Schedule of Accreditation

issued by

United Kingdom Accreditation Service

2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK



8857

Accredited to ISO 15189:2022

Mersey and West Lancashire Teaching Hospitals NHS Trust

Issue No: 019 Issue date: 06 February 2025

Department of Microbiology

Whiston Hospital

Warrington Road

Prescot L35 5DR Contact: Diane MartinBaez
Tel: +44 (0)151 290 4140

E-Mail: diane.martinBaez@sthk.nhs.uk

Website: www.sthk.nhs.uk

Testing performed by the Organisation at the locations specified below

Locations covered by the organisation and their relevant activities

Laboratory locations:

| Location details | | Activity | Location code |
|---|---|--|---------------|
| Microbiology Department Whiston Hospital Warrington Road Prescot L35 5DR | Local contact: Diane Martin Baez (details as above) | Bacteriology Virology Serology Molecular Diagnostics Andrology | STHK |
| Microbiology Department Southport and Formby District General Hospital Town Lane Kew Southport Merseyside PR8 6PN | Local contact: Diane Martin Baez (details as above) | Virology | SOHT |

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DETAIL OF ACCREDITATION

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location Code |
|---|---|--|------------------|
| HUMAN TISSUES AND FLUIDS | Microbiological examination activities for the purpose of clinical diagnosis | In-house documented procedures following current UKHSA Standards for Microbiological Investigations (SMIs) | |
| Routine samples - tissues and biopsies, mortuary samples, fluids from normally sterile sites, corneal scrapings, contact lens | General isolation and characterisation of microorganisms of clinical significance | Microbiological investigation including microscopy, manual culture and plate reading ID 23787 Inoculation of culture media ID 16291 Urgent Gram processing | STHK |
| Swabs (nasal, pernasal/nasopharyngeal, cough, throat, mouth, eye, ear, genital, wound, superficial wounds and skin, neonatal) | General isolation and characterisation of microorganisms of clinical significance | Microbiological investigation including microscopy (manual and automated staining) ProLab Polystainer, manual culture and plate reading 8489 Superficial and deep seated wound swab plating scheme ID 16725 Wounds Gram stain required ID 4042 Wound swabs, Skin superficial non-surgical abscesses and deep seated infections ID 2882 Genital tract and penile swabs plating scheme ID 7582 Genital tract and penile swabs bacteriology ID 16731 Genital bench Gram film reporting ID 9789 GUM bench duties | STHK |
| Respiratory samples - tracheal aspirates pleural fluid, bronchoalveolar samples, nasopharyngeal aspirates, | General isolation and characterisation of microorganisms of clinical significance | Microbiological investigation including microscopy, manual culture and plate reading ID 2884 Respiratory tract plating scheme ID 1023 Routine Respiratory specimen bacteriology | STHK |

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| | Type of test/Proportion | T | |
|---|---|---|------------------|
| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location Code |
| HUMAN TISSUES AND FLUIDS (cont'd) | Microbiological examination activities for the purpose of clinical diagnosis (cont'd) | In-house documented procedures following current UKHSA Standards for Microbiological Investigations (SMIs) | |
| Urine | General isolation and characterisation of microorganisms of clinical significance | Microbiological investigation including microscopy, manual culture and plate reading ID 694 Routine urine bacteriology | STHK |
| Ascitic fluids, synovial fluids, fluids from normally sterile sites | General isolation and characterisation of microorganisms of clinical significance | Microbiological investigation including microscopy, manual culture and plate reading ID19997 Quick guide Ascitic fluid neutrophil counts ID17945 Fluid processing | STHK |
| Bone, orthopaedic artificial material, intravascular cannulae, | General isolation and characterisation of microorganisms of clinical significance | Microbiological investigation including microscopy, manual culture and plate reading ID 16475 Bone soft tissue fluids intravenous tips and orthopaedic metal work plating scheme ID 17948 Bone and tissue flow diagram ID16506 Bone, soft tissues, fluids, tips and artificial material | STHK |
| CSF | General isolation and characterisation of microorganisms of clinical significance | Microbiological investigation including microscopy, manual culture and plate readingID1254 Routine CSF bacteriology | STHK |
| Sputum | General isolation and characterisation of microorganisms of clinical significance | Microbiological investigation including microscopy, manual culture and plate reading ID 7061 Sputum plating scheme ID 17950 Sputum and BAL processing flow chart ID 1020 Routine Sputum bacteriology | STHK |

