

List of activities within the flexible scope of accreditation

Accredited Body: Bioptická laboratoř s. r. o.
CAB Name: Bioptická laboratoř s. r. o.
CAB Number: 8027
Certificate of Accreditation No.: 635/2025
Field of Accreditation: Medical laboratory - ČSN EN ISO 15189 ed. 3:2023
Updated: 27. 2. 2026

1. **Biopsy Section – Section B** Mikulášské nám. 628/4, 326 00 Plzeň,
 Mikulášské nám. 589/5, 326 00 Plzeň
 Rejskova 614/8, 326 00 Plzeň
 Rejskova 855/10, 326 00 Plzeň

Examinations:

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
823 - Pathology Laboratory					
1.	Histological examination and diagnostics	Microscopy	SOP-01, v. 15	Tissues	A, B
2.	Histological examination and diagnostics	Microscopy	SOP-02, v. 15	Hard tissues	A, B
3.	Cytological examinations and diagnostics	Microscopy	SOP-03, v. 17	Cells from puncture of tissue, body fluids and pathological cavity content	A, B
4.	Immunohistochemical and immunocytochemical examination of antigens	Microscopy	SOP-05, v. 15; N-B-32, v. 32; P-B-17, v. 11	Tissues, cells	A, B, C
5.	Examination of histological and cytological samples	<i>In situ</i> hybridization	SOP-28, v. 1; P-B-23, v. 1	Tissues, cells	A, B, C

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Specification of the scope of accreditation:

