



List of activities within the flexible scope of accreditation

Accredited Body: Nemocnice Na Homolce
CAB Name: Department of Clinical Microbiology and Antibiotic Surveillance
CAB Number: 8160
Certificate of Accreditation No.: 617/2023
Field of Accreditation: Medical laboratory - ČSN EN ISO 15189:2013
Updated: 04/03/2024

Examinations:

Ordinal Number	Analyte/parameter/diagnostics	Principle of examination	Identification of method procedure/equipment	Examined material	Degrees of freedom ¹
802 – Medical Microbiology					
1.	Microbiological examination of upper respiratory tract	Aerobic cultivation	05_SOP_KMAS-kd_001, version 03; 05_SOP_KMAS-kd_007, version 03; 05_SOP_KMAS-kd_011, version 02; 05_SOP_KMAS-kd_017, version 02; 05_SPC_KMAS_035, version 06; 05_SPC_KMAS_070, version 01	Swab from throat, nose, nasopharynx, tonsils, pharynx, larynx	A, B, D
2.	Microbiological examination of lower respiratory tract	Microscopy; Aerobic cultivation	05_SOP_KMAS-kd_040, version 02; 05_SOP_KMAS-kd_042, version 03; 05_SOP_KMAS-kd_044, version 03; 05_SOP_KMAS-kd_046, version 02; 05_SPC_KMAS_035, version 06; 05_SPC_KMAS_070, version 01	Sputum, aspirate from the lower respiratory tract, BAL	A, B, D

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3.	Microbiological examination of a rectal swab	Aerobic cultivation	05_SOP_KMAS-kd_200, version 04; 05_SOP_KMAS-kd_201, version 04; 05_SPC_KMAS_035, version 06; 05_SPC_KMAS_070, version 01	Rectal swab, stool, stoma swab	A, B, D
4.	Quantitative microbiological examination of urine	Aerobic cultivation	05_SOP_KMAS-kd_240, version 05; 05_SPC_KMAS_035, version 06; 05_SPC_KMAS_070, version 01	Urine	A, B
5.	Microbiological examination of clinical material	Microscopy; Aerobic cultivation; Anaerobic cultivation	05_SOP_KMAS-kd_400, version 03; 05_SOP_KMAS-kd_520, version 03; 05_SPC_KMAS_035, version 06; 05_SPC_KMAS_070, version 01	Surgical wound swab, traumatic wound swab, pus, abscess pus, empyema pus, furuncle pus, carbuncle pus, cyst punctate, pseudocyst punctate	A, B, D
6.	Microbiological examination of primarily sterile body fluids	Microscopy; Aerobic cultivation; Anaerobic cultivation	05_SOP_KMAS-kd_440, version 03; 05_SOP_KMAS-kd_680, version 01; 05_SPC_KMAS_035, version 06; 05_SPC_KMAS_070, version 01	Cerebrospinal fluid (CSF), joint punctate, pleural punctate, pericardial effusion, ascites, dialysate	A, B, D

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7.	Microbiological examination of blood and primarily sterile body fluids	Aerobic cultivation; Anaerobic cultivation; (automatic)	05_SOP_KMAS-kd_480, version 03; 05_SOP_KMAS-kd_680, version 01; 05_SPC_KMAS_035, version 06; 05_SPC_KMAS_070, version 01; BacT/Alert 3D	Blood, cerebrospinal fluid (CSF), joint punctate, pleural punctate / effusion, ascites, dialysate	A, B, D
8.	Microbiological examination of foreign bodies	Aerobic cultivation; Anaerobic cultivation	05_SOP_KMAS-kd_640, version 03; 05_SOP_KMAS-kd_641, version 01; 05_SPC_KMAS_035, version 06; 05_SPC_KMAS_070, version 01	Cannula, catheter, drain, joint implant, electrode	A, B, D
9.	Qualitative examination of the sensitivity of microorganism	Diffusion disk test	05_SOP_KMAS-kc_001, version 04; Annex no. 1 to 05_SOP_KMAS-kc_001, version 03; 05_SPC_KMAS_035, version 06; 05_SPC_KMAS_070, version 01	Bacterial culture	A, B
10.	Quantitative examination of the sensitivity of microorganism	Microdilution method; E-test	05_SOP_KMAS-kc_001, version 04; Annex no. 1 to 05_SOP_KMAS-kc_001, version 03; 05_SOP_KMAS-kc_013, version 03; 05_SPC_KMAS_035, version 06; 05_SPC_KMAS_070, version 01	Bacterial culture	A, B

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11.	Identification of microorganism	Mass spectrometry	05_SOP_KMAS-ki_021, version 02; Microflex LT	Bacterial culture, yeast culture, filamentous fungus	A, B
12.	Reagin test (RPR)	Agglutination	05_SOP_KMAS-s_007, version 03	Serum, plasma	A, B
13.	Antigens of infectious agents	Immunoassay with luminometric detection	05_SOP_KMAS-s_012, version 02; 05_SOP_KMAS-s_010, version 04; Alinity i	Serum, plasma	A, B, C
14.	Antibodies against infectious agent	Immunoassay with luminometric detection	05_SOP_KMAS-s_013, version 03; 05_SOP_KMAS-s_014, version 03; 05_SOP_KMAS-s_015, version 02; 05_SOP_KMAS-s_017, version 02; 05_SOP_KMAS-s_018, version 02; Alinity i	Serum, plasma	A, B, C
15.	HIV markers	Immunoassay with luminometric detection	05_SOP_KMAS-s_016, version 02; Alinity i	Serum, plasma	A, B

Specification of the scope of accreditation:

Expertise/ ord. number	Detailed information on activities within the scope of accreditation
802/1	Bacteria, yeasts, filamentous fungi
802/2	Bacteria, yeasts, filamentous fungi
802/3	Bacteria, yeasts
802/4	Bacteria, yeasts
802/5	Bacteria, yeasts, filamentous fungi
802/6	Bacteria, yeasts, filamentous fungi
802/7	Bacteria, yeasts, filamentous fungi



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802/8	Bacteria, yeasts, filamentous fungi
802/13	HBsAg; confirmation of HbSAg
802/14	Anti HBs; Anti HAV in the IgM and IgG class; Anti HCV (Ig total); <i>Treponema pallidum</i> (Ig total)
802/15	Ab anti HIV 1,2 (Ig total) and Ag HIV p24

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.