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: 8. 4. 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	*In situ* 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:

Field Nr./ Ordinal Number	Detailed information on activities within the scope of accreditation
823/4	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 Membráne 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 ¾; 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 Transcriotion Faktor (TTF-1); Anti-Thyroid Transcriotion 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-

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	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 amti-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

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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

List of activities within the flexible scope of accreditation

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. 19; P-G-11, v. 10; 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. 19; P-G-9, v. 13; P-G-11, v. 10; 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. 19; P-G-11, v. 10; P-G-14, v. 5; P-G-17, v. 7; ABI Prism 3130XL	Tissues, smears, and body fluids	A, B, C, D

List of activities within the flexible scope of accreditation

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. 19; P-G-11, v. 10; P-G-17, v. 7; SOP-27, v. 2; P-G-6, v 7; P-G-8, v. 19; P-G-11, v. 10; P-G-17, v. 7; SOP-25, v. 1; P-G-7, v. 4; P-G-8, v. 19; P-G-11, v. 10; 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. 19; P-G-9, v. 13; P-G-11, v. 10; 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, NovaSeq X plus	Tissues, smears, and body fluids	A, B, C, D
5.	Examination of germline genome variants	Real-Time PCR	SOP-23, v. 7; P-G-8, v. 19; P-G-9, v. 13, P-G-11, v. 10;	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. 19; 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. 19; 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. 19; P-G-11, v. 10; SOP-23, v. 7; P-G-8, v. 19; P-G-9, v. 13, P-G-11, v. 10	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, NovaSeq X plus	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. 19; P-G-11, v. 10; 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

List of activities within the flexible scope of accreditation

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. 19; P-G-9, v. 13; P-G-11, v. 10; 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, NovaSeq X plus	Tissues, smears, and body fluids	A, B, C, D
3.	Examination of somatic genome variants	Real-Time PCR	SOP-23, v. 7; P-G-8, v. 19; P-G-9, v. 13, P-G-11, v. 10; SOP-27, v. 2; P-G-8, v. 19; P-G-11, v. 10	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. 19; P-G-11, v. 10; 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. 19; P-G-11, v. 10; P-G-17, v. 7; ABI Prism 3130XL	Tissues, smears, and body fluids	A, B, C, D

Specification of the scope of accreditation:

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802/1	Examined microorganisms: *Aktinomycetes, Aspergillus spp., Bartonella spp., Borrelia burgdorferi, Brucella spp., Echinococcus spp., Fungi, Chlamydia trachomatis, Chlamydophila psittaci, Leishmania spp., Listeria spp., Mycobacterium spp., Mycobacteruim tuberculosis complex, Pseudomonas aeruginosa, Toxoplasma gongii, Tropheryma whipplei, Yersinia enterocolitica, Yersinia pseudotuberculosis,* HHV8, HPV. MCV, CMVr
802/2	Examined microorganisms: *Francisella tularensis, Treponema pallidum, Mycobacterium spp., Haemophilus ducreyi, Chlamydia trachomatis, Neisseria gonorrheae, Trichomonas vaginalis, Ureaplasma urealiticum, Ureaplasma parvum, Mycoplasma genitalium, Mycoplasma hominis*, Adenovirus, ParvovirusB19, BKV, JCV, CMV, HSV1, HSV2, HHV6, VZV, EBV, HPV *Candida albicans, Trichophyton mentagrophytes complex, Trichophyton rubrum complex, Trichophyton tonsurans, Microsporum spp. Epidermophyton floccosum,* *Candida glabrata, Candida tropicalis, Candida parapsilosis, Candida krusei, Candida dubliniensis, Candida lusitaniae,* *Streptococcus pyogenes, Pseudomonas aeruginosa, Chlamydia pneumoniae, Haemophilus influenzae, Escherichia coli, Streptococcus agalactiae, Mycoplasma pneumoniae, Proteus spp., Serratia marcescens, Klebsiella pneumoniae, Acinetobacter calcoaceticus-baumannii complex, Legionella pneumophila, Klebsiella aerogenes, Enterobacter cloacae complex, Streptococcus pneumoniae, Staphylococcus aureus, Klebsiella oxytoca, Moraxella catarrhalis,* *Gardnerella vaginalis, Atopobium vaginae, Mobiluncus spp., Lactobacillus spp., Candida spp.,* *Campylobacter spp., Clostridium difficile toxin B, Salmonella spp., EIEC*/Shigella spp., Vibrio spp. , Yersinia enterocolitica, Aeromonas spp.,* hypervirulent *Clostridium difficile, E. coli O157, EHEC-enterohemoragic E. coli (stx1/2), EPEC-enteropatogene E. coli (eaeA), ETEC-enterotoxigene E. coli (It/st), EAEC-enteroagregative E. coli (aggR),* *Norovirus GI, Norovirus GII, Rotavirus, Adenovirus, Astrovirus, Sapovirus,*

