

## List of activities within the flexible scope of accreditation

**Accredited Body:** Fakultní nemocnice Brno

**CAB Name:** Institute of Laboratory Medicine

**CAB Number:** 8060

**Certificate of Accreditation No.:** 40/2025

**Field of Accreditation:** Medical Laboratory - ČSN EN ISO 15189 ed. 3:2023

**Updated:** 18/11/2025, 05/01/2026

1. **Clinical Biochemistry Department (OKB), NBP Workplace**

Jihlavská 340/20, 625 00 Brno

**Examinations:**

Ordinal Number	Analyte/parameter/diagnostics	Principle of examination	Identification of method procedure/equipment	Examined material	Degrees of freedom <sup>1</sup>
<b>801 – Clinical Biochemistry</b>					
1.	Minerals	Potentiometry	SOPV 3742 1 982, version 1; SOPT 3742 3 316, version 12; SOPT 3742 3 321, version 4; PI 3701 1 725, version 1; cobas 8000	Serum, plasma, urine	A, B, C
2.	Minerals	Absorption spectrophotometry	SOPV 3742 1 973, version 1; SOPT 3742 3 316, version 12; SOPT 3742 3 321, version 4; PI 3701 1 725, version 1; cobas 8000	Serum, plasma, urine	A, B, C
3.	Enzymes	Absorption spectrophotometry	SOPV 3742 1 981, version 1; SOPV 3742 1 975, version 1; SOPV 3742 1 977, version 1; SOPV 3742 1 978, version 1; SOPT 3742 3 316, version 12; SOPT 3742 3 321, version 4; PI 3701 1 725, version 1; cobas 8000	Serum, plasma	A, B, C

## List of activities within the flexible scope of accreditation

Ordinal Number	Analyte/parameter/diagnostics	Principle of examination	Identification of method procedure/equipment	Examined material	Degrees of freedom <sup>1</sup>
4.	Glucose	Absorption spectrophotometry	SOPV 3742 1 979, version 1; SOPT 3742 3 316, version 12; SOPT 3742 3 321, version 4; PI 3701 1 725, version 1; cobas 8000	Serum, plasma, cerebrospinal fluid	A, B
5.	Lipids	Absorption spectrophotometry	SOPV 3742 1 974, version 1; SOPT 3742 3 316, version 12; PI 3701 1 725, version 1; cobas 8000	Serum, plasma	A, B, C
6.	Non-protein nitrogenous compounds	Absorption spectrophotometry	SOPV 3742 1 972, version 1; SOPT 3742 3 316, version 12; SOPT 3742 3 321, version 4; PI 3701 1 725, version 1; cobas 8000	Serum, plasma, urine	A, B, C
7.	Proteins	Absorption spectrophotometry	SOPV 3742 1 976, version 1; SOPT 3742 3 316, version 12; SOPT 3742 3 321, version 4; PI 3701 1 725, version 1; cobas 8000	Serum, plasma, urine, cerebrospinal fluid	A, B, C
8.	Pigments	Absorption spectrophotometry	SOPV 3742 1 980, <b>version 2</b> ; SOPT 3742 3 316, version 12; SOPT 3742 3 321, version 4; PI 3701 1 725, version 1; cobas 8000	Serum, plasma	A, B, C
9.	Lactate	Absorption spectrophotometry	SOPV 3742 1 979, version 1; SOPT 3742 3 316, version 12; SOPT 3742 3 321, version 4; PI 3701 1 725, version 1; cobas 8000	Plasma, cerebrospinal fluid	A, B
10.	Glycated haemoglobin (HbA1c)	High-Performance Liquid Chromatography	SOPV <b>3743</b> 1 815 version 4; PI 3701 1 725, version 1; capillarys 2	Blood	A, B

