# Schedule of Accreditation

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## Norfolk & Norwich University Hospitals NHS Foundation Trust

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**Testing performed at the above address only**

DETAIL OF ACCREDITATION

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used |
|---|---|---|
| HUMAN BODY TISSUE AND FLUIDS | Histopathological examination activities for the purposes of clinical diagnosis | |
| Fixed and fresh tissue, excisional and incisional biopsies and surgical resection specimens | Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis | Macroscopic and Microscopic examination supported by documented in house methods incorporating manufacturers' instructions where relevant:<br>Specimen dissection:<br>HIS.CUT.P.1& 7<br>HIS.LT.P.1&2 |
| Calcified Tissue samples | | Decalcification of bony samples to allow subsequent histopathological examination:<br>HIS.CUT.P.09A<br>HIS.CUT.P.11 |
| Fixed and fresh tissue, excisional and incisional biopsies and surgical resection specimens | | Macroscopic tissue description, dissection and creation of 'block' size pieces for processing:<br>HIS.BD.P.1-6<br>HIS.MED.P.04 |
| Fixed and fresh tissue, excisional and incisional biopsies and surgical resection specimens | | Routine Paraffin Wax (Xylene and IPA based) processing and tissue sectioning:<br>Leica Peloris & Tissue TEK VIP Tissue Processors<br>Leica HistoCore Multicut Microtomes<br>Leica H&E, following in house procedures:-<br>HIS.PR.P.02<br>HIS.BL.P.01<br>HIS.BL.P.02 |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used |
|---|---|---|
| HUMAN BODY TISSUE AND FLUIDS (cont'd) | Histopathological examination activities for the purposes of clinical diagnosis (cont'd) | Macroscopic and Microscopic examination supported by documented in house methods incorporating manufacturers' instructions where relevant: |
| Fresh tissue, excisional and incisional biopsies and surgical resection specimens | | Cryostar NX70<br>Routine Frozen Sections following in house procedures:-HIS.FS.P.01 |
| Fresh tissue, excisional and incisional biopsies and surgical resection specimens | | , Cryostar NX70<br>MOHs Frozen Sections following in house procedures:- HIS.FS.P.06 |
| Fixed and frozen tissue prepared as above | Visualisation of nuclear detail in cells | Automated Haematoxylin and Eosin stain:<br>Leica Autostainer 5020 with Coverslipper CV5030 module, following in house procedures:- HIS.SL.P.1-2 |
| Fixed tissue prepared as above | Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis | Manual special stains - |
| | Demonstration of: | |
| | Mucins | AB PAS/+-D/Hales<br>Mucicarmine HIS.SS.P.1,2,16,21,25 & 26 |
| | Acid Mucins | Alcian Blue. |
| | Amyloid | Alkaline<br>Congo red,<br>HIS.SS.P.4 &31 |
| | Elastin | Elastin van Gieson,<br>Elastin Picro Sirius red<br>HIS.SS.P.8 |
| | Haemopoetic tissue | Giemsa<br>HIS.SS.P.11 |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used |
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| HUMAN BODY TISSUE AND FLUIDS (cont'd) | Histopathological examination activities for the purposes of clinical diagnosis (cont'd) | Microscopic examination supported by documented in house methods incorporating manufacturers' instructions where relevant: |
| Fixed tissue prepared as above (cont'd) | Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd) | Manual special stains:- |
| | Demonstration of: (cont'd) | |
| | Diferentiation of gram positive and gram negative bacteria | Gram<br>Gram twort<br>HIS.SS.P.12 & 13 |
| | Connective Tissue | Haematoxylin van Gieson<br>HIS.SS.P.38 |
| | Fibrin | Martius Scarlet Blue<br>HIS.SS.P.18 |
| | Melanin pigment | Masson Fontana,<br>Schmorl's Ferricyanide<br>HIS.SS.P.19&34 |
| | Fungi | Microwave Grocott<br>PAS+D<br>HIS.SS.P.15 |
| | Lipid droplets | Oil red 'o'<br>HIS.SS.P.22 |
