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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 TISSUES AND BODY FLUIDS	Molecular Genetics activities for the purpose of clinical diagnosis	Documented in-house methods incorporating manufacturer's instructions (where relevant)
Blood, bone marrow, body fluid and human tissue (fresh, frozen or fixed)		DNA extraction using QIACube and SOP HODS.SOP.MOL 01015 Extraction of DNA from Lysis buffer using the Qiacube.
Formalin fixed parraffin embedded tissue		FFPE Tissue DNA extraction using a manual process and SOP HODS.SOP.MOL.01095 DNA extraction from formalin fixed and paraffin embedded tissue.
Blood, bone marrow, body fluid and human tissue (fresh, frozen or fixed)		RNA extraction and preparation of cDNA using QIACube and PTC-200 DNA engine MJ-Research (Biorad) thermal cycler and SOP HODS.SOP.MOL0001 Extraction of RNA from RLT buffer using the QIACube. HODS.SOP.MOL.32382 : Conversion of RNA to cDNA by reverse transcription HODS.SOP.MOL.95245 :BCR RT-PCR amplification for quality control of RNA extraction and cDNA synthesis HODS.SOP.MOL.32056 Use of the Syngene Genius Bioimaging system

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUES AND BODY FLUIDS (cont'd)	Molecular Genetics activities for the purpose of clinical diagnosis (cont'd)	Documented in-house methods incorporating manufacturer's instructions (where relevant) Using the following technique/equipment :
Human Nucleic acid obtained from: A. DNA extracted from blood, bone marrow, body fluid and human tissue (fresh, frozen or fixed) B. cDNA derived from RNA extracted from blood, bone marrow, body fluid and human tissue (fresh, frozen or fixed)	Technique -5 & 8 Sequencing data derived externally	1. Real time PCR using Applied Biosystems Realtime 7500 real time analyser 2. High resolution melt analysis using Rotorgene 6000 series – QIAgen 3. Real time PCR using Rotorgene 6000 series - QIAgen 4. PCR detection of gene rearrangements using Thermal cyclers (PTC-200) DNA engine MJ-Research (Biorad) DNA Engine Peltier Thermal cycler (Biorad), Thermo PCR cycler (Fisher Scientific) MJ Research PCR cycler (Biorad), G Storm PCR Cycler (G Storm) 5. Fragment analysis with ABI3130/3730 (External testing) 6. Pyrosequencing of Bisulphite modified DNA using the Pyromark Q24 Pyrosequencer 7. Next generation sequencing using Ion Torrent One touch TM2 instrument, Ion Torrent One Touch TM ES Ion, Ion Torrent PGM System 8. Sanger sequencing with ABI3130/3730 (External testing)

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUES AND BODY FLUIDS (cont'd) Human Nucleic acid obtained from: A. DNA extracted from blood, bone marrow, body fluid and human tissue (fresh, frozen or fixed) B. cDNA derived from RNA extracted from blood, bone marrow, body fluid and human tissue (fresh, frozen or fixed) See above	<u>Molecular Genetics activities for the purpose of clinical diagnosis</u> (cont'd)	Documented in-house methods incorporating manufacturer's instructions (where relevant) Using the following technique/equipment : 9. Heteroduplex treatment and polyacrylamide gel electrophoresis of PCR products (ADD-Mol. 32010) 10. Agarose Gel electrophoresis of PCR products (ADD-Mol. 32055) 11. Gel Documentation System using Syngene Genius Bioimaging System and Agilent 4200TapeStation
A	JAK2 V617F Mutation	Technique - 1 HODS.SOP.MOL.32173Real time PCR for the detection of the JAK2 V617F Mutation in myeloprofliferative neoplasms
B	BCR-ABL 1 Quantification	Technique - 1 HODS.SOP.MOL.32303 Real Time PCR for the quantification of E13A2 or E14A2 BCR-ABL fusion transcripts
A	BRAF V600-FFPE	Technique - 2 HDS.SOP.MOL.01882 Detection of BRAF V600 mutations in FFPE specimens by PCR and HRM analysis
A	NPM1 exon 12 mutation	Technique - 2 HODS.SOP.MOL.01919 Melting curve analysis for the detection of NPM1 exon 12 mutations

