


Schedule of Accreditation

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United Kingdom Accreditation Service

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

 <p>UKAS MEDICAL 8059</p> <p>Accredited to ISO 15189:2012</p>	<h3>HSL (Analytics) LLP</h3> <p>Issue No: 012 Issue date: 20 August 2021</p>	
	<p>HSL (Analytics) LLP Department of Molecular Sciences The Halo Building 1 Mabledon Place London WC1H 9AJ</p>	<p>Contact: Jacqueline Sutherland Tel: +44 (0) 207 307 7342 E-Mail: jacqueline.sutherland@hslpathology.com Website: www.hslpathology.com</p>
<p>Testing performed at the above address only</p>		

DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
<p>HUMAN BODY TISSUE AND FLUIDS</p> <p>Whole Blood Bone marrow Ascitic fluid Pleural Effusion Biopsy samples</p>	<p>Cytogenetics examination procedures for the purposes of clinical diagnosis</p> <p>Chromosome analysis for - for detection and analysis of genetic re-arrangements and/or genomic imbalance in</p> <p>Haemato/Oncology Disorders</p>	<p>Chromosome Culture by In-house procedures using commercial medias and SOP- LP-Cyto-SampSet</p> <p>Preparation of material for chromosome analysis by manual harvesting by in-house methods and SOP- LP-Cyto-SampPro</p> <p>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 LP-CYTO-AnaGuid LP-CYTO-RepRes</p> <p>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 LP-CYTO-FISH LP-CYTO-AnaGuid LP-CYTO-RepRes</p>



8059

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HUMAN BODY TISSUE AND FLUIDS Amniotic fluid, CVS & POC	Cytogenetics examination procedures for the purposes of clinical diagnosis (cont'd) G-band karyotype to identify numerical & structural chromosome aberrations (pre-natal)	Logging in and sample set up CYG-PRE-005 to 010 Culturing CYG-PRE-011 & CYG-PRE-012 Harvesting and slide making CYG-PRE-013 G banding CYG-PRE-014 Scanning GEN-MAN-013 Karyotyping/analysis of G banding using CytoVision and/or microscope CYG-ANA-005, CYG-ANA-006 & CYG-ANA-010 Reporting CYG-ANA-012, CYG-ANA-014 & GEN-MAN-005
Blood	G-band karyotype to identify numerical & structural chromosome aberrations (post-natal)	Logging in and sample set up CYG- POS-003 & CYG- POS-004 Culturing CYG- POS-005 Harvesting and slide making CYG- POS-006 & CYG- POS-007 G banding CYG- POS-008 Scanning GEN-MAN-013 Karyotyping/analysis of G banding using CytoVision and/or microscope CYG-ANA-005, 007 & 010 Reporting CYG-ANA-012 & CYG-ANA-014



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HUMAN BODY TISSUE AND FLUIDS	<u>Cytogenetics examination procedures for the purposes of clinical diagnosis (cont'd)</u>	
Blood, amniotic fluid, CVS & POC	Whole genotype screening to detect copy variations	DNA extraction using iGen (manual), Qiagen & QIA Symphony (automated) followed by analysis using Agilent Array Scanner
HUMAN BODY FLUIDS	<u>Virology/ Microbiology</u>	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 MOL-PCR-086
Thin-Prep material from cervical smears	HPV types 16, 18, 31, 33 & 45	RNA extraction using QIA Symphony followed by molecular analysis using PreTech Analyser & NorChip assay SOP MOL-PCR-009
Urine, Thin-Prep material from cervical smears	DNA from: Mycoplasma genitalium Ureaplasma urealyticum / parvum Gardnerella vaginalis Trichomonas vaginalis Chlamydia trachomatis Neisseria gonorrhoea Herpes Simplex Virus 1 & 2	DNA extraction using QIA Symphony and analysis using Qiagen Rotorgene with STD9 Fast Tract Diagnostics kit SOP MOL-PCR-027



