



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. 578/2019

Zdravotní ústav se sídlem v Ostravě
with registered office Partyzánské náměstí 2633/7, Moravská Ostrava, 702 00 Ostrava,
Company Registration No. 71009396

to the Testing Laboratory No. 1554
Centre of Clinical Laboratories

Scope of accreditation:

Detection of mycobacteria in water; testing in the field of genetic toxicology; determination of efficacy of disinfectants 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/IEC 17025:2018

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.: 532/2018 of 9. 10. 2018, or any administrative acts building upon it.

The Certificate of Accreditation is valid until: **28. 2. 2022**

Prague: 6. 11. 2019



Jiří Růžička
Director
Czech Accreditation Institute
Public Service Company



Accredited entity according to ČSN EN ISO/IEC 17025:2018:

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Centre of Clinical Laboratories
Partyzánské náměstí 2633/7, Moravská Ostrava, 702 00 Ostrava

Testing laboratory locations:

1. **Location 1 – Ostrava** Partyzánské náměstí 2633/7, Moravská Ostrava, 702 00 Ostrava
2. **Location 5 – Vsetín** 4. května 287, 755 01 Vsetín

The Laboratory has a flexible scope of accreditation permitted as detailed in the Annex.

Updated list of activities provided within the flexible scope of accreditation is available in the laboratory from the CCL Manager.

The Laboratory provides expert opinions and interprets test results.

Tests:

Ordinal number ¹	Test procedure/ method name	Test procedure/ method identification ²	Tested object
1. ⁽¹⁾	Determination of disinfecting efficiency by suspension micromethod	SOP 3030 (Čs. epidemiologie, mikrobiologie a imunologie, 37, 1988, 2: 97-104)	Disinfectant
2. ⁽¹⁾	Determination of atypical mycobacteria by culture method	SOP 4015 (Decree No. 252/2004 Coll., Annex No. III as amended)	Cold drinking water, hot water for personal hygiene produced from drinking water, surface and service water, mine water and hot water for personal hygiene produced from these types of water, waste water
3. ⁽⁵⁾	Cytogenetic analysis of human peripheral lymphocytes – conventional technique	SOP 10001 (Acta hygienica, epidemiologica et microbiologica No. 1/2007 SZÚ Praha)	Blood
4. ⁽¹⁾	Quantitative suspension and/or carrier test for the evaluation of mycobactericidal activity of chemical disinfectants by microbiological method - phase 2/step 1 and phase 2/step 2	SOP 4016 (ČSN EN 14348, ČSN EN 14563)	Disinfectant



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Ordinal number ¹	Test procedure/ method name	Test procedure/ method identification ²	Tested object
5. ⁽¹⁾	Quantitative suspension test for the evaluation of virucidal activity of chemical disinfectants by microbiological method - phase 2/step 1	SOP 1901 (ČSN EN 14476+A1, ČSN EN 14675, DVV RKI/*)	Disinfectant
6. ⁽¹⁾	Quantitative suspension test for the evaluation of sporicidal activity of chemical disinfectants by microbiological method - phase 2/step 1	SOP 3036 (ČSN EN 13704)	Disinfectant
7. ⁽¹⁾	Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants by microbiological method - phase 2/step 1	SOP 3037 (ČSN EN 13727+A2)	Disinfectant
8. ⁽¹⁾	Quantitative carrier test for the evaluation of bactericidal activity of chemical disinfectants by microbiological method - phase 2/step 2	SOP 3038 (ČSN EN 14561)	Disinfectant
9. ⁽¹⁾	Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity of chemical disinfectants by microbiological method - phase 2/step 1	SOP 3039 (ČSN EN 13624)	Disinfectant
10. ⁽¹⁾	Quantitative non-porous surface test for the evaluation of bactericidal and/or fungicidal activity of chemical disinfectants by microbiological method - phase 2/step 2	SOP 3040 (ČSN EN 13697)	Disinfectant
11. ⁽¹⁾	Evaluation of bactericidal and yeasticidal activity of chemical disinfectants on non-porous surfaces with mechanical action employing wipes – phase 2/step 2	SOP 3041 (ČSN EN 16615)	Disinfectant



**The Appendix is an integral part of
Certificate of Accreditation No. 578/2019 of 06/11/2019**

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Ordinal number ¹	Test procedure/ method name	Test procedure/ method identification ²	Tested object
12. ⁽¹⁾	Determination of virucidal activity of disinfectants used for surfaces – phase 2 /step 2 (Quantitative non-porous surface test)	SOP 1902 (EN 16777)	Disinfectant
13. ⁽¹⁾	Determination of virucidal activity of disinfectants used for instruments – phase 2 /step 2 (Quantitative carrier test)	SOP 1903 (EN 17111)	Disinfectant

¹ Asterisk at the ordinal number identifies the tests, which the Laboratory is qualified to carry out outside the permanent laboratory premises.

² If the document identifying the test procedure is dated, only these specific procedures are used. If the document identifying the test procedure is not dated, the latest edition of the specified procedure is used (including any changes).

Explanations:

SOP – Standard Operating Procedure

Superscript at the test ordinal number identifies the CCL location carrying out the test.

⁽¹⁾ - Location 1 - Ostrava (includes the Mycobacteria Diagnostics Laboratory;
Disinfectant Efficacy Inspection Laboratory;
Disinfectant Virucidal Activity Testing Laboratory)

⁽⁵⁾ - Location 5 - Vsetín (includes the Genetic Toxicology Laboratory Vsetín)

/*DVV RKI - Guideline¹ of „Deutsche Vereinigung zur Bekämpfung der Viruskrankheiten e.V.“ (DVV; German Association for the Control of Virus Diseases)² and Robert Koch Institute (RKI; German Federal Health Authority) for testing the virucidal efficacy of chemical disinfectants in the human medical Area. Version of 1 August 2008

Annex:

Flexible scope of accreditation

Ordinal numbers of tests
1, 5

The Laboratory is allowed to modify the test methods listed in the Annex within the specified scope of accreditation provided the measuring principle is observed.

The flexible approach to the scope of accreditation cannot be applied to the tests not included in the Annex.