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUES AND BODY FLUIDS (cont'd) See above	<u>Molecular Genetics activities for the purpose of clinical diagnosis</u> (cont'd)	Documented in-house methods incorporating manufacturer's instructions (where relevant)
A	MPL exon 10 mutation	Technique - 2 HODS.SOP.MOL.32053 Melting curve analysis for the detection of mutations within MPL exon 10
A	JAK2 exon 12 mutation	Technique - 2 HODS.SOP.MOL.32067 Melting curve analysis for the detection of mutations within JAK2 exon 12
A	KRAS codons 12 and 13	Technique - 2 HODS.SOP.MOL 95229 Detection of KRAS codon 12 and 13 mutations by PCR and high resolution melting analysis
A	KIT D816V Mutation	Technique - 3 HODS.SOP.MOL. 01568 Real time PCR for the detection of the KIT D816V Mutation
B	FIP1L1-PDGFRA Fusion gene	Technique - 3 HODS.SOP.MOL 00811 Real time PCR for the detection of the FIP1L1-PDGFRA Fusion transcript
B	NPM-ALK fusion gene	Technique - 3 HODS.SOP.MOL 00550 Real time PCR for the detection of the NPM-ALK fusion transcript
A	MYD88 L265P Mutation	Technique - 3 HODS.SOP.MOL 95250 Real time PCR for the detection of the MYD88 L265P Mutation in lymphoblastic lymphoma

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUES AND BODY FLUIDS (cont'd) See above	<u>Molecular Genetics activities for the purpose of clinical diagnosis</u> (cont'd)	Documented in-house methods incorporating manufacturer's instructions (where relevant)
A Externally generated DNA sequence data from sample/PCR products as above	Production of PCR products for the purposes of external sequencing IG Gene rearrangements	Technique – 4, (5), 9, 10, 11 ADD-Mol.Mal 32224: PCR analysis of immunoglobulin (IG) gene rearrangements to demonstrate clonality ADD-Mol.Mal 31996: B cell and T cell clonality analysis in suspect lymphoproliferations using FFPE tissue
A Externally generated DNA sequence data from sample/PCR products as above	Production of PCR products for the purposes of external sequencing TCR Gene rearrangements	Technique – 4, (5), 9,10, 11 ADD-Mol.Mal 32222: PCR analysis of T cell receptors (TCR) gene rearrangements to demonstrate clonality ADD-Mol.Mal 31996: B cell and T cell clonality analysis in suspect lymphoproliferations using FFPE tissue
A	Chimerism analysis	Technique – 4,,5 ADD-Mol. 95242: Chimerism 1:Lineage specific cell extraction from peripheral blood HOD.SOP.MOL.0043 Chimerism analysis and reporting using Chimermarker HODS.SOP-MOL.00041 Chimerism detection by the Promega Powerplex 16 short tandem rpeat system

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUES AND BODY FLUIDS (cont'd) See above	<u>Molecular Genetics activities for the purpose of clinical diagnosis</u> (cont'd)	Documented in-house methods incorporating manufacturer's instructions (where relevant)
A	Genotyping	Technique – 4,5 HODS.SOP.MOL.02214 STR (Short tandem repeat) genotyping by PCR and genescan for tissue identity testing ADD-Mol.Mal 95244: Chimerism 3:Data interpretation
A	CALR Exon 9 mutation analysis	Technique – 4,5 HODS.SOP.MOL.96000 PCR and fragment analysis for the detection of mutations within CALR exon 9 using the ABI 3730
A Externally generated DNA sequence data from sample/PCR products as above	Production of PCR products for the purposes of external sequencing Microsatellite analysis Technique 6 – sequencing data derived externally	Technique – 4, (5) HODS.SOP.MOL 02357: Detection of microsatellite instability by: PCR and fragment analysis for screening of Lynch Syndrome
A	MGMT Promoter methylation	Technique – 4, 6 HODS.SOP.MOL 02718: Bisulphite modification of DNA for assessment of MGMT methylation status HODS.SOP.MOL 02723:PCR and pyrosequencing of Bisuplhite modified DNA for the analysis of MGMT promoter methylation