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HUMAN BODY TISSUE AND FLUIDS	<u>Cytogenetics examination procedures for the purposes of clinical diagnosis (cont'd)</u>	
Faeces	DNA from Adenovirus 40/41 Campylobacter Clostridium difficile toxin A / B Entamoeba histolytica E. coli O157 Enterotoxigenic E. coli (ETEC) LT/ST Giardia sp. Norovirus GI/GII Rotavirus A Salmonella Shiga-like Toxin producing E. coli (STEC) stx 1/stx 2 Shigella sp. Vibrio cholerae Yersinia enterocolitica	DNA set up and extraction using Qiagen QIAcube and analysis using Proflex and Luminex 200 GPP assay SOP MOL-PCR-024
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 QIAasympyphony followed by sequencing and analysis using Proflex, AB3730 XL and eGels SOP MOL-PCR-083 and the following:
RNA extracted from EDTA blood, plasma and PBMCs	HIV-1 Pol resistance	SOP MOL-PCR-053
	HIV-1 integrase	SOP MOL-PCR-053
	HIV-1 tropism	SOP MOL-PCR-053
	HIV-1 T20	SOP MOL-PCR-053
	Hepatitis C virus NS3	SOP MOL-PCR-053
	Hepatitis C virus NS5a	SOP MOL-PCR-053
	Hepatitis C virus Ns5b	SOP MOL-PCR-053
	Hepatitis B pol genotyping / resistance	SOP MOL-PCR-053



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HUMAN BODY TISSUE AND FLUIDS	<u>Virology/ Microbiology</u> 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:
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 QIA Symphony followed by sequencing and analysis using Proflex, AB3730 XL and eGels SOP MOL-PCR-083 and the following:
EDTA blood, clotted blood, serum, plasma	Hepatitis C 5' NCR genotyping	SOP MOL-PCR-072
EDTA blood, clotted blood, serum, plasma, CSF	Cytomegalovirus (CMV) UL97 & UL54 resistance	SOP MOL-PCR-053
EDTA plasma / serum	Hepatitis C Virus 5'UTR and NS5B regions	RNA extraction, sequencing and analysis using Abbott M2000 SP / RT SOP MOL-PCR-058
Neonatal dried blood spots (Guthrie cards)	Cytomegalovirus (qualitative only)	DNA extraction using QIA Symphony followed by analysis using QuantStudio 5 SOP MOL-PCR-066
Biopsy material, urine, tissue, saliva, CSF & pleural fluid	Cytomegalovirus (qualitative only)	DNA extraction using EZ1 followed by real-time PCR analysis using QuantStudio 5 SOP MOL-PCR-057
EDTA plasma	Human Herpes Virus 8	DNA extraction using QIA Symphony / EZ1 followed by real-time PCR analysis using QuantStudio 5 SOP MOL-PCR-088
EDTA plasma & urine	BK virus	DNA extraction using QIA Symphony followed by real-time PCR analysis using Qiagen Rotorgene and Artus kit SOP MOL-PCR-060
EDTA plasma, urine & CSF	JC virus (qualitative only)	DNA extraction using Qiagen EZ1 followed by analysis Quantstudio 5 using in-house developed kit SOP MOL-PCR-085