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|-----------------------------------|--|--|------------------|
| HUMAN TISSUES AND FLUIDS (cont'd) | Microbiological examination activities for the purpose of clinical diagnosis (cont'd) | In-house documented procedures following current UKHSA Standards for Microbiological Investigations (SMIs) | |
| Blood and joint fluids | Bacterial growth detection of pathogenic organisms | BacT/Alert blood culture system ID 23891 BacT/ALERT blood culture ID 18576 Positive blood culture sample processing ID 1253 Blood culture bacteriology | STHK |
| Urine | Detection of red cells, white cells, epithelial cells, bacteria and yeasts | Investigation of urine by UF5000i by flow cytometry, microscopy and culture UF5000i by flow cytometry PREVI-Isola ID 6591 UF5000i Urine analyser ID 694 Routine urine bacteriology | STHK |
| Urine | Determination of antimicrobial susceptibility including direct susceptibility | Disc Diffusion (EUCAST method) ID 1250 Sensitivity testing | STHK |
| CSF | Detection, identification and quantification (including differential) of: White blood cells Red blood cells Bacterial and fungal cells | Investigation of cerebrospinal fluids Microscopy stained and unstained including Gram and differential) Cell count and differential using Kova slides ID1254 Routine CSF bacteriology ID 8170 Staining methods ID 735 Microscopy | STHK |
| Synovial fluids | Presence of crystals: Monosodium urate monohydrate (MSUM) Calcium Pyrophosphate Dihydrate (CPPD) | Microscopy - stained and unstained Cell count and differential using Kova slides ID 8170 Staining methods ID 735 Microscopy ID 16506 Bone, soft tissues, fluids, | STHK |
| Prosthetic Joint Fluids | Detection, identification and quantification (including differential) of: White blood cells | tips and artificial material ID 1005 Joint Fluid Preparation and Crystal Identification | |

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|--|---|---|------------------|
| HUMAN TISSUES AND FLUIDS (cont'd) | Microbiological examination activities for the purpose of clinical diagnosis (cont'd) | In-house documented procedures following current UKHSA Standards for Microbiological Investigations (SMIs) | |
| Ascitic fluid | Detection and quantification of White cells and differential reporting of Leucocyte count | Staining (Gram and differential) and microscopy Cell count and differential using Kova slides ID17945 Fluid processing ID19997 Quick guide Ascitic fluid neutrophil counts ID 735 Microscopy ID 8170 Staining methods | STHK |
| Sputum, Pleural fluid, bronchoalveolar samples (BAL), Tissue/Lymph nodes; Urgent samples only) | Screening and detection of acid-alcohol fast bacilli | ID 17945 Fluid processing ID 16506 Bone, soft tissues, fluids, tips and artificial material ID 17948 Bone and tissue flow diagram ID 735 Microscopy - Fluorescence ID 8170 Staining methods using Auramine phenol and Cold ZN ID 1020 Routine sputum bacteriology | STHK |
| Screening samples: Nasal, Throat, Perineum, Groin, Axillae, Nasal swab for hip & Knee replacement patients, Rectal, Wound swabs, CSU, Urine, Faeces, Sputum | MRSA screening Isolation of MRSA; MSSA; CPE; VRE; ESBL; Group A Streptococci | Manual culture and manual chromogenic culture ID 16313 Epidemiology plating scheme ID 2588 Epidemiological screening ID 17003 Associate Practitioner: Epidemiology screens | STHK |
| Faeces & Faecal microbiota transplant (FMT) Donor Testing | Detection of enteric pathogens | Nucleic acid testing DNA PCR Semi-automated procedure - Enteric bioreal PCR (Serosep) and Roche PCR Light cycler ID 22915 Faecal PCR Testing, Serosep | STHK |