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823/4	<p>Antibodies: Actin, (Muscle); Smooth Muscle Actin; Anti-Human Cytokeratin; α-1-Fetoprotein (AFP); Anti- ALK 1, CONFIRM; Anti-Human P 504S; Androgen Receptor; BCL2 Oncoprotein; BCL6 Protein; Epithelial Antigen; Beta-catenin; Anti-Human Kappa Light Chains; Anti-Human Lambda Light Chains; BOB.1 (SP92) Rabbit Monoclonal Antibody; C4d; Calcitonin; Caldesmon; Calponin; Calretinin, CONFIRM; Anti-Cytokeratin CAM 5,2; CD 1a; CD 10; CD 105, Endoglin; CD 117, c-kit; CD 13; CD 138; CD14; CD 15, CONFIRM; CD 16; CD 163; CD 2; CD20 , CONFIRM; CD 21; Anti-Human CD 23; CD 25; CD 3; CD 30; Endothelial Cell; CD 33; CD 34, class II; Purified Mouse Anti-Human CD34; CD 35; Anti-Human CD4; CD 42b (GPIb); CD 43; CD 5; CD 56(NCAM); CD 57; CD 61; CD 68; CD 7; CD 79a; CD 8; CD 99, CONFIRM; CDX2; Carcinoembryonie Antigen (CEA); c-erbB Oncoprotein (internal domain); Cytokeratin 10/13; Cytokeratin 14; Cytokeratin 17; Cytokeratin 18; Cytokeratin 19; Cytokeratin 20; Cytokeratin 5; Cytokeratin 5/6; Cytokeratin 7; Cytokeratin (35betaH11); Cytokeratin; Cytomegalovirus; Follicular Dendritic Cell; COX-2; Cyclin A; Anti-Human Cyclin D1; Cyclin D1/bcl1; Monoclonal Mouse Anti-Human Podoplanin; Desmin; Dog – 1; Epstein-Barr Virus, LMP; E-cadherin; Epidermal Growth Factor Receptor (EGFR); Epithelial Membrane Antigen (EMA); Estrogen Receptor α; Factor VIII Related Antigen; Factor XIIIa; Galectin 3; Gastrin; GCDFP-15; Glial Fibrillary Acidit Protein; Glycophorin A; Human Chorionic Gonadotropin; Leukaemia, Hairy Cell; HER-2/neu; HercepTestTM; HHV 8 (Human Herpes Virus Type 8); Melanosome; Human Placental Lactogel (hPL); HSA (Hepatocyte Specific Antigen); Chromogranin A; IgA (Immunoglobulin A); IgD (Immunoglobulin D); IgG (Immunoglobulin G); IgM (Immunoglobulin M); mouse anti-human IgG 4; Inhibin ; Anti-Insulin; Cytokeratin HMW; Anti- LCT ; Laminin; Lin28; Lysozyme; Mast Cell Tryptase; MCM3 Protein; Melan-A; Mammaglobin; Anti-Mitochondrial Antigen; Ki-67 ; MITF (Microphthalmia Transcription Factor); MLH 1; Myeloperoxidase; MSH 2; MSH 6 ; MUC 2; MUC 5 AC; MUC 6; MyoD1; Myogenin; Myosin, Smooth Musle; Nanog; Neurofilament 200 kD; Neurofilament; Anti-Melanoma Associated Antigen; nm23 Protein; c-erbB Oncoprotein (external domain); Neuron Specific Enolase; OCT $\frac{3}{4}$; Oct-2; Cytokeratin OSCAR; p16 – Protein; p21WAF1; p 27 ; p53 Protein; p63 Protein; PSAP (Prostatic Acid Phosphatase); Parvalbumin (Alpha); PAX 5, CONFIRM; PAX 8; PD-1 (NAT105) Mouse Monoclonal Antibody; Perforin; Peripherin; CD 68; Anti-PLAG1; Placental Alkaline Phosphatase (PLAP); PMS2; Progesterone Receptor; Prostate Specific Antigen (PSA); S 100; SALL 4; Anti-SDHB; Serotonin; Anti-SOX 11; Anti-STAT5a antibody; Synaptophysin; CD45,Leucocyte Common Antigen; TdT Terminal Deoxynucleotidyl Transferase; TFE 3; Thyroglobulin; Thyroglobulin; Thyroid Peroxidase (TPO); TRAcP (Tartrate-Resistant Acid Phosphatase); Anti-Thyroid Transcription Faktor (TTF-1); Anti-Thyroid Transcription Faktor (TTF-1); Tyrosinase, CONFIRM; CD45RO; Vimentin; Wilms' Tumor 1 (WT 1) Protein; BG-8; anti-ERG; anti-Glypican 3; Napsin A; PIN-Cocktail (P5045 + p63); CD 123; Anti-Human Cytokeratin 10; GATA-3; Anti – glutamine synthetase; anti-INI-1; Mesothelin; anti-p120 catenin; P40; Anti – ATRX antibody; Anti-Clusterin α chain (human); Anti-Mucin monoclonal antibody M-GGMC-1; Anti – Bcl-2 antibody; cd k4 Monoclonal Antibody, Mouse; Recombinant Anti-PRAME antibody; Anti-Human IMP3; Anti-Human LMO2 Monoclonal Antibody; VEGF Receptor 2 (55B11) Rabbit mAb ; NUT (C52B1) Rabbit mAb; NKX3.1; Prostein (Synonyma antigenu P501S); anti-BRAF V600E Mouse Monoclonal Primary Antibody; Langerin Mouse Monoclonal Antibody; Anti-SOX 9 antibody; Brachyury, RMab; Claudin 1; MUM 1 protein; Anti – TIA-1; Anti – Arginase-1; Anti – Hemoglobin A; Anti – Pancreatic Amylase; Anti – Pancreatic Lipase; Mouse Monoclonal Antibody Parathyroid Hormone; α-1-Antitrypsin (AAT); Fli-1; GLUT-1; PDGFR alpha; SOX-10; Adrenocorticotropin (ACTH); Mouse anti-Claudin-5; Anti-Claudin 5; Anti - c- Myc antibody; E-</p>

