



EA MLA Signatory
Český institut pro akreditaci, o.p.s.
Hájkova 2747/22, Žižkov, 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. 144/2025

Bioinova, a.s.
with registered office Vídeňská 1083, 142 00 Praha - Krč,
Company Registration No. 28452682

for the Medical Laboratory No. 8336
Molecular Diagnostics Department

Scope of accreditation:

Examination in the field of clinical 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 ed. 3:2023

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.

The Certificate of Accreditation is valid until: 25/03/2028

Prague: 25/03/2025



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

Accredited entity according to ČSN EN ISO 15189 ed. 3:2023:

Bioinova, a.s.
CAB Number 8336, Molecular Diagnostics Department
Videňská 1083, 142 00 Praha 4-Krč

Examinations:

Ordinal Number	Analyte/parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
802 – Medical Microbiology					
1.	Detection of nucleic acids of infectious agents	DNA flow technologie	BI-L-SOPM-04, version 02; BI-L-SOPM-05, version 02; BI-L-SOPM-06, version 02; BI-L-SOPM-07, version 02; BI-L-SOPM-08, version 02; HybriSpot 12; PCR cycler ESCO Aeris; PCR cycler qTower3 G	Swab/smear from nasopharynx, tonsils, nose, throat, urethra, cervix, vagina, rectum, blister or lesion, eye, ear; urine, cerebrospinal fluid, blood, bronchoalveolar lavage, sputum, aspirate, stool, joint puncture, amniotic fluid, DNA, hemoculture, microbial culture, tissue, surgical material and surgical implants	-
2.	Examination of susceptibility / resistance genes mutations	DNA flow technologie	BI-L-SOPM-04, version 02; BI-L-SOPM-05, version 02; BI-L-SOPM-06, version 02; BI-L-SOPM-07, version 02; BI-L-SOPM-08, version 02; HybriSpot 12; PCR cycler ESCO Aeris; PCR cycler qTower3 G	Swab/smear from nasopharynx, tonsils, nose, throat, urethra, cervix, vagina, rectum, blister or lesion, eye, ear; urine, cerebrospinal fluid, blood, bronchoalveolar lavage, sputum, aspirate, stool, joint puncture, amniotic fluid, DNA, hemoculture, microbial culture, tissue, surgical material and surgical implants	-



**The Appendix is an integral part of
Certificate of Accreditation No. 144/2025 of 25/03/2025**

Accredited entity according to ČSN EN ISO 15189 ed. 3:2023:

Bioinova, a.s.
CAB Number 8336, Molecular Diagnostics Department
Videňská 1083, 142 00 Praha 4-Krč

Specification of the scope of accreditation:

Field Nr. / Ordinal Number	Detailed information on activities within the scope of accreditation
802/1	DNA: HPV (high-risk HPV 16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 53, 56, 58, 59, 66, 68, 73 and 82; low-risk HPV 6, 11, 40, 42, 43, 44, 54, 55, 61, 62, 67, 69, 70, 71, 72, 81 and 84), Adenovirus (Type 1, Type 2, Type 3, Type 4, Type 6, Type 7, Type 8, Type 11, Type 12, Type 16, Type 18, Type 21, Type 31, Type 34), Bocavirus, <i>Bordetella pertussis</i>, <i>Bordetella parapertussis</i>, <i>Mycoplasma pneumoniae</i>, coagulase-negative staphylococci, <i>Staphylococcus aureus</i>, <i>Streptococcus spp.</i>, <i>Streptococcus pneumoniae</i>, <i>Streptococcus agalactiae</i>, <i>Streptococcus pyogenes</i>, <i>Listeria monocytogenes</i>, <i>Enterococcus spp.</i>, <i>Pseudomonas aeruginosa</i>, <i>Acinetobacter baumannii</i>, <i>Neisseria meningitidis</i>, <i>Stenotrophomonas maltophilia</i>, <i>Escherichia coli</i>, <i>Klebsiella pneumoniae</i>, <i>Serratia marcescens</i>, species of the family <i>Enterobacteriaceae</i> and <i>Proteus/Morganella spp.</i>, <i>Candida albicans</i> and <i>Candida spp.</i> RNA: Influenza virus (influenza type B, influenza type A: subtype H3 and subtype H1N1), Coronavirus (229E, HKU-1, NL63, OC43, SARS-CoV-2), Metapneumovirus, Parainfluenza virus (Type 1, Type 2, Type 3, Type 4), Respiratory Syncytial Virus (subtype A and subtype B), Rhinovirus, Enterovirus (EV-A, EV-B, EV-D)
802/2	Resistance genes: Aminoglycosides (aac (6')-Ib, armA, rmtB, rmtC, rmtF), β-lactam antibiotics (blaCMY, blaDHA, sim, mecA, mecC), Cephalosporins (blaCTX, blaSHV-SK, blaSHV-S, blaSHV), Carbapenems (gim, imp_like, kpc, ndm, nmc/imi, oxa23_like, oxa24_like, oxa48_like, oxa51_like, oxa58_like, sme, spm, vim), Cephalosporins / Carbapenems (ges), Vancomycin (vanA, vanB), Colistin (mcr1, mcr2), Quinolones (gyrE-S83L, gyrE-S83L-D87G, gyrE-S83L-D87G, parES80I, gyrE-S83L-D87N, gyrE-S83W-D87G, parE-S80I, gyrP-T83I, gyrP-T83I-D87G, gyrP-T83I-D87N, qnrA, qnrB, qnrS), Fenicol / quinolones (oqxA, oqxB), Chloramphenicol (catB3), Macrolides (ermA, ermB, ermC, mefA/E, msrA), Macrolides / Lincosamides / Streptogramin (cfr), Sulfonamides (sul1, sul2, sul3)

Explanatory notes:

- ¹ The laboratory does not apply a flexible approach to the scope of accreditation.

"This document is an appendix to the certificate of accreditation. In case of any discrepancies between the English and Czech versions, the Czech version shall prevail both for the certificate appendix and the certificate itself."