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HUMAN BODY TISSUE AND FLUIDS	<u>Virology/ Microbiology</u> 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:
Swabs from skin vesicular lesions, vesical fluid or blood	Herpes Simplex Virus-1 Herpes Simplex Virus-2 Varicella Zoster Virus	DNA extraction using QIA Symphony followed by multiplex real-time PCR analysis using QuantStudio 5 with Fast Track Diagnostics kit SOP MOL-PCR-079
Swabs from genital vesicular lesions, vesical fluid	Herpes Simplex Virus-1 Herpes Simplex Virus-2 Treponema pallidum (Syphilis)	DNA extraction using QIA Symphony followed by multiplex real-time PCR analysis using QuantStudio 5 with Fast Track Diagnostics kit SOP MOL-PCR-078
Eye swabs	Herpes Simplex Virus-1 Herpes Simplex Virus-2 Varicella Zoster Virus Chlamydia trachomatis Adenovirus	DNA extraction using QIA Symphony followed by multiplex real-time PCR analysis using QuantStudio 5 with Fast Track Diagnostics kit SOP MOL-PCR-061
Plasma	Adenovirus	DNA extraction using QIA Symphony followed by real-time PCR analysis using Qiagen Rotorgene with Qiagen kit SOP MOL-PCR-084
CSF, biopsy material, urine, amniotic fluids, bronchoalveolar lavage, saliva, bile, throat swabs, nasopharyngeal aspirate, serum, plasma	Herpes Simplex Virus-1 Herpes Simplex Virus-2 Cytomegalovirus Epstein Barr Virus Varicella Zoster Virus Human Herpes Virus-6 Human Herpes Virus-7 Parvovirus Enterovirus Parechovirus	DNA extraction using Qiagen EZ1 followed by multiplex real-time PCR analysis using QuantStudio 5 with Fast Track Diagnostics kit SOP MOL-PCR-062
Plasma / whole blood	Cytomegalovirus	DNA extraction using QIA Symphony followed by real-time PCR analysis using Qiagen Rotorgene with Qiagen kit SOP MOL-PCR-084



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Plasma / whole blood	Epstein Barr Virus	DNA extraction using QIAAsymphony followed by real-time PCR analysis using Qiagen Rotorgene with Qiagen kit SOP MOL-PCR-084
Plasma / whole blood, bronchoalveolar lavage	Hepatitis D virus	RNA extraction using QIAAsymphony followed by real-time PCR analysis using QuantStudio 5 with in-house assay SOP MOL-PCR-067
Plasma, faeces	Hepatitis E virus	RNA extraction using QIAAsymphony followed by real-time PCR analysis using QuantStudio 5 with Fast Track Diagnostics kit SOP MOL-PCR-069
Plasma / serum	Parvovirus B19	DNA extraction using EZ1 followed by real-time PCR analysis using QuantStudio 5 or Qiagene Rotorgene with Qiagen kit SOP MOL-PCR-054
Plasma / whole blood	Human Herpes Virus-6	DNA extraction using EZ1 followed by real-time PCR analysis using QuantStudio 5 or Qiagene Rotorgene with Qiagen kit SOP MOL-PCR-070
Plasma	HIV-2 (pro-viral and quantitation)	DNA / RNA extraction using QIAAsymphony followed by real-time PCR analysis using QuantStudio 5 with in-house developed kit SOP MOL-PCR-077
Faeces	Rotavirus Norovirus Sapovirus Adenovirus (pan genotype 40 & 41) Astrovirus	DNA / RNA extraction using QIAAsymphony followed by multiplex real-time PCR analysis using QuantStudio 5 with in-house developed kit SOP MOL-PCR-065



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HUMAN BODY TISSUE AND FLUIDS	<u>Virology/ Microbiology</u> 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	Middle East Respiratory Syndrome Coronavirus	RNA extraction using EZ1 followed by real-time PCR analysis using QuantStudio 5 SOP MOL-PCR-056
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 MOL-PCR-076
Nasopharyngeal swabs, Bronchoalveolar lavage, Nasopharyngeal aspirate	Influenza A typing (H1, H3)	Real-time PCR using Hologic Panther Fusion SOP MOL-PCR-076
Nasopharyngeal swabs, throat swabs, bronchoalveolar lavage, Nasopharyngeal aspirate	Influenza A & B virus Parainfluenza 1-4 virus Adenovirus Respiratory Syncytial A & B Virus Enterovirus Human Metapneumo A & B Virus Parechovirus Coronavirus (229e, OC43, NL63, HKU1)	DNA / RNA extraction using QIAAsymphony followed by multiplex real-time PCR analysis using QuantStudio 5 with in-house developed kit SOP MOL-PCR-064
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 MOL-PCR-071
Saliva swabs, plasma	Measles virus	RNA extraction using QIAAsymphony / EZ1 followed by real-time PCR analysis using QuantStudio 5 with in-house developed kit SOP MOL-PCR-081