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUES AND BODY FLUIDS (cont'd) See above	<u>Molecular Genetics activities for the purpose of clinical diagnosis</u> (cont'd)	Documented in-house methods incorporating manufacturer's instructions (where relevant)
A	Cancer hot spot panel for the detection of gene presence, mutations and deletions (ABL1, AKT1, ALK, APC, ATM, BRAF, CDH1, CDKN2A, CTNNB1, CSF1R, EGFR, ERBB2, ERBB4, EZH2, FBXW7, FGFR1, FGFR2, FGFR3, FLT3, GNA11, GNAS, GNAQ, HNF1A, HRAS, IDH1, JAK2, JAK3, IDH2, KDR, KIT, KRAS, MET, MLH1, MPL, NOTCH1, NPM1, NRAS, PDGFRA, PIK3CA, PTEN, PTPN11, RB1, RET, SMAD4, SMARCB1, SMO, SRC, STK11, TP53, VHL)	Technique – 7 HODS.SOP.MOL.03251 Next Generation Sequencing 1: Preparation of DNA library using the Cancer Hotspot Panel v2 HODS.SOP.MOL.03252 Next Generation Sequencing 2: Amplification & Quantification of Patient specific libraries HODS.SOP.MOL .03258 Next Generation Sequencing 3: Using Ion Chef™ System for Emulsion PCR, Enrichment of Patient Libraries and Loading ISPs onto Chips
A	Targeted Myeloid gene panel for the detection of gene presence, mutations and deletions (ASXL1, BRAF, CBL, CEBPA, DNMT3A, FLT3, GATA2, IDH1, IDH2, JAK2, KIT, KRAS, NPM1, NRAS, PTPN11, RUNX1, TET2, TP53, WT1, SF3B1, SRSF2)	HODS.SOP.MOL.03259 Next Generation Sequencing: Preparation of DNA library using the Custom Ampliseq Myeloid Panel HODS.SOP.MOL.03260 Next Generation Sequencing: Purification and Quantification of Patient specific libraries of Custom Myeloid Panel HODS.MOL.03253 Next Generation Sequencing: Using the Ion One Touch-2 Instrument to prepare Template Positive Ion Sphere Particles (ISPs). HODS.MOL.03254 Next Generation Sequencing: Initialization and Setting up the ION PGM System for sequencing Patient Libraries

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUES AND BODY FLUIDS (cont'd) See above	<u>Molecular Genetics activities for the purpose of clinical diagnosis</u> (cont'd)	Documented in-house methods incorporating manufacturer's instructions (where relevant)
A	Cancer hot spot panel for the detection of gene presence, mutations and deletions (ABL1, AKT1, ALK, APC, ATM, BRAF, CDH1, CDKN2A, CTNNB1, CSF1R, EGFR, ERBB2, ERBB4, EZH2, FBXW7, FGFR1, FGFR2, FGFR3, FLT3, GNA11, GNAS, GNAQ, HNF1A, HRAS, IDH1, JAK2, JAK3, IDH2, KDR, KIT, KRAS, MET, MLH1, MPL, NOTCH1, NPM1, NRAS, PDGFRA, PIK3CA, PTEN, PTPN11, RB1, RET, SMAD4, SMARCB1, SMO, SRC, STK11, TP53, VHL)	HODS.MOL.03255 Next Generation Sequencing: Sequencing Protocol using the Ion 316™ Chip v2 or Ion 318™Chip v2 HODS.MOL.03256 Next Generation Sequencing: Cleaning & Maintenance of the Ion Personal Genome Machine® (PGM™) HODS.MOL.03257 Next Generation Sequencing: Data Assessment, Analysis, Annotation and Reporting using the Torrent Suite Software and Ion Reporter Software
A	Targeted Myeloid gene panel for the detection of gene presence, mutations and deletions (ASXL1, BRAF, CBL, CEBPA, DNMT3A, FLT3, GATA2, IDH1, IDH2, JAK2, KIT, KRAS, NPM1, NRAS, PTPN11, RUNX1, TET2, TP53, WT1, SF3B1, SRSF2)	HODS.MOL.03356 Next Generation Sequencing: Enrichment of Template Positive Ion Sphere Particles (ISPs) using the Ion OneTouch™ ES
B Externally generated DNA sequence data from sample/PCR products as above	Production of PCR products for the purposes of external sequencing BCR-ABL1 Kinase domain	Technique – 4, (8), 10,11 HODS.SOP.MOL 02489 BCR-ABL1 Kinase domain mutation analysis
A Externally generated DNA sequence data from sample/PCR products as above	Production of PCR products for the purposes of external sequencing NRAS exons 2/3	Technique – 3, 4, (5) HODS.SOP.MOL 02538:PCR and sequence analysis for the detection of mutations within the NRAS exons 2 or 3

