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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	<u>Cytogenetics examination procedures for the purposes of clinical diagnosis</u>	
Whole Blood Bone marrow Ascitic fluid Pleural Effusion Biopsy samples	Chromosome analysis for - for detection and analysis of genetic re-arrangements and/or genomic imbalance in Haemato/Oncology Disorders	Chromosome Culture by In-house procedures using commercial medias and SOP CYG1-MP6-10 Preparation of material for chromosome analysis by manual harvesting by in-house methods and SOP CYG1-MP6-9 Macroscopic and microscopic examination, detection, analysis and reporting of G banding and Karyotyping against considered normal pattern/profile by in-house methods and using SOPs CYG1-MP6-1 CYG1-MP6-8 Fluorescent in situ Hybridisation (FISH) In-house procedures and commercial kits (including Cytocell, Abbott-Vysis, Dako, Kreatech); and Thermobrite hybridisation station Macroscopic and microscopic using SOPs CYG1-MP6-3 CYG1-MP6-1 CYG1-MP6-6
Blood, amniotic fluid, CVS & POC	Whole genotype screening to detect copy variations	DNA extraction using iGen (manual), Qiagen & QIAsymphony (automated) followed by analysis using Agilent Array Scanner

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE and FLUIDS (cont'd)	Cytogenetics examination procedures for the purposes of clinical diagnosis (cont'd)	
Amniotic fluid, CVS & POC	G-band karyotype to identify numerical & structural chromosome aberrations (pre-natal)	Logging in and sample set up CYG-MP6-45 to 50 Culturing CYG-MP6-51, 52 Harvesting and slide making CYG-MP6-53 G banding CYG-MP6-54 Scanning GEN-MP6-4 Karyotyping/analysis of G banding using CytoVision and/or microscope CYG-MP6-9, CYG-MP6-10 & CYG-MP6-14 Reporting CYG-MP6-16, CYG-MP6-18 & PCR2-MP5-14
Blood	G-band karyotype to identify numerical & structural chromosome aberrations (post-natal)	Logging in and sample set up CYG-MP6-32 & CYG-MP6-33 Culturing CYG-MP6-34 Harvesting and slide making CYG-MP6-35 & CYG-MP6-36 G banding CYG-MP6-37 Scanning CYG-MP6-4 Karyotyping/analysis of G banding using CytoVision and/or microscope CYG-MP6-9, 11 & 14 Reporting CYG-MP6-16 & CYG-MP6-18

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS	Virology/ Microbiology	
	Examination activities for the purposes of clinical diagnosis. Detection and quantification of:	Documented in-house methods for DNA / RNA manufacture, purification and detection using techniques and kits in combination with manufacturer's instructions:
Liquid Based Cytology (LBC) samples in PreservCyt solution or SurePath transport media from cervical smear	Human Papilloma Virus E6/E7 Viral mRNA and other high-risk types (16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68	RNA extraction and analysis using Aptima mRNA HPV assay on Hologic Panther platform SOP PCR-MP9-12
Thin–Prep material from cervical smears	HPV types 16, 18, 31, 33 & 45	RNA extraction using QIAcube followed by molecular analysis using PreTect Analyser & NorChip assay SOP PCR2-MP5-59
Faeces	DNA from: Entamoeba histolytica Cryptosporidium spp. Giardia lamblia Cyclospora cayetanensis Vibrio vulnificus Vibrio parahaemolyticus Vibrio cholerae Campylobacter spp. (C. jejuni, C. upsaliensis, C. coli) Salmonella spp. Clostridium difficile (tcdA/tcdB) Yersinia enterocolitica Enteroaggregative E. coli (EAEC), Enterotoxigenic E. coli (ETEC), Shiga-like toxin producing E. coli (STEC) Shiga-toxin producing E. coli (STEC) serotype O157:H7 Enteropathogenic E. coli (EPEC), Enteroinvasive E. coli (EIEC) / Shigella Plesiomonas shigelloides Human Adenovirus F40/F41, Norovirus GI, Norovirus GII, Rotavirus A Astrovirus Sapovirus GI, GII, GIV, GV)	Qualitative real-time PCR using Qiagen QIAstat analyser and Qiagen Gastrointestinal pathogen panel PCR2-MP5-166