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HUMAN BODY TISSUE AND FLUIDS	<u>Virology/ Microbiology</u>	In house documented procedures based on equipment manuals and standard methods as specified:
Plasma / serum	Influenza A type H3 & H1	DNA / RNA extraction using QIA Symphony followed by real-time PCR analysis using QuantStudio 5 with in-house developed kit SOP MOL-PCR-055
Nasopharyngeal swabs, Bronchoalveolar lavage, Nasopharyngeal aspirate	Parainfluenza A type 1-4	
Throat swab, rectal swab, vulval swab and urine	Chlamydia trachomatis Neisseria gonorrhoea	DNA / RNA extraction and analysis by qualitative transcription mediated amplification using Hologic Panther SOP MOL-PCR-086
	Trichomonas vaginalis Mycoplasma genitalium	
Urine, thin prep swabs from genital sites (rectal swabs, cervical swabs, endocervical swabs, vaginal swabs, high vaginal swabs)	Mycoplasma genitalium resistance	RNA extraction using QIA Symphony/EZ1 followed by real-time PCR analysis using Lightcycler LC480 SOP MOL-PCR-087
Throat swab, rectal swab, vulval swab and urine	Chlamydia trachomatis serovars L1, L2 & L3 (lymphogranuloma venereum)	DNA extraction using QIA Symphony / EZ1 followed by real-time PCR analysis using QuantStudio 5 with in-house developed kit SOP MOL-PCR-082
		DNA / RNA extraction and analysis by qualitative transcription mediated amplification using Hologic Panther and Aptima Panther assay SOP MOL-INS-017
EDTA Plasma	HIV-1 viral load	
Serum	HIV-1 RNA	
EDTA Plasma / serum	Hepatitis B viral load	
EDTA Plasma / serum	Hepatitis C viral load	
Sputum	Bacterial Atypical pneumonia: Legionella pneumophila/ Legionella longbeachae Chlamydia pneumoniae Mycoplasma pneumoniae	DNA extraction using QIA Symphony followed by real-time PCR analysis using Qiagen RotorGene 6000 with Qiagen kit with Fast Track Diagnostics kit SOP MOL-PCR-103



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<p>HUMAN BODY TISSUE AND FLUIDS</p> <p>EDTA whole blood</p> <p>EDTA plasma</p> <p>Urine & genital swabs</p> <p>Nasopharyngeal and combined nose / throat swabs in viral transport media (VTM)</p> <p>Nasopharyngeal and combined nose / throat swabs in VTM, nasopharyngeal aspirates (NPA), bronchoalveolar lavage (BAL)</p> <p>Nasopharyngeal and combined nose / throat swabs in VTM</p> <p>Samples self-collected or collected by a Provider accredited to ISO 15189:2012 or ISO/IEC 17025:2017 and who is listed on the DHSC Approved Lists for General Population testing</p>	<p><u>Virology/ Microbiology</u></p> <p>Examination activities for the purposes of clinical diagnosis. Detection and quantification of:</p> <p>HIV-1 detection (qualitative)</p> <p>HIV-1 viral load</p> <p>Chlamydia trachomatis Neisseria gonorrhoea</p> <p>Detection of SARS CoV-2 virus RNA (COVID-19) specific gene sequences; N gene</p> <p>Detection of SARS CoV-2 virus RNA (COVID-19) specific gene sequences; N gene</p> <p>Detection of SARS CoV-2 virus RNA (COVID-19) specific gene sequences; ORF1ab gene</p> <p>Detection of SARS CoV-2 virus RNA (COVID-19) specific gene sequences; ORF1ab gene</p> <p>for:</p> <p>General Population testing</p>	<p>In house documented procedures based on equipment manuals and standard methods as specified:</p> <p>PCR using Cepheid Infinity SOP SAM-004</p> <p>PCR using Cepheid Infinity SOP SAM-004</p> <p>PCR using Cepheid Infinity SOP SAM-004</p> <p>RNA extraction free in-house method using ABI QuantStudio 5 SOP PCR2-MP5-176 SOP PCR-MP9-1</p> <p>Testing performed on Floor 5 and the Covid-19- Surge Testing laboratory on Floor 9</p> <p>Real time PCR using Hologic Panther Fusion with in-house primers and probes SOP PCR2-MP5-104</p> <p>Real time PCR using Hologic Panther Fusion and Aptima assay SOP PCR3-MP5-2</p> <p>Real time PCR using Hologic Panther Fusion and Aptima assay SOP PCR3-MP5-2</p>