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	<p>Cadherin (RM); Granzym B; Anti – Histone H3 antibody; MDM2; BAP1 (C-4) monoclonal antibody; CD 11c; Anti-Human CD15; CD 56 Rabbit Monoclonal Antibody; Anti - C Reactive Protein; Anti – HNF1B antibody produced in rabbit; Anti-Islet 1 antibody [1H9]; Anti – NKX6-1 antibody; Ani- LEF1 antibody; Anti-LYVE1 antibody - Lymphatic Vessel Marker; MCPyV large T-antigen Antibody; Nerve Growth Factor Receptor (NGFR); Olig2 Antibody; Anti-Smoothelin; TLE1 (M-101) monoclonal antibody; TrkA (12G8) Rabbit mAb; Collagen Type IV; anti-MUC1 Mouse Monoclonal Primary Antibody; Cytochrome P450 Aromatase Antibody; Phosphohistone H3 (PHH3); SATB2 (EP281) Rabbit Monoclonal Primary Antibody; Anti - SATB2 antibody; Anti-STAT6 antibody; Stat6 (S-20); Anti-serum amyloid A (AA); ERG; Anti-v-Myb + c-Myb antibody; Phospho-S6 Ribosomal Protein (Ser235/236); Prospero Homeobox 1 (PROX1) (C-Term) antibody; Anti – SDHA antibody; Anti-Somatostatin Receptor 2 antibody; Annexin A10; Anti FABP1; Anti - Hsp70 ,(Heath shock protein); Anti – Human IDH1 R132H; ROS1 (D4D6®) Rabbit mAb; SOX-2; Purified anti-human VEGFR-3 (FLT-4); Anti-Human C3c Complement/FITC; Anti-Human Fibrinogen/FITC; Anti-Human IgA/FITC; Anti-Human IgG/FITC; Anti-Human IgM/FITC; Anti-Hydrogen Potassium ATPase Beta antibody; MIST1 (6E8); Anti-Pepsinogen I antibody; Anti-RUNX3 antibody; Anti-FSH; Anti-GH – Growth Hormon; Anti-LH; Anti-Prolactin; Anti-TSH; Anti-CA6 antibody produced in rabbit; CAMTA1 antibody; Anti-CCNB3 antibody produced in rabbit; Anti-CD 64 antibody; Anti-DMRT1 antibody; Anti-FGF-23 (human); Anti-Neuronal Nuclei (NeuN); Anti-p 16 rabbitmonoclonal antibody; Anti-Human Plasma Cell; Stathmin (D1Y5A) Rabbit mAb; Fascin; FosB (5G4) Rabbit mAb; Tri-Methyl-Histone H3 (Lys27) Rabbit mAb; HMGA2 (D1A7) Rabbit mAb; Nkx2.2 transcription factor; PD-L1 (E1L3N®) XP® Rabbit mAb; PD-L2 (D7U8C) XP® Rabbit mAb; Anti-Human PTEN; Skp2 p45 (H-435); BCoR antibody (c 10); Anti-BCOR antibody produced in rabbit ; CD 71; Ezh2 (D2C9) XP® Rabbit mAb; Anti-Histone H3.3 G34W; INSM 1 (A-8); Anti – Histone H3 Antibody, K27M mutant; Anti-Epithelial Related Antigen (MOC-31); Pit-1 (D-7) monoclonal antibody; Anti-BRG1 Antibody; Anti- Trypsin Antibody; ICOS Monoclonal Antibody; CXCL13 Polyclonal Antibody; Telomerase (hEst2/TERT) Antibodies; MYF-5 Antibody; Uroplakin II Monoclonal Antibody; Mucin 4 (1G8); Anti-PHOX2B antibody - C-terminal; Myoglobin; Anti- HMGA1 antibody; Nestin (10c2) monoclonal antibody; PRDM10; Anti – PRKD1 antibody; CD246-ALKI; Monoclonal Mouse Anti-Human PD-L1; VENTANA PD-L1 (SP142) Assay; Purified Mouse Anti- PKA [RI]; Claudin 4 Monoclonal Antibody; PAX 7 antibody; Anti-Histone H3 (di methyl K27) antibody - ChIP Grade; NOR-1 Antibody; Anti-Steroidogenic Factor 1/SF-1 antibody; FOXL2 Antibody; SS18-SSX (E9X9V) XP® Rabbit mAb; SSX (E5A2C) Rabbit mAb (Carboxy-terminal Antigen); T-Box 19 antibody; Anti-ARID1 A antibody; MTAP monoclonal antibody (M01); Anti-PAN Trk antibody; Anti-CLDN 18 rabbit antibody; SARS-CoV-2; SARS-CoV-2/ SARS-CoV-2 spike antibody; Anti-c-Fos antibody; Anti-DDIT3 antibody; fumarate hydratase (J-13); Anti-HLA Class 1 ABC antibody; Anti-SNARCA2 antibody; Anti-Nurr1 antibody; Anti-CXorf67 antibody produced in rabbit; Anti – Histone H3 K27M Rabbit Monoclonal Antibody; Tri-Methyl-Histone H3 (Lys27) (C36B11) Rabbit mAb; Anti-IFITM1 antibody produced in rabbit; IGSF4B/SynCAM3; TRPS1 Polyclonal Antibody; Anti-Metallothionein antibody [UC1MT]; CD19 antibody; Anti-CD171; Anti-MAP2; Anti-SOX-17; DUX4 Monoclonal Antibody (P4H2); POU2F3 Antibody (6D1); Purified Mouse Anti-Human PU.1; Purified Mouse Anti-Human Retinoblastoma Protein; YAP (D8H1X) XP® Rabbit mAb; CINtec® PLUS Cytology Kit; FOXP3 antibody; GLI-1 (C-1); PAX-2 Rabbit Monoclonal; Anti-Ras (mutated Q61R) antibody; SMAD4/DPC4 Rabbit Monoclonal; VENTANA CLDN18 (43-14A) RxDx Assay; VENTANA FOLR1 (FOLR1-2.1) RxDx Assay; anti-p57^{Kip2} (Kp10) Mouse Monoclonal Primary Antibody; Anti-AFF 2; Anti-Helicobacter</p>