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Ordinal Number	Analyte/parameter/diagnostics	Principle of examination	Identification of method procedure/equipment	Examined material	Degrees of freedom <sup>1</sup>
<b>813 - Allergology and Immunology Laboratory</b>					
1.	Immunoglobulins	Immunoturbidimetry	SOPV 3742 1 985, version 1; SOPT 3742 3 316, version 12; PI 3701 1 725, version 1; cobas 8000	Serum, plasma	A, B, C
2.	C-reactive protein (CRP)	Immunoturbidimetry	SOPV 3742 1 986, version 1; SOPT 3742 3 316, version 12; SOPT 3742 3 321, version 4; PI 3701 1 725, version 1; cobas 8000	Serum, plasma	A, B
3.	Proteins	Immunonephelometry	SOPV 3741 1 844, <b>version 2</b> ; SOPT 3741 3 144, version 1; PI 3701 1 725, version 1; Atellica NEPH 630	Cerebrospinal fluid, urine	A, B, C
4.	Immunoglobulins	Immunonephelometry	SOPV 3741 1 <b>844, version 2</b> ; SOPT 3741 3 144, version 1; PI 3701 1 725, version 1; Atellica NEPH 630	Cerebrospinal fluid	A, B, C
5.	Specific proteins	Immunonephelometry	SOPV 3741 1 805, version 7; SOPT 3741 3 144, version 1; PI 3701 1 725, version 1; Atellica NEPH 630	Serum, plasma	A, B, C
<b>815 - Nuclear Medicine Laboratory</b>					
1.	Cardiac markers	Immunoassay with luminometric detection	SOPV 3742 1 993, version 1; SOPV 3742 1 994, version 1; SOPV 3742 1 995, version 1; SOPV 3742 1 996, version 1; SOPT 3742 3 330, version 2; PI 3701 1 725, version 1; cobas 8000	Serum, plasma	A, B, C

## List of activities within the flexible scope of accreditation

Ordinal Number	Analyte/parameter/diagnostics	Principle of examination	Identification of method procedure/equipment	Examined material	Degrees of freedom <sup>1</sup>
2.	Hormones	Immunoassay with luminometric detection	SOPV 3742 1 990, version 1; SOPV 3742 1 971, version 1; SOPT 3742 3 316, version 12; PI 3701 1 725, version 1; cobas 8000	Serum, plasma	A, B, C
3.	Hormones	Immunoassay with luminometric detection	SOPV 3742 1 882 version 1; SOPV 3742 1 991, version 1; SOPV 3742 1 992, version 1; SOPT 3742 3 331, version 3; PI 3701 1 725, version 1; Architect i 2000 SR	Serum, plasma	A, B, C

### Specification of the scope of accreditation:

Field Nr. / Ordinal Number	Detailed information on activities within the scope of accreditation
801/1	Sodium ions, Potassium ions, Chloride ions
801/2	Calcium ions, Inorganic phosphates, Magnesium ions
801/3	Alanine transaminase (ALT), Aspartate transaminase (AST), Lactate dehydrogenase a (LD), Alkaline phosphatase (ALP), Gamma-glutamyl transferase (GGT), Creatin kinase (CK), $\alpha$ -Amylase (AMS)
801/5	Total cholesterol, Triacylglycerols
801/6	Urea, Uric acid
801/7	Albumin, Total proteins
801/8	Total bilirubin
813/1	IgG, IgM, IgA
813/3	Albumin
813/4	IgG, IgM, IgA
813/5	Ceruloplasmin
815/1	Carcinoembryonic antigen (CEA), CA 125, CA 15-3, CA 19-9, Prostate-specific antigen – total (PSA celkové), Prostate-specific antigen - free (FPSA), CA 72-4, Cytokeratin fragment 19 (CYFRA 21-1), Neuron-specific enolase (NSE)
815/2	Thyrotropin (TSH), Thyroxine free (FT4), Total hCG+ free beta-subunit HCG

## List of activities within the flexible scope of accreditation

Field Nr. / Ordinal Number	Detailed information on activities within the scope of accreditation
815/3	Alfa-1-fetoprotein (AFP), Cortisol, Estradiol, Folitropin (FSH), Lutropine (LH), Progesterone, Prolactine, Testosterone