| | Glycogen (and other PAS +ve substances) | PAS+/- Diastase<br>HIS.SS.P.25 & 26 |
| | Basement membranes | PAS+Diastase,<br>PA Silver<br>HIS.SS.P.23 & 26 |
| | Haemosiderin pigment | Perl's Stain<br>HIS.SS.P.27 |
| | Asbestos Fibres | Perls Stains<br>HIS.SS.P.28 |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used |
|---|---|---|
| HUMAN BODY TISSUE AND FLUIDS (cont'd) | Histopathological examination activities for the purposes of clinical diagnosis (cont'd) | Microscopic examination supported by documented in house methods incorporating manufacturers' instructions where relevant: |
| Fixed tissue prepared as above (cont'd) | Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd) | Manual special stains:- |
| | Demonstration of: (cont'd) | |
| | Reticulin Fibres | CopperHIS.SS.P.32 |
| | Copper Associated Protein | Shikata's Orcein HIS.SS.P.35 |
| | Calcium Salts | Von Kossa van Gieson HIS.SS.P.39 |
| | Detection of: | Immunohistochemistry by detection of antigens using DAKO 48 Stainer: HIS.IM.P.25 |
| Formalin Fixed paraffin processed material | Non-small cell lung cancer PD-L1 expression | PD-L1 (clone 22C3) |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used |
|---|---|---|
| HUMAN BODY TISSUE AND FLUIDS (cont'd) | Histopathological examination activities for the purposes of clinical diagnosis (cont'd) | Microscopic examination supported by documented in house methods incorporating manufacturers' instructions where relevant: |
| Fixed tissue prepared as above (cont'd) | Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd) | Immunohistochemistry by detection of antigens using Leica Bond IIIAutostainers: HIS.IM.P.01-15 |
| | Demonstration of: | |
| | Basal Cells | 34 BE12 |
| | Endocrine Tissue | ACTH |
| | Pan Cytokeratin | AE1/AE3 |
| | Lymphoma/Non-Small Cell Lung Carcinoma | ALK1 |
| | Prostate grading | AMACR (Racemase) |
| | Amyloid A | Amyloid A |
| | Salivary Gland Tumour | Androgen |
| | Hepatocellular Carcinoma | Arginase-1 |
| | Malignant Mesothelioma | BAP 1 |
| | Melanoma BRAF Mutations | BRAF v600E |
| | Lymphoma/Skin Tumours | bcl-2 |
| | Lymphoma | bcl-6 |
| | Basal Cell Tumours | BER EP4 |
| | Renal Transplant rejection | C4 d |
| | Gynae Carcinoma | Ca 125 |
| | Gastrointestinal Carcinomas | CA19.9 |
| | Endocrine tissue | Calcitonin |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used |
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| HUMAN BODY TISSUE AND FLUIDS (cont'd) | Histopathological examination activities for the purposes of clinical diagnosis (cont'd) | Microscopic examination supported by documented in house methods incorporating manufacturers' instructions where relevant: |
| Fixed tissue prepared as above (cont'd) | Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis | Immunohistochemistry by detection of antigens using Leica Bond III Autostainers: HIS.IM.P.01-15 |
| | Demonstration of: (cont'd) | |
| | Mesothelial cells | Calretinin |
| | Renal cell carcinoma | Carbonic Anhydrase IX (CA9) |
| | Translocation renal cell carcinomas and Micro-granulomas | Cathepsin K |
| | Lymphoma | CD 2, CD1a, CD20, CD21, CD23, CD3, CD4, CD44, CD5, CD61, CD7, CD79a, CD8, CD6, |
| | Lymphoma/Renal Tumour | CD10, CD15 |
| | Mast Cells /GIST | CD117 (C-KIT) |
| | Lymphoma/Germ Cell Tumour | CD30 |
| | Endothelial Cells | CD31 |
| | Endothelial Cells / GIST | CD34 |
| | Neuroendocrine/Lymphoma | CD56(N-cam) |
| | Monocytes | CD68 |
| | Sarcoma/Genital Tract Tumour | CD99 |
| | Sarcoma Typing | CDK4 |
| | Adenocarcinoma Typing | CEA |
| | Neuroendocrine Cells | CEA |
| | Pagets Disease | C-erb 2 |
| | Neuroendocrine Cells | Chromagranin A |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used |
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| HUMAN BODY TISSUE AND FLUIDS (cont'd) | Histopathological examination activities for the purposes of clinical diagnosis (cont'd) | Microscopic examination supported by documented in house methods incorporating manufacturers' instructions where relevant: |