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	Pylori; H3 K36M (RM193) Rabbit Monoclonal Antibody; HOXB13 (D7N8O) Rabbit mAb; TCR Delta Rabbit Monoclonal; Treponema pallidum Rabbit Monoclonal
823/5	EBER

2. Cytology section – Section C

Mikulášské nám. 392/7, 326 00 Plzeň

Barrandova 392/2, 326 00 Plzeň

Barrandova 388/4, 326 00 Plzeň

Examinations:

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
817 - Clinical Cytology Laboratory					
1.	Cervicovaginal cytological examination and diagnostics (screening)	Microscopy	SOP-06, v. 7; P-D-1, v. 9; P-D-2, v. 2; P-D-5, v. 1	Cells from the cervix, vagina and vulva	A, B
2.	Examination of gynecologic cytology in thin layer (LBC)	Microscopy	SOP-17, v. 7; P-D-3, v. 6; P-D-4, v. 3; P-D-5, v. 1	Cells from the cervix, vagina and vulva	A, B

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3. Molecular-genetics section – Section G Rejskova 855/10, 326 00 Plzeň Rejskova 560/12, 326 00 Plzeň

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	PCR – Direct sequencing	SOP-18, v. 9; P-G-6, v. 7; P-G-8, v. 18; P-G-11, v. 9; P-G-14, v. 5; P-G-17, v. 7; Sequencer ABI Prism 3130XL	Tissues, smears, and body fluids	A, B, C, D
2.	Detection of nucleic acids of infectious agents	Real-Time PCR	SOP-19, v. 9; P-G-8, v. 18; P-G-9, v. 13; P-G-11, v. 9; P-G-17, v. 7; Alinity_m;	Tissues, smears, body fluids, stool	A, B, C, D
3.	Detection of nucleic acids of infectious agents	TMA	SOP-21, v. 5; P-G-19, v. 3; Panther	Smears, urine	A, B, C, D
816 – Medical Genetics Laboratory					
1.	Examination of chromosomal aberrations	FISH	SOP-07, v. 12; P-G-1, v. 13	Tissues, smears, and body fluids	A, B, C, D
2.	Examination of somatic genome variants	Direct sequencing	SOP-09, v. 9; P-G-6, v. 7; P-G-8, v. 18; P-G-11, v. 9; P-G-14, v. 5; P-G-17, v. 7; ABI Prism 3130XL	Tissues, smears, and body fluids	A, B, C, D