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	Virology/ Microbiology (cont'd)	
Urogenital, endocervical swabs, rectal-vaginal swabs, rectal swabs and urine	Neisseria gonorrhoea Chlamydia trachomatis Mycoplasma genitalium Trichomonas vaginalis Ureaplasma urealyticum Ureaplasma parvum Gardnerella vaginalis Herpes virus 1 Herpes virus 2	DNA extraction using QIAsymphony and analysis using Qiagen Rotorgene with Viasure test panel kit SOP PCR2-MP5-179
EDTA Plasma/ clotted blood serum	Detection of HBV DNA, HCV DNA, HIV 1&2 RNA	Roche Cobas 6800 system. Multi Dye Real-time PCR. SOP PCR-MP9-11
CSF / Vitreous fluid / Aqueous fluid / Urine /Bronchoalveolar lavage fluid (BAL) / swabs including saliva swabs/ stools / EDTA whole blood or plasma samples and Tissue Samples	Detection of HSV1&2 DNA, CMV DNA, EBV DNA, VZV DNA, Enterovirus (EV) RNA and Parechovirus RNA	Extraction using Qiagen EZ1 PCR2-MP5-29 Real-time qualitative PCR and analysis using the ABI Quantstudio 5 PCR2-MP5-94
Genital ulcer swab (COPAN UTM)	Detection of HSV1&2 DNA and Treponema pallidum DNA	Extraction on QIASymphony PCR2-MP5-28 Real-time qualitative PCR and analysis using ABI QuantStudio 5 PCR2-MP5-106

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE and FLUIDS	Virology/ Microbiology (cont'd) Examination activities for the purposes of clinical diagnosis. Detection and quantification of:	
CSF, joint fluid, tissues, pus and bacterial isolates	16s ribosomal sequencing for mutation detection in genes and mutation confirmation using profiling	DNA / RNA extraction using QIAsymphony followed by sequencing and analysis using Proflex, AB3730 XL and eGels SOP PCR2-MP5-110 and the following:
RNA extracted from EDTA blood, plasma and PBMCs	HIV-1 Pol resistance	SOP PCR2-MP5-87
	HIV-1 integrase	SOP PCR2-MP5-87
	HIV-1 tropism	SOP PCR2-MP5-87
	HIV-1 T20	SOP PCR2-MP5-87
	Hepatitis C virus NS3	SOP PCR2-MP5-87
	Hepatitis C virus NS5a	SOP PCR2-MP5-87
	Hepatitis C virus Ns5b	SOP PCR2-MP5-87
	Hepatitis B pol genotyping / resistance	SOP PCR2-MP5-87
EDTA blood, clotted blood, serum, plasma, CSF	Cytomegalovirus (CMV) UL97 & UL54 resistance	SOP PCR2-MP5-87
Neonatal dried blood spots (Guthrie cards)	Cytomegalovirus (qualitative only)	DNA extraction using QIAsymphony followed by analysis using QuantStudio 5 SOP PCR2-MP5-97
EDTA plasma	Human Herpes Virus 8	DNA extraction using QIAsymphony / EZ1 followed by real-time PCR analysis using QuantStudio 5 SOP PCR2-MP5-203 & PCR2-MP5-14

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE and FLUIDS (cont'd)	Virology/ Microbiology (cont'd)	
	Examination activities for the purposes of clinical diagnosis. Detection and quantification of: (cont'd)	In house documented procedures based on equipment manuals and standard methods as specified:
EDTA plasma, urine & CSF	JC virus (qualitative only)	DNA extraction using Qiagen EZ1 followed by analysis Quantstudio 5 using in-house developed kit SOP PCR2-MP5-112
Plasma	Adenovirus	DNA extraction using QIAsymphony followed by real-time PCR analysis using Qiagen Rotorgene with Qiagen kit SOP PCR2-MP5-111
Plasma / whole blood	Cytomegalovirus	DNA extraction using QIAsymphony followed by real-time PCR analysis using Qiagen Rotorgene with Qiagen kit SOP PCR2-MP5-111
Lesion (skin, genital) and throat swabs in UTM/VTM/STM	Detection of Monkey Pox DNA	Extraction on either QIASymphony or Qiagen EZ1 PCR2-MP5-28/PCR2-MP5-29 PCR and Analysis on the ABI QuantStudio 5 PCR2-MP5-206
Vesicular swabs (COPAN UTM), eye dry swabs expressed into COPAN UTM	Detection of HSV1&2 DNA and VZV DNA	Extraction on QIASymphony PCR2-MP5-28 Real-time qualitative PCR and analysis using ABI QuantStudio 5 PCR2-MP5-106
Eye swabs (COPAN UTM)	Detection of Adenovirus DNA	Extraction on QIASymphony PCR2-MP5-28 Real-time qualitative PCR and analysis using ABI QuantStudio 5 PCR2-MP5-106