| Fixed tissue prepared as above (cont'd) | Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd) | Immunohistochemistry by detection of antigens using Leica BondIII Autostainers: HIS.IM.P.01-15 |
| | Demonstration of: (cont'd) | |
| | Basal Cells/Carcinoma Invasion | CK 5 |
| | Adenocarcinoma typing | CK 7 |
| | Pan Cytokeratin | CK(MNF116) |
| | Basal Cells/Carcinoma Invasion | CK14 |
| | Basal/Immature epithelium | CK17 |
| | Adenocarcinoma Typing | CK20, CK8/18 (CAM 5.2) |
| | Lymphoma | C-Myc |
| | Cytomegalo Virus Infection | CMV |
| | Basement membranes | Collagen IV |
| | Myocardial Infarction | Complement C9 |
| | Lymphoma | Cyclin D1 |
| | Lymphatics | D2 40 |
| | Muscle related intermediate filaments | DESMIN |
| | Tumour grading | IMP 3 |
| | Breast Cancer Differentiation | E-Cadherin |
| | Adenocarcinoma / mesothelioma / Squamous Cell carcinoma | EMA |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used |
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| HUMAN BODY TISSUE AND FLUIDS (cont'd) | Histopathological examination activities for the purposes of clinical diagnosis (cont'd) | Microscopic examination supported by documented in house methods incorporating manufacturers' instructions where relevant: |
| Fixed tissue prepared as above (cont'd) | Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd) | Immunohistochemistry by detection of antigens using Leica Bond IIIAutostainers: HIS.IM.P.1-15 |
| | Demonstration of: (cont'd) | |
| | Breast/Gynae Tumour Tamoxifen grading | ER |
| | Sarcoma | ERG |
| | Fibrohistocytic Tumour | Factor 13 |
| | Endothelial cells | FACTOR 8 |
| | Fibrinogen | Fibrinogen |
| | Carcinoma | GATA-3 |
| | Adenocarcinoma Typing (Breast/Salivary Gland) | GCDFP 15 |
| | Brain Tumours | GFAP |
| | Endocrine Tumours | Glucagon |
| | Lymphoma | Glycophorin |
| | Hepatocellular carcinoma | Glutamine Synthetase |
| | Lymphoma | Granzyme |
| | Sarcoma Typing | h-Caldesmon |
| | Hep B virus | Hep B core Ag |
| | Hep B Virus | Hep B surface Ag |
| | Clear cell carcinoma | HNF-1B |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used |
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| HUMAN BODY TISSUE AND FLUIDS (cont'd) | Histopathological examination activities for the purposes of clinical diagnosis (cont'd) | Microscopic examination supported by documented in house methods incorporating manufacturers' instructions where relevant: |
| Fixed tissue prepared as above (cont'd) | Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd) | Immunohistochemistry by detection of antigens using Leica Bond III Autostainers: HIS.IM.P.1-15 |
| | Demonstration of: (cont'd) | |
| | Lymphoma/Mastocytosis | Mast Cell Tryptase |
| | Hepatocytes (tumours) | Hepatocyte |
| | Herpes Virus | Herpes virus |
| | Germ Cell Tumours | HCG |
| | Human Herpes Virus 8 / Kaposi's Sarcoma<br>H. pylori | HHV8<br>HLO (H.pylori) |
| | Melanoma | HMB 45 |
| | Lymphoma/Renal Disease | IgG |
| | Gynae Tumours | Inhibin |
| | Endocrine tissue | Insulin |
| | Lymphoma | Kappa / Lambda B Cell |
| | Proliferation Marker | Ki-67 (MIB-1) |
| | Lymphoma/Autoimmune Diseases | Kappa / Lambda Plasma Cell |
| | Basement Membrane | Laminin |
| | Lymphoma | LCA (CD45) |
| | Monocytes | MAC 387 |
| | Melanoma | Melan A |
| | Liposarcoma | MDM2 |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used |
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| HUMAN BODY TISSUE AND FLUIDS (cont'd) | Histopathological examination activities for the purposes of clinical diagnosis (cont'd) | Microscopic examination supported by documented in house methods incorporating manufacturers' instructions where relevant: |