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Ordinal Number	Analyte/parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
3.	Examination of somatic genome variants	PCR - Fragment analysis	SOP-14, v. 6; P-G-6, v. 7; P-G-7, v. 4; P-G-8, v. 18; P-G-11, v. 9; P-G-17, v. 7; SOP-27, v. 2; P-G-6, v. 7; P-G-8, v. 18; P-G-11, v. 9; P-G-17, v. 7; SOP-25, v. 1; P-G-7, v. 4; P-G-8, v. 18; P-G-11, v. 9; P-G-17, v. 7; ABI Prism 3130XL	Tissues, smears, and body fluids	A, B, C, D
4.	Examination of somatic genome variants	NGS – MPS	SOP-22, v. 13; P-G-8, v. 18; P-G-9, v. 13; P-G-11, v. 9; P-G-17, v. 7; P-G-24, v. 4; P-G-30, v. 5; P-G-34, v. 3; P-G-35, v. 1; P-G-36, v. 2; P-G-37, v. 3; P-G-38, v. 2; P-G-39, v. 2; P-G-40, v. 1; P-G-41, v. 1; P-G-42, v. 1, P-G-43, v. 1; P-G-44, v. 1; P-G-45, v. 1; P-G-46, v. 1; P-G-47, v. 1; P-G-48, v. 1; P-G-49, v. 1; P-G-51, v. 3; P-G-55, v. 2; P-G-56, v. 1; P-G-57, v. 1; NovaSeq 6000; NextSeq 500; NextSeq 550	Tissues, smears, and body fluids	A, B, C, D
5.	Examination of germline genome variants	Real-Time PCR	SOP-23, v. 6; P-G-8, v. 18; P-G-9, v. 13, P-G-11, v. 9;	Tissues, smears, and body fluids	A, B, C, D

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Ordinal Number	Analyte/parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
6.	Noninvasive examination of genome	NGS – MPS	SOP-24, v. 2; P-G-8, v. 18; P-G-24, v. 4; P-G-25, v. 4; NextSeq 500; NextSeq 550	Blood, plasma	A, B, C
7.	Examination of somatic genome variants	aCGH	SOP-26, v. 1; P-G-8, v. 18; P-G-24, v. 4; P-G-50, v. 3; P-G-53, v. 1; Infinium Methylation EPIC V2.0 kit; NextSeq 550	Tissues, smears, and body fluids	A, B, C, D
8.	Examination of somatic genome variants	Real-Time PCR	SOP-27, v. 2; P-G-8, v. 18; P-G-11, v. 9; SOP-23, v. 6; P-G-8, v. 18; P-G-9, v. 13, P-G-11, v. 9	Tissues, smears, and body fluids	A, B, C, D
9.	Examination of germline genome variants	NGS – MPS	SOP-22, v. 13; P-G-54, v. 2 NovaSeq 6000	Tissues, smears, and body fluids	A, B, C, D
817 - Clinical Cytology Laboratory					
1.	Detection and typization of human papillomavirus	Real-Time PCR	SOP-19, v. 9; P-G-8, v. 18; P-G-11, v. 9; Alinity_m	Smears and body fluids	A, B, C, D
2.	Detection and typization of human papillomavirus	TMA	SOP-21, v. 5; P-G-18, v. 3; Panther	Smears and body fluids	A, B, C, D
823 - Pathology Laboratory					
1.	Examination of chromosomal aberrations	FISH	SOP-07, v. 12; P-G-1, v. 13	Tissues, smears, and body fluids	A, B, C, D

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Ordinal Number	Analyte/parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
2.	Examination of somatic genome variants	NGS – MPS	SOP-22, v. 13; P-G-8, v. 18; P-G-9, v. 13; P-G-11, v. 9; P-G-17, v. 7; P-G-24, v. 4; P-G-30, v. 5; P-G-34, v. 3; P-G-35, v. 1; P-G-36, v. 2; P-G-37, v. 3; P-G-38, v. 2; P-G-39, v. 2; P-G-40, v. 1; P-G-41, v. 1; P-G-42, v. 1, P-G-43, v. 1; P-G-44, v. 1; P-G-45, v. 1; P-G-46, v. 1; P-G-47, v. 1; P-G-48, v. 1; P-G-49, v. 1; P-G-51, v. 3; P-G-55, v. 2; P-G-56, v. 1; P-G-57, v. 1; NovaSeq 6000; NextSeq 500; NextSeq 550	Tissues, smears, and body fluids	A, B, C, D
3.	Examination of somatic genome variants	Real-Time PCR	SOP-23, v. 6; P-G-8, v. 18; P-G-9, v. 13, P-G-11, v. 9; SOP-27, v. 2; P-G-8, v. 18; P-G-11, v. 9	Tissues, smears, and body fluids	A, B, C, D
4.	Examination of somatic genome variants	Direct sequencing	SOP-09, v. 9; P-G-6, v. 7; P-G-8, v. 18; P-G-11, v. 9; P-G-14, v. 5; P-G-17, v. 7; ABI Prism 3130XL	Tissues, smears, and body fluids	A, B, C, D

