



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. 617/2023

Nemocnice Na Homolce
with registered office **Roentgenova 37/2, 150 30 Praha 5, Motol,**
Company Registration No. **00023884**

for the Medical Laboratory No. **8160**
Department of Clinical Microbiology and Antibiotic Surveillance (KMAS)

Scope of accreditation:

Complex diagnostics in the field of medical microbiology 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

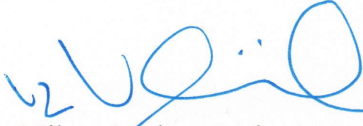
In its activities performed within the scope and for the period of validity of this Certificate, the Conformity Assessment Body is entitled to refer to this Certificate, provided that the accreditation is not suspended and the Accredited Body meets the specified accreditation requirements in accordance 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.: 360/2022 of 14. 7. 2022, or any administrative acts building upon it.

The Certificate of Accreditation is valid until: **22. 1. 2025**

Prague: 15. 11. 2023




Milena Lochmanová
Director of the Department
of Medical Laboratories
Czech Accreditation Institute

**The Appendix is an integral part of
Certificate of Accreditation No. 617/2023 of 15/11/2023**

Accredited entity according to ČSN EN ISO 15189:2013:

Nemocnice na Homolce

CAB Number 8160, Department of Clinical Microbiology and Antibiotic Surveillance (KMAS)
Roentgenova 3712, 150 00 Praha 5, Motol

The Laboratory applies a flexible approach to the scope of accreditation.

*The current "List of activities within the flexible scope" is available on the website
<https://www.homolka.cz/media/2023/10/kmas-seznam-cinnosti-v-ramci-flexibilniho-rozsahu-akreditace.pdf>*

<https://www.homolka.cz/media/2024/02/KMAS-List-of-activities-within-the-flexible-scope-of-accreditation.pdf>

Examinations:

Ordinal Number	Analyte/parameter/diagnostics	Principle of examination	Identification of method procedure/ equipment	Examined material	Degrees of freedom ¹
802 – Medical Microbiology					
1.	Microbiological examination of upper respiratory tract	Aerobic cultivation	Published procedure	Clinical material	A, B, D
2.	Microbiological examination of lower respiratory tract	Microscopy; Aerobic cultivation	Published procedure	Clinical material	A, B, D
3.	Microbiological examination of a rectal swab	Aerobic cultivation	Published procedure	Clinical material	A, B, D
4.	Quantitative microbiological examination of urine	Aerobic cultivation	Published procedure	Urine	A, B
5.	Microbiological examination of clinical material	Microscopy; Aerobic cultivation; Anaerobic cultivation	Published procedure	Clinical material	A, B, D
6.	Microbiological examination of primarily sterile body fluids	Microscopy; Aerobic cultivation; Anaerobic cultivation	Published procedure	Clinical material	A, B, D



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Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of method procedure/ equipment	Examined material	Degrees of freedom ¹
7.	Microbiological examination of blood and primarily sterile body fluids	Aerobic cultivation; Anaerobic cultivation (automatic)	Commercial procedure; Published procedure	Clinical material	A, B, D
8.	Microbiological examination of foreign bodies	Aerobic cultivation Anaerobic cultivation	Published procedure	Foreign bodies	A, B, D
9.	Qualitative examination of the sensitivity of microorganism	Diffusion disk test	Published procedure	Bacterial culture	A, B
10.	Quantitative examination of the sensitivity of microorganism	Microdilution method; E-test	Commercial procedure; Published procedure	Bacterial culture	A, B
11.	Identification of microorganism	Mass spectrometry	Commercial procedure	Bacterial culture, yeast culture, filamentous fungus	A, B
12.	Reagin test (RPR)	Agglutination	Commercial procedure	Serum, plasma	A, B
13.	Antigens of infectious agents	Immunoassay with luminometric detection	Commercial procedure	Serum, plasma	A, B, C
14.	Antibodies against infectious agent	Immunoassay with luminometric detection	Commercial procedure	Serum, plasma	A, B, C
15.	HIV markers	Immunoassay with luminometric detection	Commercial procedure	Serum, plasma	A, B



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Explanatory notes:

¹ Established degrees of freedom according to MPA 00-09-...:

A – Flexibility concerning the documented examination/ sample collection procedure

B – Flexibility concerning the technique

C – Flexibility concerning the analytes / parameters

D – Flexibility concerning the examined material

If no degree of freedom is specified, the laboratory cannot apply a flexible approach to the scope of accreditation for this examination.