| Fixed tissue prepared as above (cont'd) | Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd) | Immunohistochemistry by detection of antigens using Leica Bond III Autostainers: HIS.IM.P.01-15 |
| | Demonstration of: (cont'd) | |
| | Melanoma/Salivary Gland Tumour | MITF |
| | Adenocarcinoma Typing | Muc-1 |
| | Sarcoma | MUC 4 |
| | Adenocarcinoma Typing | MUC-5AC |
| | Lymphoma | MUM-1 |
| | Lymphoma | Myeloperoxidase |
| | Myogenic Tumour | MyoD |
| | Myogenic Tumour | Myogenin |
| | Myogenic Tumour | Myoglobin |
| | Myogenic Tumour | Myosin |
| | Neural Crest Tumour | N-Cadherin |
| | Germ Cell Tumours | OCT3/4 |
| | Neural Crest Tumour | NFP |
| | Prostate adenocarcinoma | NKX3.1 |
| | Neuroendocrine Cells | NSE |
| | Tumour Grading (Gynae, Head & Neck) | P16 |
| | Tumour Grading (Gynae Upper GI) | P53 |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used |
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| HUMAN BODY TISSUE AND FLUIDS (cont'd) | Histopathological examination activities for the purposes of clinical diagnosis (cont'd) | Microscopic examination supported by documented in house methods incorporating manufacturers' instructions where relevant: |
| Fixed tissue prepared as above | Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis | Immunohistochemistry by detection of antigens using Leica Bond III Autostainers: HIS.IM.P.01-15 |
| | Demonstration of: (cont'd) | |
| | Myoepithelial Cells- Invasion Squamous Cell Carcinoma | P63 |
| | Parathyroid | Parathyroid |
| | Parvovirus | Parvovirus |
| | Germ Cell Tumours | PLAP |
| | Endometrial hyperplasia | PAX2 |
| | Pneumocystis | PNC (PCP) |
| | Breast Tumour (Tamoxifen treatment) | PR |
| | Melanoma | PRAME |
| | Prostate Tumour | PSA |
| | Endometrial hyperplasia | PTEN |
| | Renal Tumour | RCC |
| | Neural Crest derived cells/Tumours | S100 |
| | Colorectal carcinoma | SAT B 2 |
| | Smooth Muscle and Tumours | SMA |
| | Myoepithelial Cells Invasion | SMM-HC |
| | Endocrine Tissue | Somatostatin |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used |
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| HUMAN BODY TISSUE AND FLUIDS (cont'd) | Histopathological examination activities for the purposes of clinical diagnosis (cont'd) | Microscopic examination supported by documented in house methods incorporating manufacturers' instructions where relevant: |
| Fixed tissue prepared as above (cont'd) | Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd) | Immunohistochemistry by detection of antigens using Leica Bond III Autostainers: HIS.IM.P.1-15 |
| | Demonstration of: (cont'd) | |
| | Solitary Fibrous Tumours | STAT6 |
| | JC / BK virus | SV-40 |
| | Neuroendocrine cells | Synaptophysin |
| | Lymphoma | TdT |
| | Endothelial/Mesothelium | Thrombomodulin |
| | Thyroid Tumour | Thyroglobulin |
| | Lymphoma | TIA-1 |
| | Translocation renal cell carcinomas | TFE3 |
| | Synovial Sarcoma | TLE1 |
| | Lung / Thyroid Tumours | TTF1 |
| | Sarcoma | Vimentin |
| | Lymphoma / Plasma Cells | CD138 |
| | Mesothelioma/Ovarian Serous Adenonocarcinoma | WT-1 |
| | Germ Cell Tumours | α FP |
| | Hepatitis | α1AT |
| | Colorectal Adenocarcinoma | ß catenin |
| | Myoepithelial Cells / Invasion | Calponin |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used |
|---|---|---|
| HUMAN BODY TISSUE AND FLUIDS (cont'd) | Histopathological examination activities for the purposes of clinical diagnosis (cont'd) | Microscopic examination supported by documented in house methods incorporating manufacturers' instructions where relevant: |
| Fixed tissue prepared as above (cont'd) | Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd) | Immunohistochemistry by detection of antigens using Leica Bond III Autostainers: HIS.IM.P.1-15 |
| | Demonstration of: (cont'd) | |
| | Lymphoma | CD25 |
| | GI Tract Tumours | CDX2 |
| | GIST | DOG-1 |
| | Epstein Barr Virus | EBER |
| | Auto immune disease | IgG4 |
| | Mycobacterium | M-Bovis |
| | Adenocarcinoma Typing | Muc-2 |