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUES AND BODY FLUIDS (cont'd) See above	<u>Molecular Genetics activities for the purpose of clinical diagnosis</u> (cont'd)	Documented in-house methods incorporating manufacturer's instructions (where relevant)
A Externally generated DNA sequence data from sample/PCR products as above	Production of PCR products for the purposes of external sequencing KRAS exons 3/4	Technique – 3, 4, (5) HODS.SOP.MOL 02538:PCR and sequence analysis for the detection of mutations within the KRAS exons 3 or 4
A Externally generated DNA sequence data from sample/PCR products as above	Production of PCR products for the purposes of external sequencing EGFR	Technique – 3, 4, (5) HODS.SOP.MOL 00257: Detection of EGFR mutations by PCR and sequencing
A and B Externally generated DNA sequence data from sample/PCR products as above	Production of PCR products for the purposes of external sequencing IGHV Mutation status Technique 9 - sequencing data derived externally	Technique – 4, (8), 10,11 HODS.SOP.MOL95247 Multiplex PCR for the determination of mutation status of the IGHV locus
B	PML-RARA (Diagnosis)	Technique – 4, 10,11 HODS.SOP.MOL 32181: RT-PCR for the detection of PML-RARA fusion transcripts
B	MOZ-CBP	Technique – 4, 10,11 HODS.SOP.MOL 32132: RT-PCR detection of MOZ-CBP [t(8;16)(p11;p13)
B	BCR-ABL1 (Diagnosis)	Technique – 4, 10,11 HODS.SOP.MOL 32139:RT-PCR for the detection of BCR-ABL fusion transcripts

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUES AND BODY FLUIDS (cont'd) See above	<u>Molecular Genetics activities for the purpose of clinical diagnosis</u> (cont'd)	Documented in-house methods incorporating manufacturer's instructions (where relevant)
B	AML-ETO (Diagnosis)	Technique – 4, 10,11 HODS.SOP.MOL 32247:RT-PCR for the detection of AML1-ETO fusion transcripts
B	CBFB-MYH11 (Diagnosis)	Technique – 4, 10,11 HODS.SOP.MOL 32254:RT-PCR for the detection of CBFB-MYH11 fusion transcripts
B	E2A-PBX1 (Diagnosis)	Technique – 4, 10,11 HODS.SOP.MOL 32268:RT-PCR for the detection of E2A-PBX1 fusion transcripts
B	MLL-x	Technique – 4, 10,11 HODS.SOP.MOL 32270:RT-PCR for the detection of MLL-X fusion transcripts
B	TEL-AML1 (Diagnosis)	Technique – 4, 10, 11 HODS.SOP.MOL 32272:RT-PCR for the detection of TEL-AML1 fusion transcripts