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE and FLUIDS (cont'd)	Virology/ Microbiology (cont'd)	
	Examination activities for the purposes of clinical diagnosis. Detection and quantification of: (cont'd)	In house documented procedures based on equipment manuals and standard methods as specified:
Plasma / whole blood	Epstein Barr Virus	DNA extraction using QIAsymphony followed by real-time PCR analysis using Qiagen Rotorgene with Qiagen kit SOP PCR2-MP5-111
Plasma / whole blood, bronchoalveolar lavage	Hepatitis D virus	RNA extraction using QIAsymphony followed by real-time PCR analysis using QuantStudio 5 with in-house assay SOP PCR2-MP5-98
EDTA blood	Hepatitis E virus	RNA extraction using QIAsymphony SP/AS followed by real-time PCR analysis using QuantStudio 5 with Altona Realstar HEV PCR kit SOP PCR2-MP5-100
Plasma / whole blood	Human Herpes Virus-6	DNA extraction using EZ1 followed by real-time PCR analysis using QuantStudio 5 with Qiagen kit SOP PCR2-MP5-101
Plasma	HIV-2 (pro-viral and quantitation)	DNA / RNA extraction using QIAsymphony followed by real-time PCR analysis using QuantStudio 5 with in-house developed kit SOP PCR2-MP5-105 & PCR2-MP5-207
Nasopharyngeal swabs, Bronchoalveolar lavage, Nasopharyngeal aspirate	Middle East Respiratory Syndrome Coronavirus	RNA extraction using EZ1 followed by real-time PCR analysis using QuantStudio 5 SOP PCR2-MP5-90
Faeces	Rotavirus Adenovirus 40/41 Adenovirus Astrovirus Norovirus G1 & G2 Sapovirus	Real-time PCR using Hologic Panther Fusion and Hologic PCR multiplex panel SOP PCR2-MP5-210

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE and FLUIDS (cont'd)	Virology/ Microbiology (cont'd)	
	Examination activities for the purposes of clinical diagnosis. Detection and quantification of:	In house documented procedures based on equipment manuals and standard methods as specified:
Nasopharyngeal swabs, Bronchoalveolar lavage, Nasopharyngeal aspirate	Influenza A & B virus Respiratory Syncytial A & B Virus Rhinovirus Enterovirus Parainfluenza 1-4 virus Human metapneumovirus Coronavirus Parechovirus Adenovirus	Real-time PCR using Hologic Panther Fusion SOP PCR2-MP5-104
Nasopharyngeal swabs, Bronchoalveolar lavage, Nasopharyngeal aspirate	Influenza A typing (H1, H3)	Real-time PCR using Hologic Panther Fusion SOP PCR2-MP5-104
Whole blood / plasma	Proviral HIV-1	DNA extraction using Qiagen EZ1 followed by real-time PCR analysis using QuantStudio 5 with in-house developed kit SOP PCR2-MP5-102
Saliva swabs, plasma	Measles virus	RNA extraction using QIAsymphony / EZ1 followed by real-time PCR analysis using QuantStudio 5 with in-house developed kit SOP PCR2-MP5-108
Throat swab, rectal swab, vulval swab and urine	Chlamydia trachomatis Neisseria gonorrhoea Trichomonas vaginalis Mycoplasma genitalium	DNA / RNA extraction and analysis by qualitative transcription mediated amplification using Hologic Panther SOP PCR-MP9-12
Throat swab, rectal swab, vulval swab and urine	Chlamydia trachomatis serovars L1, L2 & L3 (lymphogranuloma venereum)	DNA extraction using QIAsymphony / EZ1 followed by real-time PCR analysis using QuantStudio 5 with in-house developed kit SOP PCR2-MP5-109
Urine, thin prep swabs from genital sites (rectal swabs, cervical swabs, endocervical swabs, vaginal swabs, high vaginal swabs)	Mycoplasma genitalium resistance	RNA extraction using QIAsymphony/EZ1 followed by real-time PCR analysis using Lightcycler LC480 SOP PCR2-MP5-113