| | Hydatidyform moles | P57 |
| | Breast/ Salivary Gland Adenocarcinoma | Mammaglobin |
| | HNPCC | MSI Markers (MSH2, MSH6, MLH1 and PMS2) |
| | Lung Adenocarcimoa | Napsin A |
| | Spirochetes | Spirochete |
| | Prostate cancer | CK5 / AMACR (double) |
| | Upper GI Lesions | P53 / IMP3 (double) |
| | Squamous Cell Carcinoma | P 40 |
| | Renal /Ovarian Serous Adenocarcinoma | PAX 8 |
| | Mesothelioma | SOX 10 |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used |
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| HUMAN BODY TISSUE AND FLUIDS (cont'd) | Histopathological examination activities for the purposes of clinical diagnosis (cont'd) | Microscopic examination supported by documented in house methods incorporating manufacturers' instructions where relevant: |
| Fixed tissue prepared as above (cont'd) | Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd) | Immunohistochemistry by detection of antigens using Leica Bond III Autostainers: HIS.IM.P.1-15 |
| | Demonstration of: (cont'd) | |
| | Breast Tumour Her 2 status | Her 2 |
| Tissue samples and cell blocks | Demonstration of: | ISH Probes demonstrated using a combination of a pre treatment and the Leica Bond III detection system according to in house procedures HIS.IM.P.01-11 based on manufacturers instructions and guidelines and incorporating the following probes: |
| | Antibody light chains | kappa/lambda |
| | Epstein Barr virus | EBV |
| Fixed breast tissue | HER 2 gene amplification | Leica HER2 FISH System for BOND Following in house procedure HIS.IM.P.14 based on manufacturers instructions and guidelines |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used |
|---|---|---|
| HUMAN BODY TISSUE AND FLUIDS (cont'd) | Histopathological examination activities for the purposes of clinical diagnosis (cont'd) | Microscopic examination supported by documented in house methods incorporating manufacturers' instructions where relevant: |
| Slides prepared as above | Morphological assessment and interpretation/diagnosis. | HIS.MED.P.01 Guidelines for Reporting in Histopathology<br>HIS.MED.P.02 Consultant Discrepancy, Incident and Near Miss Recording<br>HIS.MED.P.09 Histopathology Reporting in Cervical Cytology<br>HIS.MED.P.10 Histopathology Reporting of Gynaecological Cancers<br>HIS.MED.P.11 Histopathology Reporting of Bowel Cancer Screening<br>HIS.MED.P.12 Histopathology Reporting of Renal Biopsies<br>HIS.MED.P.13 Histopathology Reporting of Colorectal Tumours<br>HIS.MED.P.14 Histopathology Reporting in Uropathology<br>HIS.MED.P.15 Histopathology Reporting of Thyroid and Parathyroid<br>HIS.MED.P.16 Histopathology Reporting in Breast Pathology<br>HIS.MED.P.17 Histopathology Reporting of Upper Gastrointestinal Tumours<br>HIS.MED.P.18 Histopathology Reporting of HepatobiliaryTumours<br>HIS.MED.P.19 Histopathology Reporting of Skins |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used |
|---|---|---|
| HUMAN BODY TISSUE AND FLUIDS (cont'd) | Histopathological examination activities for the purposes of clinical diagnosis (cont'd) | Microscopic examination supported by documented in house methods incorporating manufacturers' instructions where relevant: |
| Digital images from slides prepared in house for H&E, special stains and IHC tests. | Onsite Morphological assessment and interpretation/diagnosis | Philips Ultra-Fast Scanners (FMT0351/03489),<br><br>Leica Aperio GT450 (45253)<br><br>3D HISTECH P1000 (P100021F1601) slide scanners<br><br>HIS.DIG.P.02 use of scanning machines |
| Digital images from slides prepared in house for H&E, special stains and IHC tests. | Onsite Morphological assessment and interpretation/diagnosis.<br><br>Molecular Pathology examination activities for the purposes of clinical diagnosis: | Onsite Digital Slide Reporting |