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| HUMAN TISSUES AND FLUIDS (cont'd) | Microbiological examination activities for the purpose of clinical diagnosis (cont'd) | In-house documented procedures following current UKHSA Standards for Microbiological Investigations (SMIs) | |
| Faeces | Qualitative detection of H pylori antigen | Semi-automated procedure using amplified IDEIA HpStAR; ID 23894 H pylori faecal antigen testing ID 23958 Use of the DS2 | STHK |
| Faeces | Detection of Clostridium difficile toxins A and B and Clostridium difficile glutamate dehydrogenase (GDH) | ID 2253 CI. Difficile Testings TECHLAB® C. DIFF QUIK CHECK COMPLETE® test rapid membrane enzyme immunoassay (manual back up) | STHK |
| Faeces | Isolation and characterisation of enteric bacterial pathogens Salmonella sp. Shigella sp. Campylobacter sp. Escherichia coli O157 Vibrio spp. | Manual culture ID 693 Routine faeces bench ID 16728 Useful dates for processing faeces samples ID 20651 FMT Testing main lab record Staining & Microscopy ID 8170 Staining methods ID 735 Microscopy | STHK |
| Faeces | Giardia. Cryptosporidium | Staining & Microscopy ID 8170 Staining methods ID 735 Microscopy | STHK |
| Faeces | Rota/Adenovirus antigen detection | Werfen Biokit ID 693 Routine faeces bench | STHK |

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| HUMAN TISSUES AND FLUIDS (cont'd) | Microbiological examination activities for the purpose of clinical diagnosis (cont'd) | In-house documented procedures following current UKHSA Standards for Microbiological Investigations (SMIs) | |
| Bacterial and fungal isolates | Identification of micro- organisms -preliminary identification and automated identification of medically important bacteria and yeasts | Vitek MS (MALDI-TOF) and Vitek2 and manual identification Semi-automated method: ID 20487 Vitek MS and Vitek2 Sample Preparation Procedure ID 16959 Vitek sampling process flow chart Supporting bacterial identification SOPs ID 23890 Identification of Staphylococcus, Micrococcus and Rothia species ID 24852 Identification of Streptococci, Enterococci and related organisms ID 23889 Identification of Enterobacteriaceae ID 25312 Identification of Haemophilus species and the HACEK Group of Organisms ID 24965 Identification of Neisseria species ID 25674 Identification of Neisseria species ID 25676 Identification of Pasteurella species and morphologically similar organisms ID 23888 Identification of E.coli O157 ID 24993 Identification of Vibrio and Aeromonas species ID 24841 Identification of Salmonella species ID 24994 Identification of Yersinia species ID 24994 Identification of Yersinia species ID 24994 Identification of Corynebacterium species. | STHK |

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| HUMAN TISSUES AND FLUIDS (cont'd) | Microbiological examination activities for the purpose of clinical diagnosis (cont'd) | In-house documented procedures following current UKHSA Standards for Microbiological Investigations (SMIs) | |
| Bacterial and fungal isolates (cont'd) | Identification of micro- organisms -preliminary identification and automated identification of medically important bacteria and yeasts (cont'd) | Vitek MS (MALDI-TOF) and Vitek2 and manual identification Semi-automated method: ID 26318 Identification of Shigella species ID 26320 Identification of Bordetella species ID 744 Additional identification methods Microbiology ID 26321 Identification of Clostridium species ID 26322 Identification of aerobic actinomycetes ID 57 Identification of Bacillus species ID 26322 Identification of Moraxella species and morphologically similar organisms ID 23624 Identification of Pasteurella species and morphologically similar bacterial ID 26325 Identification of anaerobic cocci ID 26326 Identification of anaerobic Actinomyces species ID 26327 Identification of anaerobic Gram negative rods | STHK |