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUES AND BODY FLUIDS (cont'd)	CYTOGENETIC analysis for detection of chromosomal aberrations in the diagnosis of Haematological malignancy.	Documented in-house methods incorporating manufacturer's instructions (where relevant)
Blood, Bone marrow, CSF, Biopsy material, body fluids and FFPE tissue		Tissue culture and harvest using the following SOPs HODS.SOP.CYTO16301 Preparation of sample transport medium bottles HODS.SOP.CYTO 32022 Estimating White cell counts HODS.SOP.CYTO 16279 one marrow culture-setting up (Slanted culture tubes) HODS.SOP.CYTO 16277 Bone marrow culture:Harvest (slanted culture tubes)
	FISH analysis using fluorescent labelled gene probes and fluorescence microscopy to detect chromosome structural rearrangements and copy number of specific regions of the genome	HODS.SOP.CYTO 16290: Standard technical procedure Cytogenetic analysis using Fluorescence in situ hybridisation (FISH) HODS.SOP.CYTO 16289 (FISH) HODS.SOP.MOL.32482: Use of pressure cooker for pre-treatment of paraffin sections for interphase FISH
	1p36 13q14.3 19q13 17p TP53 ALK AP12-MALT1 ATM ATM/CEP11 BCL2 BCL6 BCR-ABL1 TRIPLE BCR-ABL1 CBFB CBFB/MYH11 CCND1 CDKN2A/CEP9	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUES AND BODY FLUIDS (cont'd)	CYTOGENETIC analysis for detection of chromosomal aberrations in the diagnosis of Haematological malignancy. (cont'd)	Documented in-house methods incorporating manufacturer's instructions (where relevant)
Blood, Bone marrow, CSF, Biopsy material, body fluids and FFPE tissue (cont'd)		Tissue culture and harvest using the following SOPs HODS.SOP.CYTO 16301 Preparation of sample transport medium bottles HODS.SOP.CYTO 32022 Estimating White cell counts HODS.SOP.CYTO 16279 one marrow culture-setting up (Slanted culture tubes) HODS.SOP.CYTO 16277 Bone marrow culture:Harvest (slanted culture tubes)
	FISH analysis using fluorescent labelled gene probes and fluorescence microscopy to detect chromosome structural rearrangements and copy number of specific regions of the genome (cont'd)	HODS.SOP.CYTO 16290: Standard technical procedure Cytogenetic analysis using Fluorescence in situ hybridisation (FISH) HODS.SOP.CYTO 16289 (FISH) HODS.SOP.MOL .32482: Use of pressure cooker for pre-treatment of paraffin sections for interphase FISH
	CEP1 CEP2 CEP3 CEP4 CEP6 CEP7 CEP8 CEP9 CEP10 CEP11 CEP12 CEP15 CEP16 CEP17 CEP18 CEP20	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUES AND BODY FLUIDS (cont'd)	CYTOGENETIC analysis for detection of chromosomal aberrations in the diagnosis of Haematological malignancy. (cont'd)	Documented in-house methods incorporating manufacturer's instructions (where relevant)
Blood, Bone marrow, CSF, Biopsy material, body fluids and FFPE tissue (cont'd)		Tissue culture and harvest using the following SOPs HODS.SOP.CYTO 16301 Preparation of sample transport medium bottles HODS.SOP.CYTO 32022 Estimating White cell counts HODS.SOP.CYTO 16279 one marrow culture-setting up (Slanted culture tubes) HODS.SOP.CYTO 16277 Bone marrow culture:Harvest (slanted culture tubes)
	FISH analysis using fluorescent labelled gene probes and fluorescence microscopy to detect chromosome structural rearrangements and copy number of specific regions of the genome (cont'd)	HODS.SOP.CYTO 16290: Standard technical procedure Cytogenetic analysis using Fluorescence in situ hybridisation (FISH) HODS.SOP.CYTO 16289 (FISH) HODS.SOP.MOL 32482: Use of pressure cooker for pre-treatment of paraffin sections for interphase FISH