| Fixed tissue prepared as above | Detection of mutations:<br>BRAF<br>KRAS<br>NRAS<br>EGFR | Real time PCR using Biocartis Idylla SystemHIS.IM.P.21 Tumour Mutation Analysis on the Idylla System |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used |
|---|---|---|
| HUMAN BODY TISSUE AND FLUIDS (cont'd) | <u>Cytological examination activities for the purposes of clinical diagnosis:</u> | |
| Cervical/vaginal cells (Liquid Based Cytology/LBC sample) | Preparation and screening to identify or exclude gynae-cytological abnormalities for the purpose of diagnosis | Use of ThinPrep T5000, Prisma Stainer & Coverslipper according to in house procedures:-<br>C.SR.P.408 – Minimum Standards for Acceptance of Cervical Samples & Requests<br>C.SR.P.407 – Checking & Labelling Vials & Forms<br>C.SR.P.415 – Operation of the Cytyc ThinPrep 5000<br>C.SR.P.421 – Operation of the Prisma Staining & Coverslipper<br>C.SR.P.424 – Papanicolaou Staining Protocol<br>C.SR.P.405 – Rejection of Samples Taken Outside Recommended Recall Intervals |
| Cervical/vaginal cells (Liquid Based Cytology/LBC sample) | Morphological assessment and interpretation/diagnosis | Microscopy. according to in house procedures:-<br>C.SC.P.801 – Primary Screening of LBC Samples<br>C.SC.P.806 – Standardised Reporting<br>C.SC.P.805 – Computer (LabTrak) Reporting of Cervical Samples |
| Cervical/vaginal cells (Liquid Based Cytology/LBC sample) | Detection of High-Risk Human Papilloma Viral (HR HPV) DNA | Real Time PCR amplification and detection using Roche Cobas 6800 and 8800 sytems<br>C.H.P.1001 – Testing for HR-HPV |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used |
|---|---|---|
| HUMAN BODY TISSUE AND FLUIDS (cont'd) | Cytological examination activities for the purposes of clinical diagnosis: (cont'd) | Microscopic examination supported by documented in house methods incorporating manufacturers' instructions where relevant: |
| Fine needle aspirates, Serous and Non-serous fluids, Respiratory samples, CSFs) | Examination to identify or exclude non-gynae cytological abnormalities for the purpose of diagnosis: | Preparation of direct smears and cytospin slides to look for presence of malignant cells.<br>Stained with Giemsa, Papanicolaou or combination of both stains.<br>Clots made on fluids using in house procedures in conjuction with manufacturer's instructions:<br>Class 1 Safety cabinet CP.HS.P.6005<br>Heraeus centrifuge (megafuge/ biofuge)or Shandon Cytospin 2 or 4 C.SP.P.581 Use of the Centrifuge and Cytospin<br><br>Specific Preparation SOPs:<br>C.SP.P.553 Prep of a Clot<br>C.SP.P.566 Urine and Ureteric/Bladder Washing samples<br>C.SP.P.563 Sentinel Node Imprints<br>C.SP.P.555 Preparation of Bronchial and Sputum Samples<br>C.SP.P.561 FNAs – Breast, Thyroid, Parotid and Solid Masses<br>C.SP.P.570 Serous Fluid Preparation<br>C.SP.P.571 Non-serous Fluid Preparation<br>C.SP.P.556 Samples received in LBC Fixative<br>C.SP.P.557 CSF and TSE/CJD samples<br>Stained either by Giemsa method (hand-stained) or Papanicolaou stained using Tissue Tek Prisma Stainer<br>C.SP.P.532 Preparation of Reagents and Giemsa Stain Solution |

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|---|---|---|
| HUMAN BODY TISSUE AND FLUIDS (cont'd) | Cytological examination activities for the purposes of clinical diagnosis: (cont'd) | Microscopic examination supported by documented in house methods incorporating manufacturers' instructions where relevant: |
| Fine needle aspirates, Blood, Serous and Non-serous fluids, Respiratory samples, CSFs) | Examination to identify or exclude non-gynae cytological abnormalities for the purpose of diagnosis:<br><br>Morphological assessment and interpretation/diagnosis. | C.SP.P.591 Staining Protocols for Non-Gynae Samples<br>C.SR.P.424 Papanicolaou Staining Protocol<br>Data Entry to LabTrak LIMS following<br>C.SP.P.547 Non-Gynae sample registration<br>Reported from LabTrak LIMS following<br>LTO P2 Reports |
| END | | |