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	Giardia lamblia, Entamoeba histolytica, Cryptosporidium spp., Blastocystis hominis, Dientamoeba fragilis, Cyclospora cayetanensis, *Haemophilus influenzae, Bordetella pertussis, Bordetella parapertussis,* *SARS-CoV-2, Virus hepatitydy E*
802/3	Examined microorganisms: *Chlamydia trachomatis*
816/1	Examined genes/loci: amplification of genes *EGFR*, *HER2*, *MDM2*, *MYC*, *MYCN* a *TFEB*; delece genu *CDKN2A,* lokusů 1p36, 19q13, a chromosomu 10; zlom genů *ALK*, *BCL1*, *BCL2*, *BCL6*, *CSF1*, *DEK*, *ERG*, *ETV6*, *EWSR1*, *FLI1*, *FUS*, *HMGA2*, *IGH*, *IRF4, MALT1*, *MAML2*, *MYB*, *MYBL1*, *MYC, NR4A3*, *PDGFB*, *PHF1*, *PLAG1*, *TFE3*, *TFEB*, *ROS1* a *USP6;* fúze genů *API2::MALT1*, *IGH::BCL1*, *IGH::BCL2, IGH::MYC*
816/2	Examined genes: *IDH1, IDH2, TERT*
816/3	Examined genes: *IgH, IgK, IgL, TCR β, TCR δ, TCR γ ;* 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 promotors *MGMT*, *MLH1* (metylation)
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: *F2, F5, HLA-DQ2/DQ8/DRB, F13, MTHFR, PAI-1, HFE, LCT*
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 promotors *FAM19A4+hsa-mir124-2 (metylace),* examined genes *BRAF, EGFR, KRAS, NRAS,* examined loci MSI (*ACVF2A, BTBD7, DIDO1, MRE11, RYR3, SEC31A, SULF1*), examined gene expression alteration *NOS2, CCL27, SDHAF2, TBP, LCK, HOMER1*
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*(typy: 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68)*
817/2	Examined microorganisms:: HR-HPV*(typy: 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68)*

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 *EGFR*, *HER2*, *MDM2*, *MYC*, *MYCN* a *TFEB*; delece of gene *CDKN2A,* lokusů 1p36, 19q13, and chromosome 10; gene break *ALK*, *BCL1*, *BCL2*, *BCL6*, *CSF1*, *DEK*, *ERG*, *ETV6*, *EWSR1*, *FLI1*, *FUS*, *HMGA2*, *IGH*, *IRF4, MALT1*, *MAML2*, *MYB*, *MYBL1*, *MYC, NR4A3*, *PDGFB*, *PHF1*, *PLAG1*, *TFE3*, *TFEB*, *ROS1* a *USP6;* gene fusion *API2::MALT1*, *IGH::BCL1*, *IGH::BCL2, IGH::MYC*
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: *BRAF, EGFR, KRAS, NRAS;* and examined loci MSI (*ACVF2A, BTBD7, DIDO1, MRE11, RYR3, SEC31A, SULF1)*, examined genes promotors *FAM19A4+hsa-mir124-2 (metylation),* examined gene expression alteration *NOS2, CCL27, SDHAF2, TBP, LCK, HOMER1*
823/4	Examined genes: *IDH1, IDH2, TERT*
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 *chain reaction*
NGS-MPS	Next *generation sequencing* (Massively parallel sequencing)
TMA	*Transcription Mediated Amplification*
FISH	Fluorescence *in situ* hybridization
Real-Time PCR	Polymerase *chain reaction* in real time
aCGH	array comparative genomic hybridisation