## List of activities within the flexible scope of accreditation

### 2. Clinical Biochemistry Department (OKB), NBP Workplace, Obilní trh

Obilní trh 526/11, 625 00 Brno

#### Examinations:

Ordinal Number	Analyte/ parameter/diagnos- tics	Principle of examination	Identification of method procedure/ equipment	Examined material	Degrees of freedom <sup>1</sup>
<b>801 – Clinical Biochemistry</b>					
1.	Minerals	Potentiometry	SOPV 3747 1 940, version 1; PI 3701 1 725, version 1; cobas pure	Serum, plasma, urine	A, B, C
2.	Minerals	Absorption spectrophotometry	SOPV 3747 1 938, version 1; PI 3701 1 725, version 1; cobas pure	Serum, plasma, urine	A, B, C
3.	Enzymes	Absorption spectrophotometry	SOPV 3747 1 937, version 1; SOPV 3747 1 936, version 1; SOPV 3747 1 907, version 5; PI 3701 1 725, version 1; cobas pure	Serum, plasma	A, B, C
4.	Glucose	Absorption spectrophotometry	SOPV 3747 1 909, version 5; PI 3701 1 725, version 1; cobas pure	Serum, plasma	A, B
5.	Non-protein nitrogenous compounds	Absorption spectrophotometry	SOPV 3747 1 939, <b>version 2</b> ; PI 3701 1 725, version 1; cobas pure	Serum, plasma, urine	A, B, C
6.	Proteins	Absorption spectrophotometry	SOPV 3747 1 935, <b>version 2</b> ; PI 3701 1 725, version 1; cobas pure	Serum, plasma, urine	A, B, C
7.	Pigments	Absorption spectrophotometry	SOPV 3747 1 <b>941, version 2</b> ; PI 3701 1 725, version 1; cobas pure	Serum, plasma	A, B, C
<b>813 - Allergology and Immunology Laboratory</b>					
1.	C-reactive protein (CRP)	Immunoturbidimetry	SOPV 3747 1 914, <b>version 6</b> ; PI 3701 1 725, version 1; cobas pure	Serum, plasma	A, B

## List of activities within the flexible scope of accreditation

### Specification of the scope of accreditation:

Field Nr. / Ordinal Number	Detailed information on activities within the scope of accreditation
801/1	Sodium ions (Na <sup>+</sup> ), Potassium ions (K <sup>+</sup> ), Chloride ions (Cl <sup>-</sup> )
801/2	Calcium ions (Ca)
801/3	Alanine transaminase (ALT), Aspartate transaminase (AST), Lactate dehydrogenase a (LD), Alcaline phosphatase (ALP), Gamma-glutamyl transferase (GGT), $\alpha$ -Amylase (AMS)
801/5	Urea, Urin acid
801/6	Albumin, Total proteins
801/7	Total bilirubin

## List of activities within the flexible scope of accreditation

### 3. Clinical Microbiology and Immunology Department (OKMI)

Jihlavská 340/20, 625 00 Brno

#### Examinations:

Ordinal Number	Analyte/parameter/diagnostics	Principle of examination	Identification of method procedure/ equipment	Examined material	Degrees of freedom <sup>1</sup>
<b>802 – Medical Microbiology</b>					
1.	Microbiological examination of the lower respiratory tract	Microscopy; Aerobic culture Anaerobic culture	SOPV 44417017, <b>version 2;</b> SOPV 44417001, version 1; PI 4401 0 011, version 1	Sputum, lower respiratory tract aspirate, bronchoalveolar lavage	A, B, C, D
2.	Microbiological examination of upper respiratory tract	Aerobic culture	SOPV 44417006, version 1; PI 4401 0 011, version 1	Swab from throat, nose, throat, oral cavity, tongue, tonsils, pharynx, larynx	A, B, C, D
3.	Clinically relevant antibiotic resistance screening	Aerobic culture	SOPV 4441 7 006, version 1; PI 4401 0 011, version 1	Sswab from throat, nose, rectum, perianal	A, B, C, D
4.	Microbiological examination of clinical material	Aerobic culture	SOPV 4441 7 006, version 1; PI 4401 0 011, version 1	Swab or smear from the eye, ear, skin, conjunctival sac, axillae, morpchs, deposits, erosions, pustules, blisters, impressions from wounds and burns, breast milk, swabs from catheters	A, B, C, D
5.	Microbiological examination of foreign bodies	Aerobic culture	SOPV 4441 7 006, version 1; PI 4401 0 011, version 1	Suction and tracheostomy cannula, drain, splint, urinary catheter, epicystostomy catheter, vascular catheter, implant, shunt, swab	A, B, C, D