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| HUMAN TISSUES AND FLUIDS (cont'd) | Microbiological examination activities for the purpose of clinical diagnosis (cont'd) | In-house documented procedures following current UKHSA Standards for Microbiological Investigations (SMIs) | |
| Bacterial isolates | Antimicrobial susceptibility testing of micro-organisms | Determination of Antimicrobial Susceptibility by Disc Diffusion based on EUCAST Guidelines also gradient MIC (etest) and Automated MIC (Vitek 2) EUCAST (manual disc /strip diffusion) Broth dilution MIC testing for colistin sensitivity on Enterobacteriaceae, Pseudomonas and Acinetobacter species ID 16644 Associate Practitioner Disc diffusion sensitivity ID 1250 Sensitivity testing ID 745 MIC using E test strips ID 1251 Detection of Extended-Spectrum β-Lactamases (ESBL) and AmpC Semi-automated method: ID 20487 Vitek MS and Vitek2 Sample Preparation Procedure ID 16959 Vitek sampling process flow chart ID 1250 ID16644 | STHK |
| Hair, Nail Skin, Sputum, BAL | Examination and general isolation and characterisation of fungal organisms of clinical significance | Manual inoculation, media culture, and macroscopic & Fluorescence microscopic examination (stained & unstained) using: ID 20650 Routine Mycology ID 735 Microscopy ID 8170 Staining methods ID 1020 Routine sputum bacteriology | STHK |

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| HUMAN TISSUES AND FLUIDS (cont'd) | Microbiological examination activities for the purpose of clinical diagnosis (cont'd) | In-house documented procedures following current UKHSA Standards for Microbiological Investigations (SMIs) | |
| Faeces, urine and perianal sellotape slides | Detection of clinically significant faecal ova, cysts and parasites | Parasep Concentration method, direct examination and microscopy ID 693 Routine faeces bench ID 735 Microscopy ID 8170 Staining methods ID 694 Routine urine bacteriology | STHK |
| Blood | Therapeutic Drug Monitoring: Teicoplanin | Indiko Plus Analyser by turbidimetric immunoassay ID 44944 | STHK |
| HUMAN BODY FLUIDS | Serological examination activities for the purpose of clinical diagnosis | Following in-house documented procedures | |
| Serum | Detection of Measles IgG antibody, Mumps IgG antibody, Toxoplasma IgM/IgG antibody VZV IgG antibody CMV IgG/IgM antibody EBV IgG/IgM antibody Rubella IgG antibody Lymes IgG/IgM antibody to Borrelia burgdorferi | BioMerieux VIDAS3 analyser Immunoassays using enzyme linked fluorescent assay ID 9526 Routine serology ID 23634 Use of VIDAS3 | STHK |
| Serum | Detection of Parvovirus | Semi-automated procedure ID 23958 Use of the DS2 ID 9526 Routine serology ID 23895 Parvovirus B19 IgM and IgG | STHK |
| Serum | Quantitative detection of anti - streptolysin O (ASL) | Biokit rheumajet ASO ID 9526 Routine serology | STHK |
| Urine | Detection of soluble Pneumococcal urinary antigen | Binax Now kit by Alere Lateral flow device ID 4595 Detection of Pneumococcal antigens in urine | STHK |

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| HUMAN BODY FLUIDS | Serological examination activities for the purpose of clinical diagnosis | Following in-house documented procedures | |
| Urine | Detection of Legionella pneumophila serotype 1 antigen | Binax Now kit by Alere Lateral flow device ID 4595 Detection of Legionella antigen in urine Documented in-house methods to meet the requirements of the IDPS screening programme(s) as defined in the July 2018 'Infectious diseases in pregnancy screening: Laboratory QC evidence requirements (relevant tests marked with *) | STHK |
| Blood, serum | Detection of: HIV antigen/antibody* (HIV-antibodies, HIV-2 antibodies, p24 antigen) HBV surface antigen* HBV surface antibody HBV core antibody HCV antibody Hepatitis A IgM antibody Total Hepatitis A antibody Syphilis IgG & IgM antibody* | Siemens Atellica (Spectrophotometry) System ID 43976 Serology Biochemistry ID 8655 Routine Serology ID 9526 | STHK |