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Ordinal Number	Analyte/parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
5.	Examination of somatic genome variants	PCR - Fragment analysis	SOP-25, v. 1; P-G-7, v. 4; P-G-8, v. 18; P-G-11, v. 9; P-G-17, v. 7; ABI Prism 3130XL	Tissues, smears, and body fluids	A, B, C, D

Specification of the scope of accreditation:

Field Nr./ Ordinal Number	Detailed information on activities within the scope of accreditation
802/1	Examined microorganisms: <i>Aktinomycetes</i> , <i>Aspergillus spp.</i> , <i>Bartonella spp.</i> , <i>Borrelia burgdorferi</i> , <i>Brucella spp.</i> , <i>Echinococcus spp.</i> , <i>Fungi</i> , <i>Chlamydia trachomatis</i> , <i>Chlamydophila psittaci</i> , <i>Leishmania spp.</i> , <i>Listeria spp.</i> , <i>Mycobacterium spp.</i> , <i>Mycobacterium tuberculosis complex</i> , <i>Pseudomonas aeruginosa</i> , <i>Toxoplasma gondii</i> , <i>Tropheryma whipplei</i> , <i>Yersinia enterocolitica</i> , <i>Yersinia pseudotuberculosis</i> , HHV8, HPV, MCV, CMV _r
802/2	Examined microorganisms: <i>Francisella tularensis</i> , <i>Treponema pallidum</i> , <i>Mycobacterium spp.</i> , <i>Haemophilus ducreyi</i> , <i>Chlamydia trachomatis</i> , <i>Neisseria gonorrhoeae</i> , <i>Trichomonas vaginalis</i> , <i>Ureaplasma urealiticum</i> , <i>Ureaplasma parvum</i> , <i>Mycoplasma genitalium</i> , <i>Mycoplasma hominis</i> , <i>Adenovirus</i> , <i>Parvovirus B19</i> , <i>BKV</i> , <i>JCV</i> , <i>CMV</i> , <i>HSV1</i> , <i>HSV2</i> , <i>HHV6</i> , <i>VZV</i> , <i>EBV</i> , <i>HPV</i> <i>Candida albicans</i> , <i>Trichophyton mentagrophytes complex</i> , <i>Trichophyton rubrum complex</i> , <i>Trichophyton tonsurans</i> , <i>Microsporum spp.</i> <i>Epidermophyton floccosum</i> , <i>Candida glabrata</i> , <i>Candida tropicalis</i> , <i>Candida parapsilosis</i> , <i>Candida krusei</i> , <i>Candida dubliniensis</i> , <i>Candida lusitanae</i> , <i>Streptococcus pyogenes</i> , <i>Pseudomonas aeruginosa</i> , <i>Chlamydia pneumoniae</i> , <i>Haemophilus influenzae</i> , <i>Escherichia coli</i> , <i>Streptococcus agalactiae</i> , <i>Mycoplasma pneumoniae</i> , <i>Proteus spp.</i> , <i>Serratia marcescens</i> , <i>Klebsiella pneumoniae</i> , <i>Acinetobacter calcoaceticus-baumannii complex</i> , <i>Legionella pneumophila</i> , <i>Klebsiella aerogenes</i> , <i>Enterobacter cloacae complex</i> , <i>Streptococcus pneumoniae</i> , <i>Staphylococcus aureus</i> , <i>Klebsiella oxytoca</i> , <i>Moraxella catarrhalis</i> , <i>Gardnerella vaginalis</i> , <i>Atopobium vaginae</i> , <i>Mobiluncus spp.</i> , <i>Lactobacillus spp.</i> , <i>Candida spp.</i> , <i>Campylobacter spp.</i> , <i>Clostridium difficile toxin B</i> , <i>Salmonella spp.</i> , <i>EIEC*/Shigella spp.</i> , <i>Vibrio spp.</i> , <i>Yersinia enterocolitica</i> , <i>Aeromonas spp.</i> , hypervirulent <i>Clostridium difficile</i> , <i>E. coli O157</i> , <i>EHEC-enterohemorrhagic E. coli (stx1/2)</i> , <i>EPEC-enteropatogene E. coli (eaeA)</i> , <i>ETEC-enterotoxigene E. coli (It/st)</i> , <i>EAEC-enteroagregative E. coli (aggR)</i> , <i>Norovirus GI</i> , <i>Norovirus GII</i> , <i>Rotavirus</i> , <i>Adenovirus</i> , <i>Astrovirus</i> , <i>Sapovirus</i> ,