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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 MOL-PCR-109
EDTA blood, chorionic villus sample	F8	SOP MOL-PCR-108
EDTA blood, chorionic villus sample	F9	SOP MOL-PCR-110
	F10	SOP MOL-PCR-116
	F11	SOP MOL-PCR-113
EDTA blood, bone marrow	FLT3	SOP MOL-PCR-127
	SERPINC 1	SOP MOL-PCR-111
	VWF Exon specific	SOP MOL-PCR-114
	PROC	SOP MOL-PCR-115
	TL-MTHFR c.677c>T	SOP MOL-PCR-117
		DNA extraction, preparation, analysis using Maxwell RSC, Proflex, Nanodrop and eGels
	F8 Intron 22 Inversion	SOP MOL-PCR-118
	F8 Intron 1 Inversion	SOP MOL-PCR-112
		DNA extraction, preparation, MLPA analysis using size fractionation, Maxwell RSC, Proflex, Nanodrop, ABI3500XL and eGels
	VWF copy number variant	SOP MOL-PCR-120
	F8 copy number	SOP MOL-PCR-120
	F9 copy number	SOP MOL-PCR-120



8059

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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:
	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	Exonic and splice site mutations and the 'chinese' intronic mutation in the GLA gene (Anderson-Fabry Disease)	SOP MOL-PCR-089
EDTA blood, bone marrow, CSF, formalin fixed paraffin-embedded tissue	B-cell clonality rearrangement in IgH & IgK	SOP MOL-PCR-095
	T-cell clonality rearrangement in TCRb & TCRg	SOP MOL-PCR-101
EDTA blood	Sequencing of the exons and intron / exon junctions of the GBA gene (Gauchers Disease)	SOP MOL-PCR-094
EDTA blood	IgVH gene mutation (CLL)	SOP MOL-PCR-124
EDTA blood	Sequencing of the exons and intron / exon junctions of the Acid α -Glucosidase gene	SOP MOL-PCR-099
EDTA blood	Deletions in exon 9 of the CALR gene	DNA extraction, preparation, analysis and sequencing using QIASymphony, Rotorgene RGQ & Ipsogen CALR RGQ assay SOP MOL-PCR-091
EDTA blood, bone marrow	JAK2 V617F mutation and JAK2 V617	DNA extraction, preparation, analysis and sequencing using QIASymphony, Rotorgene RGQ & Ipsogen JAK2 RGQ assay SOP MOL-PCR-097



