Western blot method	SOP 17	Serum
212.	Reserved		
213.	Determination of IgM, IgG antibodies to <i>Borrelia afzelii</i> , <i>Borrelia garinii</i> by ELISA method	SOP 25	Serum
214.	Parasitological examination of stool by microscopy by Faust's flotation method	SOP 38	Stool
215.	Parasitological examination of stool by microscopy by Kato Thick Smear method	SOP 39	Stool
216.	Examination for enterobiasis and taeniasis by Graham imprint method	SOP 41	Slide with lepex
217.*	Testing of efficiency of sterilizers using biological indicators and chemical tests	SOP 47	Steam, hot air and formaldehyde sterilizers

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Ordinal number	Examination procedure name	Examination procedure identification	Examined object
218.	Determination of antibodies to CMV (IgM, IgG, avidity IgG) and EBV (EBNA IgG, VCA IgM, IgG, EA-D IgM, IgG) by ELISA method on an analyzer	SOP 49	Serum
219.	Determination of IgG, IgA, IgM antibodies to <i>Chlamydia pneumoniae</i> by ELISA method on an automatic analyzer	SOP 50	Serum

* Test partially carried out outside the Mikrochem Laboratories workplaces.



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4. Valašské Meziříčí

Examinations:

Ordinal number	Examination procedure name	Examination procedure identification	Examined object
802 - Medical microbiology			
301.	Quantitative examination of urine by culture method	SOP 01/4	Urine
302.	Examination of rectal swab by culture, microscopic and biochemical method	SOP 02/4	Rectal swab
303.	Examination of material from upper respiratory tract by culture method	SOP 03/4	Nasal, tonsillar, nasopharyngeal, and laryngeal swab
304.	Examination of material from lower respiratory tract by culture and microscopy	SOP 04/4	Sputum, endotracheal aspirate, extracted material, flush, BAL
305.	Examination of material from urogenital tract including <i>Neisseria gonorrhoeae</i> , <i>Ureaplasma spp.</i> and <i>Mycoplasma hominis</i> by culture method	SOP 05/4	Vulval, vaginal, cervical, urethral, and rectal swab
306.	Examination of clinical material by culture and microscopy	SOP 06/4	Swabs and smears of eyes, ears, mucous membrane and skin lesions, pieces of organs, pus, punctate and other materials, cannulas, drains, catheters, etc.
307.	Determination of sensitivity of microorganisms to antibiotics by disk diffusion test	SOP 07	Isolated bacterial cultures
308.	Identification of microorganisms by microscopic method, simple identification tests, biochemical tests and by agglutination	SOP 08	Isolated bacterial cultures

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Ordinal number	Examination procedure name	Examination procedure identification	Examined object
309.	Reserved		
310.	Determination of non-specific and specific antibodies to <i>Treponema pallidum</i> by agglutination (TPHA, RRR)	SOP 18	Serum



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5. Šumperk Sampling Site

Primary sampling:

Ordinal number	Primary sampling procedure name	Primary sampling procedure identification	Primary sample
601.	Sampling of biological materials	SOP 42a	HCD swabs
602.	Sampling of biological materials	SOP 42b	Rectal swabs and leplex
603.	Venous blood sampling	SOP 43	Venous blood



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