	CEP XY CKS1B/CDKN2C D20S108 D7S522/CEP7 DEK/NUP214 EGR1/D5S23 EML4-ALK ETV6 ETV6/RUNX1 EV11 (MECOM) EWSR1 FGFR1 FIPIL1/PDGFRA FOX01 IGH IGH/MAF	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUES AND BODY FLUIDS (cont'd)	CYTOGENETIC analysis for detection of chromosomal aberrations in the diagnosis of Haematological malignancy. (cont'd)	Documented in-house methods incorporating manufacturer's instructions (where relevant)
Blood, Bone marrow, CSF, Biopsy material, body fluids and FFPE tissue (cont'd)		Tissue culture and harvest using the following SOPs HODS.SOP.CYTO 16301 Preparation of sample transport medium bottles HODS.SOP.CYTO 32022 Estimating White cell counts HODS.SOP.CYTO 16279 one marrow culture-setting up (Slanted culture tubes) HODS.SOP.CYTO 16277 Bone marrow culture:Harvest (slanted culture tubes)
	FISH analysis using fluorescent labelled gene probes and fluorescence microscopy to detect chromosome structural rearrangements and copy number of specific regions of the genome (cont'd)	HODS.SOP.CYTO 16290: Standard technical procedure Cytogenetic analysis using Fluorescence in situ hybridisation (FISH) HODS.SOP.CYTO 16289 (FISH) HODS.SOP.MOL .32482: Use of pressure cooker for pre-treatment of paraffin sections for interphase FISH
	IGH-BCL2 IGH-CCND1 IGH-FGFR3 IGH-MALT1 IGH-MYC/CEP8 IGK IGL KIAA1549-BRAF MALT1 MDM2 MLL MYB/CEP6 MYC MYCN PAX3 PAX7	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUES AND BODY FLUIDS (cont'd)	CYTOGENETIC analysis for detection of chromosomal aberrations in the diagnosis of Haematological malignancy. (cont'd)	Documented in-house methods incorporating manufacturer's instructions (where relevant)
Blood, Bone marrow, CSF, Biopsy material, body fluids and FFPE tissue (cont'd)		Tissue culture and harvest using the following SOPs HODS.SOP.CYTO 16301 Preparation of sample transport medium bottles HODS.SOP.CYTO 32022 Estimating White cell counts HODS.SOP.CYTO 16279 one marrow culture-setting up (Slanted culture tubes) HODS.SOP.CYTO 16277 Bone marrow culture:Harvest (slanted culture tubes)
	FISH analysis using fluorescent labelled gene probes and fluorescence microscopy to detect chromosome structural rearrangements and copy number of specific regions of the genome (cont'd)	HODS.SOP.CYTO 16290: Standard technical procedure Cytogenetic analysis using Fluorescence in situ hybridisation (FISH) HODS.SOP.CYTO 6289 (FISH) HODS.SOP.MOL 32482: Use of pressure cooker for pre-treatment of paraffin sections for interphase FISH
	PDGFB PDGFRB PML/RARA RARA RUNX1/RUNX1T1 SS18 STIL/TAL1 TCF (E2A) TLX3 TOP2A TP53/CEP17 TRA/TRD TRB TRG	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUES AND BODY FLUIDS (cont'd)	CYTOGENETIC analysis for detection of chromosomal aberrations in the diagnosis of Haematological malignancy (cont'd)	Documented in-house methods incorporating manufacturer's instructions (where relevant)
Blood, bone marrow	G-Banded karyotype analysis for detection of chromosome abnormalities associated with haemato-oncology disorders.	Tissue culture and harvest using the following SOPs HODS.SOP.CYTO 16301 Preparation of sample transport medium bottles HODS.SOP.CYTO 32022 Estimating White cell counts HODS.SOP.CYTO 16279 one marrow culture-setting up (Slanted culture tubes) HODS.SOP.CYTO 16277 Bone marrow culture:Harvest (slanted culture tubes) HODS.SOP.CYTO 16313:Slide making HODS.SOP.CYTO 16292: G-Banding SOP HODS.SOP.CYTO 919 GenASIs manual G band Image capture HODS.SOP.CYTO 2308 GenaASIs metaphase automated scan and capture SOP HODS.SOP.CYTO 16284 G banded karyotype analysis Cytogenetic Report writing HODS.SOP.CYTO 16319 and issuing reports HODS.SOP.CYTO 16297 Issuing Cytogenetics reports