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	<i>Giardia lamblia</i> , <i>Entamoeba histolytica</i> , <i>Cryptosporidium spp.</i> , <i>Blastocystis hominis</i> , <i>Dientamoeba fragilis</i> , <i>Cyclospora cayetanensis</i> , <i>Haemophilus influenzae</i> , <i>Bordetella pertussis</i> , <i>Bordetella parapertussis</i> , <i>SARS-CoV-2</i> , <i>Virus hepatitidy E</i>
802/3	Examined microorganisms: <i>Chlamydia trachomatis</i>
816/1	Examined genes/loci: amplification of genes <i>EGFR</i> , <i>HER2</i> , <i>MDM2</i> , <i>MYC</i> , <i>MYCN</i> a <i>TFEB</i> ; delece genu <i>CDKN2A</i> , lokusů 1p36, 19q13, a chromosomu 10; zlom genů <i>ALK</i> , <i>BCL1</i> , <i>BCL2</i> , <i>BCL6</i> , <i>CSF1</i> , <i>DEK</i> , <i>ERG</i> , <i>ETV6</i> , <i>EWSR1</i> , <i>FLI1</i> , <i>FUS</i> , <i>HMG2</i> , <i>IGH</i> , <i>IRF4</i> , <i>MALT1</i> , <i>MAML2</i> , <i>MYB</i> , <i>MYBL1</i> , <i>MYC</i> , <i>NR4A3</i> , <i>PDGFB</i> , <i>PHF1</i> , <i>PLAG1</i> , <i>TFE3</i> , <i>TFEB</i> , <i>ROS1</i> a <i>USP6</i> ; fůze genů <i>API2::MALT1</i> , <i>IGH::BCL1</i> , <i>IGH::BCL2</i> , <i>IGH::MYC</i>
816/2	Examined genes: <i>IDH1</i> , <i>IDH2</i> , <i>TERT</i>
816/3	Examined genes: <i>IgH</i> , <i>IgK</i> , <i>IgL</i> , <i>TCR β</i> , <i>TCR δ</i> , <i>TCR γ</i> ; examined loci: AML, D13S305, D13S325, D13S628, D13S634, D13S742, D13S762, D13S797, D13S800, D13S317, D18S386, D18S391, D18S535, D18S819, D18S976, D18S1002, D18S390, D18S878, D21S11, D21S1246, D21S1409, D21S1435, D21S1442, D21S1444, D21S1437, DXS6854, DXYS218, SRY, TAF9B, XHPRT, DXS6803, DXS6809, DXS8377, DXYS267, G10_STS47, D7S820, D2S1338, D16S539, FGA, CSF1PO; examined loci MSI (BAT-25, BAT-26, NR-21, NR-24 a MONO-27), examined genes promoters <i>MGMT</i> , <i>MLH1</i> (methylation)
816/4	The list of genes is provided in form F 417 Seznam analyzovaných genů, which is available on the website: https://www.biopticka.cz/cz/laborator/akreditace.php
816/5	Examined genes: <i>F2</i> , <i>F5</i> , <i>HLA-DQ2/DQ8/DRB</i> , <i>F13</i> , <i>MTHFR</i> , <i>PAI-1</i> , <i>HFE</i>
816/6	Examined chomozomes 13, 18, 21, X, Y; examined microdeletion syndromes: DiGeorge syndrom (22q11), syndrom of deletion 1p36, Cri-du-chat syndrom (5p15.2), Prader-Willi/Angelman syndrom (15q11-13) ane other referral loci. Examination of the majority/minority fraction for the purposes of non-invasive prenatal testing (NIPT) and the body's immune response after transplantation.
816/7	Examined CpG loci: https://emea.illumina.com/products/by-type/microarray-kits/infinium-methylation-epic.html
816/8	Examined genes promoters <i>FAM19A4+hsa-mir124-2</i> (metylace), examined genes <i>BRAF</i> , <i>EGFR</i> , <i>KRAS</i> , <i>NRAS</i> , examined loci MSI (<i>ACVF2A</i> , <i>BTBD7</i> , <i>DIDO1</i> , <i>MRE11</i> , <i>RYR3</i> , <i>SEC31A</i> , <i>SULF1</i>), examined gene expression alteration <i>NOS2</i> , <i>CCL27</i> , <i>SDHAF2</i> , <i>TBP</i> .
816/9	The list of genes is provided in form F 420 Seznam analyzovaných genů EXOMg which is available on the website: https://www.biopticka.cz/cz/laborator/akreditace.php
817/1	Examined microorganisms: HR-HPV(<i>typy: 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68</i>)
817/2	Examined microorganisms:: HR-HPV(<i>typy: 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68</i>)