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HUMAN BODY TISSUE AND FLUIDS	<u>Molecular Haematology / Oncology</u> DNA Profiling and mutation analysis for detection of abnormal sequences for disease conditions (cont'd)	Documented in-house methods for DNA manufacture, purification and detection using techniques and kits in combination with manufacturer's instructions:
EDTA blood	MPL exon 10 W515L/K mutations	DNA extraction, preparation and analysis using QIASymphony, Rotorgene RGQ & Ipsogen MPL W515KL MutaScreen assay SOP MOL-PCR-098
EDTA blood, bone marrow	Nucleophosmin 1 (NPM1)	DNA extraction, preparation and analysis using Maxwell RSC, Rotorgene RGQ & Ipsogen NPM1 MutaScreen assay SOP MOL-PCR-128
EDTA blood, bone marrow	Quantification of the BCR-ABL p190 transcript	DNA extraction, preparation, analysis and sequencing using QIASymphony, Proflex & Rotorgene RGQ using Ipsogen BCR-ABL1 mbc assay SOP MOL-PCR-126
EDTA blood, bone marrow	Quantification of the BCR-ABL p210 transcript	DNA extraction, preparation, analysis and sequencing using QIASymphony, Proflex & Quantstudio 5 SOP MOL-PCR-100
EDTA blood, bone marrow	Quantification of the BCR-ABL e13a2 and e14a2 transcripts	DNA extraction, preparation, analysis and sequencing using Maxwell RSC, Rotorgene RGQ, Proflex and eGels. SOP MOL-PCR-100
EDTA blood, bone marrow	Translocations in AML/ALL including BCR-ABL, PML-RAR and Inv16	DNA extraction, preparation and analysis by Q-30 multiplex PCR using Maxwell RSC Rotorgene RGQ and QuantStudio 5 SOP MOL-PCR-123



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HUMAN BODY FLUIDS	<u>Molecular Haemoglobinopathies</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:
EDTA blood, amniotic fluid, chorionic villus sample and cultured cells	Beta-Globin Gene mutations (Beta thalassaemia and Abnormal haemoglobins)	DNA extraction, preparation, and mutation analysis by amplification-refractory mutation system (ARMS-PCR) and/or gap-PCR with gel electrophoresis using QIASymphony, Proflex, Nanoview and QiAxcel / eGels SOP MOL-PCR-034
EDTA blood, amniotic fluid, chorionic villus sample and cultured cells	Common deletions in the Alpha-Globin gene cluster (Alpha-Thalassemia profiling)	DNA extraction, preparation, and amplification using GAP-PCR, electrophoresis and analysis using QIASymphony, QIAcube, NanoDrop, Proflex, ReadySet Gels and the QiAxcel Advanced. SOP MOL-PCR-037
EDTA blood, amniotic fluid, chorionic villus sample and cultured cells	Larger deletions in Beta Globin (HBB) Gene Cluster	DNA extraction, preparation, Multiple Ligation-Dependent Probe Amplification using QIASymphony, QIAcube, Nanodrop, Proflex, ABI3730 XL, and GeneMapper. SOP MOL-PCR-042
EDTA blood, amniotic fluid, chorionic villus sample and cultured cells	Larger deletions in the Alpha Globin (HBA1&HBA2) Gene Cluster	
EDTA blood, amniotic fluid, chorionic villus sample and cultured cells	Sequencing of the entire alpha globin HBA1, HBA2 and HBB genes	DNA extraction, preparation, sequencing, and analysis by Sanger sequencing using QIASymphony, QIAcube, Nanodrop, Proflex, E-Gels, ABI3730 XL, and Mutation Surveyor. SOP MOL-PCR-045
EDTA blood, amniotic fluid, chorionic villus sample and cultured cells	Sequencing of the entire beta globin HBB genes	DNA extraction, preparation, analysis and sequencing by Sanger sequencing using QIASymphony, Proflex, Nanoview, ABI3730 XL and QiAxcel / eGels SOP MOL-PCR-045