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUES AND BODY FLUIDS (cont'd)	<u>Diagnosis and monitoring of haematological malignancy and bone marrow failure syndromes</u>	Documented in-house methods incorporating manufacturer's instructions (where relevant)
Blood, Bone marrow, CSF, biopsy material, FNA and body fluids	Morphological assessment and examination of fixed and unfixed stained human tissue/cells/fluid haematological cells to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis and monitoring of a range of malignant and non-malignant haematological disorders.	Hematek automated stainer using modified wrights stain and Shandon cytocentrifuge II HODS.SOP.FLOW.16403 Peripheral blood HODS.SOP.FLOW 16360 Bone marrow HODS.SOP.FLOW 16365 CSF HODS.SOP.FLOW 16406 Lymph node preparation HODS.SOP.FLOW 32280 Hematek slide stainer HODS.SOP.FLOW 16389 Iron stain HODS.SOP.FLOW 16382Haemosiderin HODS.SOP.FLOW 16396 Myeloperoxidase stain HODS.SOP.FLOW 995 Morphology review-Microscopy

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUES AND BODY FLUIDS (cont'd)	<u>Diagnosis and monitoring of haematological malignancy and bone marrow failure syndromes</u>	Documented in-house methods incorporating manufacturer's instructions (where relevant)
Blood, bone marrow, CSF, Biopsy material, FNA's, body fluids	Immunophenotyping of the following markers/antigens to diagnose and monitor the following disorders:	Flow cytometry 8 colour BDBioscience FACSCanto II flow cytometer HODS.SOP.FLOW 16403 Peripheral bloodHODS.SOP.FLOW 16360 Bone marrow HODS.SOP.FLOW 16365 CSF HODS.SOP.FLOW 16406 Lymph Node Preparation HODS.SOP.FLOW 3226 Broncho alveolar lavage HODS.SOP.FLOW 32358 Nuclear and cytoplasmic staining HODS.SOP.FLOW 32450 DNA Index and with reference to the following specific SOPs
	Acute leukaemia Chronic leukaemia T and B lymphoproliferative disorders	HODS.SOP.FLOW 32357 HODS.SOP.FLOW 32362 B cell panel HODS.SOP.FLOW 32438 T cell panel
	Plasma cell disorders	HODS.SOP.FLOW 32360 Plasma cell panel
	Hairy Cell panel	HODS.SOP.FLOW 32363 Hairy cell panel
	CD1a CD2 CD3	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUES AND BODY FLUIDS (cont'd)	<u>Diagnosis and monitoring of haematological malignancy and bone marrow failure syndromes</u> (cont'd)	Documented in-house methods incorporating manufacturer's instructions (where relevant)
Blood, bone marrow, CSF, Biopsy material, FNA's, body fluids (cont'd)	Immunophenotyping of the following markers/antigens to diagnose and monitor the following disorders: (cont'd)	Flow cytometry 8 colour BDBioscience FACSCanto II flow cytometer HODS.SOP.FLOW 16403 Peripheral blood HODS.SOP.FLOW 16360 Bone marrow HODS.SOP.FLOW 16365 CSF HODS.SOP.FLOW 16406 Lymph Node Preparation HODS.SOP.FLOW 3226 Broncho alveolar lavage HODS.SOP.FLOW 32358 Nuclear and cytoplasmic staining HODS.SOP.FLOW 32450 DNA Index and with reference to the following specific SOPs
	Acute leukaemia Chronic leukaemia T and B lymphoproliferative disorders	HODS.SOP.FLOW 32357 HODS.SOP.FLOW 32362 B cell panel HODS.SOP.FLOW 32438 T cell panel
	Plasma cell disorders	HODS.SOP.FLOW 32360 Plasma cell panel
	Hairy Cell panel	HODS.SOP.FLOW 32363 Hairy cell panel
	CD4 CD5 CD7 CD8 CD9 CD10 CD11b CD11c CD13 CD14 CD15 CD16 CD19 CD20	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUES AND BODY FLUIDS (cont'd)	Diagnosis and monitoring of haematological malignancy and bone marrow failure syndromes (cont'd)	Documented in-house methods incorporating manufacturer's instructions (where relevant)
Blood, bone marrow, CSF, Biopsy material, FNA's, body fluids (cont'd)	**Immunophenotyping of the following markers/antigens to diagnose and monitor the following disorders (cont'd):** **Acute leukaemia** **Chronic leukaemia** **T and B lymphoproliferative disorders** **Plasma cell disorders** **Hairy Cell panel** CD22 CD23 CD24 CD25 CD33 CD34 CD36 CD38 CD41 CD42 CD43 CD45 CD52 CD56 CD57	Flow cytometry 8 colour BDBioscience FACSCanto II flow cytometer HODS.SOP.FLOW 16403 Peripheral blood HODS.SOP.FLOW 16360 Bone marrow HODS.SOP.FLOW 16365 CSF HODS.SOP.FLOW 16406 Lymph Node Preparation HODS.SOP.FLOW 3226 Broncho alveolar lavage HODS.SOP.FLOW 32358 Nuclear and cytoplasmic staining HODS.SOP.FLOW 32450 DNA Index and with reference to the following specific SOPs HODS.SOP.FLOW 32357 Acute Leukaemia HODS.SOP.FLOW 32362 B cell panel HODS.SOP.FLOW 32438 T cell panel HODS.SOP.FLOW 32360 Plasma cell panel HODS.SOP.FLOW 32363 Hairy cell panel