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| HUMAN BODY FLUIDS (cont'd) | Molecular diagnostic examination activities for the purpose of clinical diagnosis | Following in-house documented procedures | |
| Urines and genital swabs, screening samples from national screening programme | Chlamydia trachomatis and Neisseria gonorrhoeae rRNA and confirmation by secondary probes | Hologic Panther Aptima Combo 2 assay Molecular: transcription mediated amplification of the RNA target detected by hybridisation and real time fluorescence ID 14142 Detection of Chlamydia trachomatis and Neisseria gonorrhoeae by nucleic acid amplification test (NAAT) | STHK |
| Bacterial culture isolates | Staphylococcus aureus (SA) and methicillin-resistant Staphylococcus aureus (MRSA); detection and differentiation of the blaKPC, blaNDM, blaVIM, blaOXA-48, and blaIMP-1 gene sequences associated with carbapenemnonsusceptibility in gramnegative bacteria (CPE) used for confirmation | Cepheid GeneXpert ID 24499 Cepheid | STHK |
| Swabs, blood culture samples Faeces | MRSA, MSSA Detection of norovirus | Cepheid GeneXpert ID 24499 Cepheid PCR ID 1253 Blood culture Bacteriology ID 18576 Positive blood culture sample processing | STHK |

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| HUMAN BODY FLUIDS (cont'd) | Molecular diagnostic examination activities for the purpose of clinical diagnosis | Following in-house documented procedures | |
| | (cont'd) | Hologic Panther Aptima assay Molecular: transcription mediated amplification of the RNA target detected by hybridisation and real time fluorescence | STHK |
| Anogenital skin lesions | HSV I/II | ID 38789 | |
| Endocervical swabs, vaginal swabs and female urine | Trichomonas vaginalis | ID 38828 | |
| Endocervical swabs, vaginal swabs, female urine, male urethral swabs, penile swabs and male urine | Mycoplasma genitalium | ID 38827 | |
| Nasopharyngeal Aspirates and Nose/Throat swabs in VTM | Influenza A, influenza B, Respiratory syncytial virus (RSV) viral RNA, | Cepheid GeneXpert Cepheid PCR Xpert® Xpress Flu/RSV (Ref XPRSFLU/RSV-CE-10 ID 24499 | STHK |
| Nose and Throat Swabs in VTM | Detection of SARS CoV-2 virus RNA (COVID-19) specific gene sequences: E, N2 | Cepheid GeneXpert Cepheid PCR Xpert® Xpress SARS-CoV-2 (Ref XPRSARS-COV2-10) ID 24499 | STHK |
| Nose and Throat Swabs in VTM | Detection of SARS CoV-2 virus RNA (COVID-19) specific gene sequences: E, N2 | Cepheid GeneXpert Cepheid PCR Xpert® Xpress SARS-CoV-2 (Ref XPRSARS-COV2-10) ID 44369 | SOHT |
| Nose and Throat Swabs in VTM | Detection of: Influenza A Influenza B RSV viral RNA | Cepheid GeneXpert Cepheid PCR Xpert® Xpress Flu/RSV ID 44369 | SOHT |
| Faeces | Detection of <i>Clostridium</i> difficile toxins A and B | Nucleic acid testing using PCR Cepheid GeneXpert ID 2253 Cl. difficile Testings | STHK |

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| HUMAN BODY FLUIDS (cont'd) | Molecular diagnostic examination activities for the purpose of clinical diagnosis (cont'd) | Following in-house documented procedures | |
| Nose and Throat Swabs in VTM | Detection of SARS CoV-2 virus RNA (COVID-19) specific gene sequences: ORFab region 1 and 2 | Hologic Panther Aptima Fusion using Aptima Fusion SARS-CoV-2 Assay kit by target capture-transcription-mediated amplification (TMA), and dual kinetic assay (DKA) SOP48306 Aptima SARS CoV2 Panther assay | STHK |
| Nose and Throat Swabs in VTM | Detection of SARS CoV-2 virus RNA (COVID-19) specific gene sequences: ORFab and N | SAMBA II Sars Cov2 PCR test SOP 51659 SAMBA II SARS CoV 2 PCR assay. | STHK SOHT |
| Faeces | Detection of <i>C. difficile</i> toxin B gene (tcdB) | EntericBio realtime® (Serosep) PCR ID 2253 Cl. Difficile Testings | STHK |
| CSF Excludes samples from immunocompromised patients | Detection of the following microorganisms using the Meningitis/Encephalitis panel: Escherichia coli K1 Haemophilus influenzae Listeria monocytogenes Neisseria meningitidis Streptococcus agalactiae Streptococcus pneumoniae Cryptococcus gattii/neoformans Cytomegalovirus Herpes simplex virus 1 Herpes simplex virus 2 Human herpesvirus 6 Enterovirus Human parechovirus Varicella zoster virus | Biomerieux Biofire Film Array using multiplexed nucleic acid detection (PCR) ID 37879 | STHK |