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Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of method procedure/ equipment	Examined material	Degrees of freedom <sup>1</sup>
6.	Microbiological examination of clinical material	Microscopy; Aerobic culture; Anaerobic culture	SOPV 4441 7 022, <b>version 2</b> ; SOPV 4441 7 001, version 1; PI 4401 0 011, version 1	Liquor, punctates (from joint, pericardium, pleural, peritoneum), secretions (from drain, abscess, fistula), amniotic fluid, urine from nephrostomy, pus, dialysate, ascites, abscess, bile, IUD, biopsy; swabs from wound, abscess, secretion, pus, tissue, ulceration, incision, furuncle, carbuncle, joint replacement, bone, <b>corneal scraping</b>	A, B, C, D
7.	Microbiological examination of clinical material	Microscopy; Aerobic culture	SOPV 4441 7 020, version 1; SOPV 4441 7 001, version 1; PI 4401 0 011, version 1	Wound, mucosal and surface swabs and smears, respiratory material, liquid clinical material, tissue, blood as haemoculture, foreign material, urine, faeces, skin and skin adnexa	A, B, D
8.	Identification of the micromycetes	Microscopy; Aerobic culture	SOPV 4441 7 021, version 1; SOPV 4441 7 001, version 1; PI 4401 0 011, version 1	Yeast culture, mould fungus	A, B, C
9.	Identification of the microorganism	Mass spectrometry	SOPV 4441 7 019, <b>version 2</b> ; PI 4401 0 011, version 1; Biotyper; Vitek MS	Bacterial culture, yeast culture, mould fungus	A, B, C, D

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Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of method procedure/ equipment	Examined material	Degrees of freedom <sup>1</sup>
10.	Identification of bacteria	Agglutination	SOPV 4441 7 052, version 1; SOPV 4441 7 002, version 1; PI 4401 0 011, version 1	Bacterial culture	A, B, C
11.	Identification of bacteria	Biochemically	SOPV 4441 7 052, version 1; PI 4401 0 011, version 1	Bacterial culture	A, B, C
12.	Microbiological examination of stool	Aerobic culture Anaerobic culture	SOPV 4441 7 002, version 1; SOPV 4441 7 049, version 1; PI 4401 0 011, version 1	Stool, rectal swab, swab of stomia	A, B, C
13.	Microbiological examination of urogenital tract	Microscopy; Aerobic culture; Anaerobic culture	SOPV 4441 7 009, version 1; SOPV 4441 7 001, version 1; PI 4401 0 011, version 1	External genital swab, vagina, cervix, cervix, urethra, rectum, throat, lochia, vaginal and prostatic secretions, ejaculate, scrotal swab	A, B, C, D
14.	Microbiological examination of blood and primarily sterile body fluids	Aerobic culture; Anaerobic culture; (automated)	SOPV 4441 7 051, version 1; SOPV 4441 7 001, version 1; SOPT 4441 5 011, version 1; PI 4401 0 011, version 1; BD Bactec FX 400 BD Bactec FX 200 BD Bactec FX 40	Blood, liquor, punctate (joint, pericardial, pleural, peritoneal), ascites, dialysate	A, B, C, D
15.	Quantitative microbiological examination of urine	Aerobic culture	SOPV 4441 7 043, version 1; PI 4401 0 011, version 1	Urine	A, B, C

