

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

Fakultní nemocnice Olomouc

CAB Number 8324, Laboratories of the Department of Clinical and Molecular Pathology
Hněvotínská 976/3, 775 15 Olomouc

Medical laboratory locations:

1. **ISH laboratory** Hněvotínská 976/3, 779 00 Olomouc
2. **Laboratory of immunohistochemistry** Hněvotínská 976/3, 779 00 Olomouc
3. **Laboratory of molecular medicine** Hněvotínská 1333/5, 779 00 Olomouc

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.fnol.cz/kliniky-ustavy-oddeleni/ustav-klinicke-a-molekularni-patologie>*

1. ISH laboratory

Examinations:

Ordinal Number	Analyte/parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
823 - Pathology Laboratory					
1.	Examination of HER2/neu cytogenetic changes	<i>In situ</i> hybridization	Commercial procedure	Tissues, cells	A, B

2. Laboratory of immunohistochemistry

Examinations:

Ordinal Number	Analyte/parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
823 - Pathology Laboratory					
1.	Immunohistochemical and immunocytochemical examination of antigens	Microscopy	Commercial procedure; Published procedure	Tissues, cells	A, B, C



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3. Laboratory of molecular medicine

Examinations:

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
823 - Pathology Laboratory					
1.	Examination of histological and cytological samples	Fluorescence <i>in situ</i> hybridization	Published procedure	Tissues, cells	A, B, C
2.	Examination of somatic genome variants	Real-Time PCR	Commercial procedure	Biological material containing human tumor DNA/RNA	A, B, C
3.	Examination of somatic genome variants [#]	MPS	Commercial procedure; In-house procedure	Biological material containing human tumor DNA/RNA	A, B, C

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.

[#] MPS sequencing is performed as an external provided service by a provider within the same legal entity

Real-Time PCR Polymerase chain reaction in real time

MPS Massively parallel sequencing (NGS)

"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."