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE and FLUIDS (cont'd)	Virology/ Microbiology (cont'd)	
	Examination activities for the purposes of clinical diagnosis. Detection and quantification of: (cont'd)	In house documented procedures based on equipment manuals and standard methods as specified:
EDTA Plasma	HIV-1 viral load	DNA / RNA extraction and analysis by qualitative transcription mediated amplification using Hologic Panther and Aptima Panther assay SOP PCR-MP9-11
Serum	HIV-1 RNA	
EDTA Plasma / serum	Hepatitis B viral load	
EDTA Plasma / serum	Hepatitis C viral load	
EDTA whole blood	HIV-1 detection (qualitative)	PCR using Cepheid Infinity SOP SAM2-MP0-4
EDTA plasma	HIV-1 viral load	PCR using Cepheid Infinity SOP SAM2-MP0-4
Urine & genital swabs	Chlamydia trachomatis Neisseria gonorrhoea	PCR using Cepheid Infinity SOP SAM2-MP0-4
EDTA blood or Urine	Quantitative Detection of BK virus	Real-time PCR using Hologic Panther Fusion and Hologic BKV Quant real-time PCR Assay SOP PCR2-MP5-92
Nasopharyngeal and combined nose / throat swabs in VTM	Detection of SARS CoV-2 virus RNA (COVID-19) specific gene sequences; ORF1ab gene	Real time PCR using Hologic Panther Fusion and Aptima assay SOP PCR3-MP5-2
RNA from nasal, throat or combined nose / throat swabs	Detection of SARS-CoV-2 variant lineage and designation for variants of concern and under investigation	Extraction using QIASymphony or Qiagen EZ1 Whole genome sequencing using NextSeq Illumina DNA Flex Library Preparation kit, ARTIC primer sets and Pangolin database. SOP PCR2-MP5-190
EDTA blood	Quantitative Detection of Parvovirus B19 DNA	Qiagen EZ1 extractor, Quantstudio5 Realtime PCR system using the Altona Quantitative Parvo B19 DNA kit SOP PCR2-MP5-225

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS	<u>Molecular Haemophilia</u> DNA Profiling for detection of abnormal sequences for disease conditions	Documented in-house methods for DNA / RNA manufacture, purification and detection using techniques and kits in combination with manufacturer's instructions:
EDTA blood unless stated	Mutation detection and mutation confirmation using DNA profiling for the following genes:	DNA extraction, preparation, analysis and Sanger sequencing using Maxwell RSC, Proflex, Nanodrop, ABI3500XL and eGels
	F7	SOP PCR2-MP5-127
EDTA blood, chorionic villus sample	F8	SOP PCR2-MP5-126
EDTA blood, chorionic villus sample	F9	SOP PCR2-MP5-128
	F10	SOP PCR2-MP5-134
	F11	SOP PCR2-MP5-131
	SERPINC 1	SOP PCR2-MP5-129
	VWF Exon specific	SOP PCR2-MP5-132
	PROC	SOP PCR2-MP5-133
	TL-MTHFR c.677c>T	SOP PCR2-MP5-135
		DNA extraction, preparation, analysis using Maxwell RSC, Proflex, Nanodrop and eGels
	F8 Intron 22 Inversion	SOP PCR2-MP5-136
	F8 Intron 1 Inversion	SOP PCR2-MP5-130
		DNA extraction, preparation, MLPA analysis using size fractionation, Maxwell RSC, Proflex, Nanodrop, ABI3500XL and eGels
	VWF copy number variant F8 copy number F9 copy number	SOP PCR2-MP5-138 SOP PCR2-MP5-138 SOP PCR2-MP5-138