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Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of method procedure/ equipment	Examined material	Degrees of freedom <sup>1</sup>
16.	Qualitative examination of microorganism sensitivity	Disk diffusion test	SOPV 4441 7 012, <b>version 2</b> ; PI 4401 0 011, version 1	Bacterial culture, yeast culture	A, B, C, D
17.	Quantitative examination of microorganism sensitivity	Microdilution method; (automated)	SOPV 4441 7 013, version 1; PI 4401 0 011, version 1; Microscan	Bacterial culture	A, B, C, D
18.	Quantitative examination of microorganism sensitivity	Microdilution method; E-test	SOPV 4441 7 013, version 1; SOPV 4441 7 014, version 1; PI 4401 0 011, version 1	Bacterial culture, yeast culture, mould fungus	A, B, D
19.	Identification of bacterial strains with a severe resistance phenotype	Disc test; Biochemical test	SOPV 4441 7 015, <b>version 3</b> ; PI 4401 0 011, version 1	Bacterial culture	A, B, C
20.	Parasitological examination for enterobiasis	Microscopy	SOPV 4441 7 023, <b>version 2</b> ; PI 4401 0 011, version 1	Bacterial culture	A, B
21.	Parasitological examination of stool and ectoparasites	Microscopy	SOPV 4441 7 023, <b>version 2</b> ; PI 4401 0 011, version 1	Stool, ectoparasites	A, B, C
22.	Examination for malaria and other blood tissue parasites	Microscopy	SOPV 4441 7 025, version 1; SOPV 4441 7 023, <b>version 2</b> ; PI 4401 0 011, version 1	Blood, bone marrow, punctate, duodenal secretions	A, B, D
23.	Diagnostics of <i>Trichomonas vaginalis</i>	Microscopy	SOPV 4441 7 044, version 1; PI 4401 0 011, version 1	Vaginal swab, urethral swab, urine, ejaculate	A, B, D
24.	Diagnostics of urogenital mycoplasma	Aerobic culture	SOPV 4441 7 045, version 1; PI 4401 0 011, version 1	Vaginal swab, urethral swab, urine, aspirate from the respiratory tract, primarily sterile material	A, B, C, D

## List of activities within the flexible scope of accreditation

Ordinal Number	Analyte/parameter/diagnostics	Principle of examination	Identification of method procedure/ equipment	Examined material	Degrees of freedom <sup>1</sup>
25.	Detection of a toxigenic strain of <i>Clostridioides difficile</i>	Immunoassay with fluorimetric detection	SOPV 4441 7 049, version 1; PI 4401 0 011, version 1; Standard F2400 Analyzer	Stool	A, B, C
26.	Detection of a toxigenic strain of <i>Clostridioides difficile</i>	Real-Time PCR	SOPV 4441 7 049, version 1; PI 4401 0 011, version 1; GeneXpert	Stool	A, B, C
27.	Antigens of infectious agents	Immunoassay with fluorimetric detection	SOPV 4441 7 042, version 1; PI 4401 0 011, version 1; Standard F2400 Analyzer	Cerebrospinal fluid, urine	A, B, C, D
28.	Detection of microorganisms	Aerobic culture	SOPV 4441 7 003, version 1; SOPV 4441 7 006, version 1; PI 4401 0 011, version 1	Environmental swabs, environmental and staff swabs and fingerprints, venepuncture swabs, aeroscope material, disinfection control, incubator swab	A, B, C, D
29.	Detection of microorganisms	Microscopy; Aerobic culture; Anaerobic culture	SOPV 4441 7 004, version 1; SOPV 4441 7 001, version 1; PI 4401 0 011, version 1; BD Bactec FX 200	Transfusion products and blood derivatives	A, B, C, D
30.	Detection of microorganisms	Aerobic culture; Anaerobic culture	SOPV 4441 7 005, version 1; PI 4401 0 011, version 1	Scrapings from donor tissues, donor tissues	A, B, C, D

## List of activities within the flexible scope of accreditation

Ordinal Number	Analyte/parameter/diagnostics	Principle of examination	Identification of method procedure/ equipment	Examined material	Degrees of freedom <sup>1</sup>
31.	Antigens of infectious agents	Immunoassay with luminometric detection (automated)	SOPV 4442 1 001, <b>version 2</b> ; SOPT 4442 2 002, version 4; PI 4401 0 011, version 1; Architect i2000 SR	Serum	A, B, C, D
32.	Antibodies against infectious agents	Immunoassay with luminometric detection (automated)	SOPV 4442 1 001, <b>version 2</b> ; SOPT 4442 2 002, version 4; SOPV 4442 1 051, version 1; SOPT 4442 2 003, version 4; SOPV 4442 1 021, version 4; SOPV 4442 1 022, version 4; SOPT 4442 2 001, <b>version 3</b> ; PI 4401 0 011, version 1; Architect i2000 SR; Liaison XL; cobas pure	Serum	A, B, C, D
33.	Detection of nucleic acids of infectious agents	Real-Time PCR (automated)	SOPV 4443 3 002, version 1; SOPV 4443 3 005, <b>version 2</b> ; PI 4401 0 011, version 1; Alinity m; GeneXpert	Plasma, serum	A, B, C, D