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| HUMAN BODY FLUIDS (cont'd) | Molecular diagnostic examination activities for the purpose of clinical diagnosis (cont'd) | Following in-house documented procedures | |
| Sputum/ Tracheal Aspirates/ Bronchial Lavage | Extended respiratory panel: Viruses Adenovirus Coronavirus HKU1 Coronavirus NL63 Coronavirus OC43 Human Metapneumovirus Human Rhinovirus/Enterovirus Influenza A Influenza B MERS CoV Parainfluenza Virus 1-4 Respiratory Syncytial Virus Bacteria Bordetella parapertussis Bordetella pertussis Atypical Chlamydia pneumoniae Mycoplasma pneumoniae | Biomerieux Biofire Film Array using multiplexed nucleic acid detection (PCR) ID 37879 | STHK |

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| HUMAN BODY FLUIDS (cont'd) | Molecular diagnostic examination activities for the purpose of clinical diagnosis (cont'd) | Following in-house documented procedures | |
| Sputum/ Tracheal Aspirates/ Bronchial Lavage | Pneumonia Panel: Viruses Adenovirus Coronavirus Human Metapneumovirus Human Rhinovirus/Enterovirus Influenza A Influenza B Middle East Respiratory Syndrome Coronavirus (MERS-CoV) Parainfluenza Virus Respiratory Syncytial Virus Atypicals Chlamydophila pneumoniae Mycoplasma pneumoniae Legionella pneumophila Resistant Markers mecA/C and MREJ KPC NDM OXA48 VIM IMP CTX-M (ESBL) | Biomerieux Biofire Film Array using multiplexed nucleic acid detection (PCR) ID 37879 | STHK |

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| HUMAN BODY FLUIDS (cont'd) | Molecular diagnostic examination activities for the purpose of clinical diagnosis (cont'd) | Following in-house documented procedures | |
| Sputum/ Tracheal Aspirates/ Bronchial Lavage (cont'd) | Pneumonia Panel (cont'd): Bacteria Acinetobacter complex Bordetella pertussis Enterobacter cloacae complex Escherichia coli Haemophilus influenza Klebsiella aerogenes Klebsiella oxytoca Klebsiella pneumonia group Syndrome Coronavirus Moraxella catarrhalis Proteus spp. Pseudomonas aeruginosa Staphylococcus aureus Streptococcus agalactiae Streptococcus pneumoniae Streptococcus pyogenes | Biomerieux Biofire Film Array using multiplexed nucleic acid detection (PCR) ID 37879 | SteiTHK |

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| HUMAN BODY FLUIDS (cont'd) | Andrological examination activities for the purpose of clinical diagnosis | Following in-house documented procedures | |
| Semen | Post vasectomy Detection of sperm Sperm concentration | Based on 2016 Laboratory guidelines for post vasectomy semen analysis: Association of Biomedical Andrologists, the British Andrology Society and the British Association of Urological Surgeons) Manual method using wet prep and centrifugation and documented inhouse procedure ID 691 Semen analysis | STHK |
| Semen | Fertility testing | Based on WHO laboratory manual for the examination and processing of human semen (Sixth edition 2021) and manual method / documented in-house procedure ID 691 Semen analysis | STHK |
| | Volume | Volume / weight | |
| | рН | Colorimetric strips | |
| | Sperm morphology including TZI scoring | Stained slides (Papanicolaou) microscopy (Bright Field) | |
| | Sperm concentration | Improved Neubauer Cell counting chambers and Microscopy (phase contrast) | |
| | Sperm motility | Microscopy (Phase contrast) | |
| | Sperm Vitality | Stained slide (Eosin/Nigrosin dye exclusion test) microscopy (Bright field) | |
| Semen | Fertility testing Sperm concentration | CASA SAMi (Pro-creative Diagnostics Ltd) Semi automated semen analysis and documented | STHK |
| | Sperm motility | procedure ID 691 Semen analysis | |
| END | | | |

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