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HUMAN BODY TISSUE AND FLUIDS	<u>Molecular Haemoglobinopathies</u> DNA Profiling and mutation analysis for detection of abnormal sequences for disease conditions (cont'd).	Documented in-house methods for DNA manufacture, purification and detection using techniques and kits in combination with manufacturer's instructions:
EDTA blood, amniotic fluid, chorionic villus sample and cultured cells	Analysis of RFLP's (e.g. Dde1, Xmn 1), delta mutations in globin genes	DNA extraction, preparation and analysis by restriction enzyme PCR and electrophoresis using QIASymphony, Proflex, Nanoview and QiAxcel / eGels SOP MOL-PCR-035 & 036
EDTA blood, amniotic fluid, chorionic villus sample and cultured cells	HPFH mutations and delta beta thalassaemia	DNA extraction, preparation, amplification and analysis by GAP-PCR and electrophoresis using QIASymphony, QIAcube, Proflex, Nanodrop, ReadySet Gels and E-Gels SOP MOL-PCR-040
EDTA blood, amniotic fluid, chorionic villus sample and cultured cells	Detection of maternal contamination in pre-natal diagnosis samples	DNA extraction, preparation, amplification and short tandem repeat analysis using QIASymphony, QIAcube, Nanodrop, Proflex, ABI3730 XL, and Genemapper SOP MOL-PCR-043
Bone marrow, blood, biopsy tissue, pleural effusion & ascitic fluid	Karyotyping (aCGH) and myeloid, ALL, HNLK & MM panels Covering 54 gene regions allowing detection of over 2000 gene variants	Extraction of DNA using manual (Qiagen) and automated (QIAcube & QIASymphony) methods followed by molecular analysis and next-generation sequencing using Agilent Array Scanner and Illumina MiSeq SOP CYG-ONC-019-NA Isolation SOP CYG-ONC-020-aCGH Processing SOP YG-ONC-021-aCGH Analysis and Reporting SOP CYG-ONC-022-PCR and Sanger sequencing SOP CYG-ONC-023-NGS Myeloid SOP CYG-ONC-024-NGS Analysis



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HSL (Analytics) LLP

Issue No: 012 Issue date: 20 August 2021

Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE AND FLUIDS	<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: DNA extraction, preparation, analysis and sequencing by PCR and capillary electrophoresis using QIASymphony, Proflex, ABI3730 and Elucigene TRP-F Plus kit SOP MOL-PCR-006
EDTA blood	Factor V Leiden c.1601G>A mutation (p.Arg534Gln)	
EDTA blood	Prothrombin c*97G>A mutation	
EDTA blood	MTHFR c.665C>T and c.1286A>C variant mutations	
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 ABI3730 SOP MOL-PCR-121 SOP MOL-PCR-125
Amniotic fluid, chorionic villus sample, products of conception	Chromosome 21, 18,13 and sex chromosome aneuploidies, deletions and duplication syndromes	DNA extraction, preparation, analysis and sequencing by Perkin Elmer BACS-on-Beads method using Qiagen QiACube, Proflex and Luminex 200 SOP MOL-PCR-026
Blood in cfDNA tubes	Chromosome 21, 18,13, 22q and sex chromosome aneuploidies (high or low probability)	DNA extraction, preparation and analysis using QIASymphony, TECAN Robots and Concerto Array Scanner SOP CDSL-M-4-59



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE AND FLUIDS	<u>Molecular Genetics</u> 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	E2/E3 & E4 alleles for CHD / hyperlipidaemia	DNA extraction, preparation, analysis and sequencing by amplification-refractory mutation system PCR and capillary electrophoresis using QIASymphony, Qiagen Proflex, eGels and in-house developed assay SOP MOL-PCR-005
EDTA blood	Cystic fibrosis gene mutations 5T / 7T / 9T alleles	DNA extraction, preparation, analysis and next generation sequencing using QIASymphony, Qiagen Proflex and Illumina MiSeqDx with NGS 139 assay SOP MOL-PCR-028
EDTA blood	Maternal and paternal 15q11-13 gene contributions in Prader-Willi / Angelman condition	DNA extraction, preparation, analysis and sequencing by methylation specific PCR and capillary electrophoresis using QIASymphony, Qiagen Proflex, eGels and in-house developed assay SOP MOL-PCR-011
EDTA Blood	Presence of DNA, typically GADPH	DNA extraction, preparation, analysis and sequencing by real-time PCR using QIASymphony, QuantStudio5 and in-house developed assay SOP MOL-EXT-004
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 MOL-PCR-007