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	Molecular Haemophilia (cont'd)	Documented in-house methods for DNA / RNA manufacture, purification and detection using techniques and kits in combination with manufacturer's instructions:
	DNA Profiling for detection of abnormal sequences for disease conditions	
EDTA Blood	NGS Lysomal Storage Disorder (LSD) and bleeding, Thrombosis and Platelet Disorders (BTPD)	Illumina DNA Library prep with enrichment using NextSeq 550DX and analysis of FastQ files using congenica SOP PCR2-MP5-167
HUMAN BODY TISSUE and FLUIDS	Molecular Haematology / Oncology DNA Profiling and mutation analysis for detection of abnormal sequences for disease conditions	Documented in-house methods for DNA manufacture, purification and detection using techniques and kits in combination with manufacturer's instructions:
	Mutation detection in genes and mutation analysis using DNA profiling:	DNA extraction, preparation, analysis and sequencing using QIAsymphony (bloods) or Maxwell RSC (tissues), Proflex, Quantstudio 5 & ABI3500XL
EDTA blood, bone marrow	FLT3	SOP PCR2-MP5-144
Bone marrow, blood, biopsy tissue, pleural effusion & ascitic fluid	Karyotyping (aCGH)	Extraction of DNA using manual (Qiagene) and automated (QIAcube & QIAsymphony) methods followed by molecular analysis and next-generation sequencing using Agilent Array Scanner and Illumina MiSeq SOP CYG1-MP6-17 Isolation SOP CYG1-MP6-18-aCGH Processing SOP CYG1-MP6-16 -aCGH Analysis and Reporting SOP CYG1-MP6-20 PCR and Sanger sequencing

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE and FLUIDS	<u>Molecular Haematology / Oncology</u> DNA Profiling and mutation analysis for detection of abnormal sequences for disease conditions	Documented in-house methods for DNA manufacture, purification and detection using techniques and kits in combination with manufacturer's instructions:
Extracted DNA / RNA	Detection of SNVs, RNA gene variants and fusions associated with acute leukaemia and suspected myeloproliferative neoplasms (MPNs)	GeneXus Integrated Sequencer using GeneXus Myeloid Assay V2 SOP PCR2-MP5-209 Ion Torrent Oncomine Myeloid Assay GX v2 using GeneXus Integrated Sequencer and Genexus analysis software (v6.8.2.0) SOP PCR2-MP5-209
Extracted DNA / RNA	Next Generation Sequencing for the detection of SNVs, small indels and CNVs associated with myeloid malignancies	Ilumina Next seq 500/550, RotorGene RGQ and Archer commercial analysis bioinformatics software using Archer DX Myeloid VarientPlex NGS Panel SOP PCR2-MP5-192
Extracted DNA / RNA	Next Generation Sequencing for the detection of fusion transcripts, SNVs and small indels (for BCR::ABL TKD) associated with haematological malignancies	Ilumina Next seq 500/550, RotorGene RGQ and Archer commercial analysis bioinformatics software using Archer Pan-Heme FusionPlex NGS Assay SOP PCR2-MP5-200

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE and FLUIDS (cont'd)	<u>Molecular Genetics</u> DNA Profiling for detection of abnormal sequences for disease conditions: Detection of:	Documented in-house methods for DNA manufacture, purification and detection using techniques and kits in combination with manufacturer's instructions:
Amniotic fluid, chorionic villus sample, EDTA blood, products of conception	Chromosome 21, 18,13 and sex chromosome aneuploidies	DNA extraction, preparation, analysis and sequencing by PCR and capillary electrophoresis using Proflex and ABI3730XL using Devyser QF PCR kit SOP PCR2-MP5-139 SOP PCR2-MP5-142
Cell free DNA (cfDNA) from maternal blood sample	Detection of trisomy 13, 18, 21 and foetal sex	Illumina VeriSeq NIPT Assay using Illumina VeriSeq Microlab STAR liquid handlers for plasma isolation, Gemini spectrophotometer, and Illumina NextSeq 550DX next generation sequencer, SOP NIPT-MP6-7
EDTA blood	Cystic fibrosis gene variant 5T / 7T / 9T alleles	DNA extraction, preparation, analysis and next generation sequencing using QIAsymphony, Proflex and Illumina MiSeqDx with Illumina TruSight Cystic Fibrosis 139-Variant Assay SOP PCR2-MP5-74