List of activities within the flexible scope of accreditation

Field Nr./ Ordinal Number	Detailed information on activities within the scope of accreditation
823/1	Examined genes/loci: amplification genes <i>EGFR</i> , <i>HER2</i> , <i>MDM2</i> , <i>MYC</i> , <i>MYCN</i> a <i>TFEB</i> ; delece of gene <i>CDKN2A</i> , lokusů 1p36, 19q13, and chromosome 10; gene break <i>ALK</i> , <i>BCL1</i> , <i>BCL2</i> , <i>BCL6</i> , <i>CSF1</i> , <i>DEK</i> , <i>ERG</i> , <i>ETV6</i> , <i>EWSR1</i> , <i>FLI1</i> , <i>FUS</i> , <i>HMGA2</i> , <i>IGH</i> , <i>IRF4</i> , <i>MALT1</i> , <i>MAML2</i> , <i>MYB</i> , <i>MYBL1</i> , <i>MYC</i> , <i>NR4A3</i> , <i>PDGFB</i> , <i>PHF1</i> , <i>PLAG1</i> , <i>TFE3</i> , <i>TFEB</i> , <i>ROS1</i> a <i>USP6</i> ; gene fusion <i>API2::MALT1</i> , <i>IGH::BCL1</i> , <i>IGH::BCL2</i> , <i>IGH::MYC</i>
823/2	The list of genes is provided in form F 417 Seznam analyzovaných genů which is available on the website: https://www.biopticka.cz/cz/laborator/akreditace.php
823/3	Examined genes: <i>BRAF</i> , <i>EGFR</i> , <i>KRAS</i> , <i>NRAS</i> ; and examined loci MSI (<i>ACVF2A</i> , <i>BTBD7</i> , <i>DIDO1</i> , <i>MRE11</i> , <i>RYR3</i> , <i>SEC31A</i> , <i>SULF1</i>), examined genes promotors <i>FAM19A4+hsa-mir124-2</i> (metylation), examined gene expression alteration <i>NOS2</i> , <i>CCL27</i> , <i>SDHAF2</i> , <i>TBP</i> .
823/4	Examined genes: <i>IDH1</i> , <i>IDH2</i> , <i>TERT</i>
823/5	Examined loci MSI (BAT-25, BAT-26, NR-21, NR-24 a MONO-27)

List of activities within the flexible scope of accreditation

4. **Working Site Jilemnice** Masarykova městská nemocnice a.s, Nemocnice Jilemnice, Metyšova 465, 514 15 Jilemnice
5. **Working Site Jičín** Oblastní nemocnice Jičín a.s., Bolzanova 512, 506 43 Jičín
6. **Working Site Strakonice** Nemocnice Strakonice, a.s., Radomyšlská 336, 386 01 Strakonice

Examinations:

Ordinal Number	Analyte/parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
823 - Laboratoř patologie					
1.	Peroperational histological and cytological examination and diagnostics	Microscopy	SOP-04, v. 8	Tissues, cells	A, B

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

E – Flexibility concerning the POCT delivery points

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

PCR	Polymerase <i>chain reaction</i>
NGS-MPS	Next <i>generation sequencing</i> (Massively parallel sequencing)
TMA	<i>Transcription Mediated Amplification</i>
FISH	Fluorescence <i>in situ</i> hybridization
Real-Time PCR	Polymerase <i>chain reaction</i> in real time
aCGH	array comparative genomic hybridisation