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HUMAN BODY TISSUE AND FLUIDS	<u>Molecular Genetics</u> 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	15 polymorphic autosomal DNA markers for use in paternity testing and DNA profiling	DNA extraction, preparation, analysis and sequencing by PCR, capillary electrophoresis using QIASymphony, Proflex and ABI3730 Applied Biosystems AmpFISTR Identifiler assay SOP MOL-PCR-010
EDTA blood, amniotic fluid and chorionic villus samples	Tubulin Specific Chaperone E c.155_166del gene mutation	In-house developed assay SOP SOP MOL-PCR-022
EDTA blood, amniotic fluid and chorionic villus samples	Uni-Parental Disomies 7, 11, 12, 14, 15 and 16	In-house developed assay SOP SOP MOL-PCR-008
EDTA blood	AZFa, AZFb, AZFc, Heterochromatin, Amelogenin and SRY region chromosome microdeletions	In-house developed assay SOP SOP MOL-PCR-004
EDTA blood	Spinal Muscular Atrophy gene mutations – SMN1 & SMN2 exons 7 & 8. SMN1 exon 7 dosage	DNA extraction, preparation, analysis and sequencing by multiplex ligation-dependent probe amplification using QIASymphony, Proflex, ABI3730 and MRC Holland SALSA® MLPA® probemix P060 SOP MOL-PCR-020
EDTA blood	Exons 1 to 79 of dystrophin gene mutation for Duchene Muscular Dystrophy	DNA extraction, preparation, analysis and sequencing by multiplex ligation-dependent probe amplification using QIASymphony, Proflex, and ABI3730 MRC Holland SALSA® MLPA® DMD P034/P035 probmix SOP MOL-PCR-021



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HUMAN BODY TISSUE AND FLUIDS	<u>Molecular Genetics</u> 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	Human Leukocyte Antigen (HLA) - DRB1*, HLA-DRB3*/4*/5* and HLA-DQB1* typing	DNA extraction, preparation, analysis and sequence specific oligonucleotide technology using QIASymphony, Proflex, Luminex 200 and LIFECODES HLA Rapid typing kits. SOP MOL-PCR-025
DNA extracted from EDTA blood	HLA B*27 alleles	Real-time PCR using Rotorgene and Genmark kit SOP MOL-PCR-129
EDTA blood	HLA B*57:01 allele presence or absence	DNA extraction, preparation, single specific primer PCR and electrophoresis using QIASymphony, Proflex, Luminex 200, eGel and Olerup SSP HLA-B*57:01 Kit SOP MOL-PCR-015
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 MOL-PCR-012
EDTA blood	CYP2D6 alleles *1, *2, *3, *4, *5, *6, *7, *8, *9, *10, *11, *15, *17, *29, *35, *41 detection and genotyping	DNA extraction, preparation, PCR and allele specific primer extension using QIASymphony, Proflex, Luminex 200 and Luminex xTAG CYP450 2D6 assay SOP MOL-PCR-030



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<p>HUMAN BODY TISSUE AND FLUIDS</p> <p>EDTA blood</p>	<p><u>Molecular Genetics</u></p> <p>DNA Profiling for detection of abnormal sequences for disease conditions: Detection of (cont'd):</p> <p>CYP2C19 alleles *1, *2, *3, *4, *5, *6, *7, *8, *9, *10, *17 detection and genotyping</p>	<p>Documented in-house methods for DNA manufacture, purification and detection using techniques and kits in combination with manufacturer's instructions:</p> <p>DNA extraction, preparation, PCR and allele specific primer extension using QIASymphony, Proflex, Luminex 200 and Luminex xTAG CYP450 2D6 assay SOP MOL-PCR-029</p>
<p>END</p>		