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE and FLUIDS (cont'd)	Molecular Genetics (cont'd) DNA Profiling for detection of abnormal sequences for disease conditions: Detection of (cont'd):	Documented in-house methods for DNA manufacture, purification and detection using techniques and kits in combination with manufacturer's instructions:
EDTA Blood	Presence of DNA, typically GAPDH	DNA extraction, preparation, analysis and sequencing by real-time PCR using QIAsymphony, QuantStudio5 and in-house developed assay SOP PCR2-MP5-23
EDTA blood	C282Y and H63D variants seen with Haemochromatosis	DNA extraction, preparation, analysis and sequencing by real-time PCR using QIAsymphony and QuantStudio5 with Applied Biosystems assay SOP PCR2-MP5-57
DNA extracted from EDTA blood	Detection of ApoE gene alleles E2, E3 and E4	QuantStudio5 and Quantstudio 5 Design and Analysis Software using CE IVD Clonit Duplicα RealTime ApoE Genotyping Kit SOP PCR2-MP5-221
EDTA blood	15 polymorphic autosomal DNA markers for use in paternity testing and DNA profiling	Applied Biosystems AmpFISTR Identifiler assay SOP PCR2-MP5-60
EDTA blood	Spinal Muscular Atrophy gene variants – SMN1 & SMN2 exons 7 & 8. SMN1 exon 7 dosage	DNA extraction, preparation, analysis and sequencing by multiplex ligation-dependent probe amplification using QIAsymphony, Proflex, ABI3730XL and MRC Holland SALSA® MLPA® probemix P060 SOP PCR2-MP5-66

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE and FLUIDS (cont'd)	Molecular Genetics (cont'd) DNA Profiling for detection of abnormal sequences for disease conditions: Detection of (cont'd):	Documented in-house methods for DNA manufacture, purification and detection using techniques and kits in combination with manufacturer's instructions:
EDTA blood	Exons 1 to 79 of dystrophin gene variants for Duchene Muscular Dystrophy	DNA extraction, preparation, analysis and sequencing by multiplex ligation-dependent probe amplification using QIAsymphony, Proflex, and torren MRC Holland SALSA® MLPA® DMD P034/P035 probemix SOP PCR2-MP5-67
EDTA blood	Human Leukocyte Antigen (HLA) - DRB1*, HLA-DRB3*/4*/5* and HLA-DQB1* typing , Class 1 HLA (A,B and C)	DNA extraction, preparation, analysis and sequence specific oligonucleotide technology using QIAsymphony, Proflex, Luminex 200 and LIFECODES HLA Rapid typing kits. SOP PCR2-MP5-71
DNA extracted from EDTA blood	HLA B*27 alleles	Real-time PCR and quantitative melt curve analysis using Quantstudio 5 and Genmark kit SOP PCR2-MP5-177
DNA extracted from EDTA blood	HLA B*57:01 allele presence or absence	DNA extraction, preparation, sequence specific primer PCR and electrophoresis using QIAsymphony, Proflex, Luminex 200, eGel and Olerup SSP HLA-B*57:01 Kit SOP PCR2-MP5-64
EDTA blood	HLA DQ2 and DQ8 haplotypes for Coeliac screening	DNA extraction, preparation, single specific primer PCR and electrophoresis using QIAsymphony, Proflex, Luminex 200, eGel and Protrans Coeliac kit SOP PCR2-MP5-62

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE and FLUIDS (cont'd)	Molecular Genetics (cont'd) DNA Profiling for detection of abnormal sequences for disease conditions: Detection of (cont'd):	Documented in-house methods for DNA manufacture, purification and detection using techniques and kits in combination with manufacturer's instructions:
EDTA blood	CYP2C19 alleles *1, *2, *3, *4, *5, *6, *7, *8, *9, *10, *17 detection and genotyping	DNA extraction, preparation, PCR and allele specific primer extension using QIAsymphony, Proflex, Luminex 200 and Luminex xTAG CYP2C19 assay SOP PCR2-MP5-75
Liquid based cytology specimens in ThinPrep PreservCyt solution (Hologic) as well as swab specimens expressed in PreserveCyt ThinPrep solution (Hologic).	Detection of Human Papillomavirus DNA (19 high risk and 9 low risk)	Seegene STARlet IVD extraction platform, Seegene Starlet IVD PCR plate preparation, and CF96 Real-time PCR system. Assay: Allplex HPV28 Detection assay PCR2-MP5-193
EDTA blood	Factor V Leiden c.1601G>A variant (p.Arg534Gln)	DNA extraction, preparation, analysis and sequencing by PCR and capillary electrophoresis using QIAsymphony, Proflex, ABI3730 and Elucigene TRP-F Plus kit SOP PCR2-MP5-56
EDTA blood	Prothrombin c*97G>A variant	
EDTA blood	MTHFR c.665C>T and c.1286A>C variant (p.Ala222Val) and (p.Glu429Ala)	
END		