## List of activities within the flexible scope of accreditation

Ordinal Number	Analyte/parameter/diagnostics	Principle of examination	Identification of method procedure/ equipment	Examined material	Degrees of freedom <sup>1</sup>
<b>813 - Allergology and Immunology Laboratory</b>					
1.	Antibodies	Indirect immunofluorescence	SOPV 3749 2 001, version 1; SOPV 3749 2 002, version 1; SOPT 3749 8 003, version 2; PI 4401 0 011, version 1; IF Sprinter; Mikroskop Olympus BX43	Serum	A, B, C, D
2.	Antibodies against tissue transglutaminase	Immunoassay with luminometric detection	SOPV 3749 3 004, version 1; SOPT 3749 8 004, version 3; PI 4401 0 011, version 1; Bio-Flash	Serum	A, B, D
3.	Antibodies against proteinase 3 and myeloperoxidase	Immunoassay with luminometric detection	SOPV 3749 3 003, version 1; SOPT 3749 8 004, version 3; PI 4401 0 011, version 1; Bio-Flash	Serum	A, B, D
4.	Immunophenotyping of cell populations	Flow cytometry	SOPV 3749 4 002, version 1; SOPT 3749 8 007, <b>version 6</b> ; PI 4401 0 011, version 1; DxFLEX	Blood	A, B, C

### Specification of the scope of accreditation:

Field Nr. / Ordinal Number	Detailed information on activities within the scope of accreditation
802/1	Bacteria, yeast, mould fungi
802/2	Bacteria, yeast

## List of activities within the flexible scope of accreditation

Field Nr. / Ordinal Number	Detailed information on activities within the scope of accreditation
802/3	Bacteria
802/4	Bacteria, yeast, mould fungi
802/5	Bacteria, yeast, mould fungi
802/6	Bacteria, yeast, mould fungi
802/7	Yeast, mould fungi
802/8	Yeast, mould fungi
802/9	Bacteria, yeast, mould fungi
802/10	Bacteria
802/11	Bacteria, yeast
802/12	Bacteria, yeast
802/13	Bacteria, yeast
802/14	Bacteria, yeast, mould fungi
802/15	Bacteria, yeast
802/16	Bacteria, yeast
802/17	Bacteria
802/18	Bacteria, yeast, mould fungi
802/19	Bacteria
802/24	Bacteria
802/25	Bacteria
802/26	Bacteria
802/27	<i>Streptococcus pneumoniae</i> , <i>Legionella pneumophila</i>
802/28	Bacteria, yeast, mould fungi
802/29	Bacteria, yeast, mould fungi
802/30	Bacteria, yeast, mould fungi
802/31	HBsAg, HBsAg confirmation
802/32	Anti-HAV IgG, anti-HAV IgM, anti-HBs, anti-HBc, anti-HBc IgM, anti-HBe, anti-HCV, <i>Bordetella pertussis</i> ve třídě IgG a IgA, antibodies to <i>Treponema pallidum</i> total; <i>Toxoplasma gondii</i> in classes IgG a IgM

## List of activities within the flexible scope of accreditation

Field Nr. / Ordinal Number	Detailed information on activities within the scope of accreditation
802/33	DNA HBV (Hepatitis B virus), RNA HCV (Hepatitis C virus), DNA CMV (Cytomegalovirus), DNA EBV (Epstein-Barr virus)
813/1	Antibodies against nuclear antigens (ANA IgG), antibodies against double-stranded DNA (anti-dsDNA IgG)
813/2	Antibodies against tissue transglutaminase in the classes IgA a IgG (anti-tTG IgA, anti-tTG IgG)
813/3	Antibodies against proteinase 3 (anti-PR3 IgG) and myeloperoxidase (anti-MPO IgG)
813/3	T lymphocytes (CD3+), Th lymphocytes (CD3+CD4+), Tc lymphocytes (CD3+CD8+), B lymphocytes (CD19+), NK cells (CD3-CD16+CD56+)

### Explanatory notes:

<sup>1</sup> 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.