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUES AND BODY FLUIDS (cont'd)	<u>Diagnosis and monitoring of haematological malignancy and bone marrow failure syndromes</u> (cont'd)	Documented in-house methods incorporating manufacturer's instructions (where relevant)
Blood, bone marrow, CSF, Biopsy material, FNA's, body fluids (cont'd)	Immunophenotyping of the following markers/antigens to diagnose and monitor the following disorders (cont'd): Acute leukaemia Chronic leukaemia T and B lymphoproliferative disorders Plasma cell disorders Hairy Cell panel CD61 CD64 CD66b CD79a CD79b CD81 CD99 CD103 CD117 CD123 CD138 CD200 CD235a CD303 CD304 HLA-DR IgD IgG IgM Kappa Lambda NG-2 ROR1 TCR alpha/beta TCR gamma/delta	Flow cytometry 8 colour BDBioscience FACSCanto II flow cytometer HODS.SOP.FLOW 16403 Peripheral blood HODS.SOP.FLOW 16360 Bone marrow HODS.SOP.FLOW 16365 CSF HODS.SOP.FLOW 16406 Lymph Node Preparation HODS.SOP.FLOW 3226 Broncho alveolar lavage HODS.SOP.FLOW 32358 Nuclear and cytoplasmic staining HODS.SOP.FLOW 32450 DNA Index and with reference to the following specific SOPs HODS.SOP.FLOW 32357 Acute Leukaemia HODS.SOP.FLOW 32362 B cell panel HODS.SOP.FLOW 32438 T cell panel HODS.SOP.FLOW 32360 Plasma cell panel HODS.SOP.FLOW 32363 Hairy cell panel

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUES AND BODY FLUIDS (cont'd)	Diagnosis and monitoring of haematological malignancy and bone marrow failure syndromes (cont'd)	Documented in-house methods incorporating manufacturer's instructions (where relevant)
Blood, bone marrow Stem cell harvests (Cord blood, PB, BM)	CD34 +ve stem cell enumeration	Flow cytometry 8 colour BD Bioscience FACSCanto II flow cytometer using SOPs HODS.SOP.FLOW 32455 Allogeneic cell harvests HODS.SOP.FLOW 1173 Single platform CD34 +ve cell enumerationHODS.SOP.FLOW 1004 Cord blood CD34 +ve cell enumeration
Peripheral blood	Immunological platelet enumeration	Flow cytometry 8 colour BD Bioscience FACSCanto II flow cytometer using SOPs HODS.SOP.FLOW 32049 Immunological platelet count by flow cytometer (
	Paroxysmal Nocturnal Haemoglobinuria (Red and white cells) FLAER CD14 CD24 CD33 CD64 CD66b CD59 CD235a	Flow cytometry 8 colour BD Bioscience FACSCanto II flow cytometer using SOPs HODS.SOP.FLOW 32373 Paroxysmal Nocturnal Haemoglobinuria (PNH) diagnosis by flow cytometry of neutrophils (Canto II) HODS.SOP.FLOW 1463 Paroxysmal Nocturnal Haemoglobinuria (PNH) diagnosis by flow cytometry of red cells (Canto II)
HUMAN TISSUES AND BODY	Diagnosis and monitoring of	Documented in-house methods

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
FLUIDS (cont'd)	haematological malignancy and bone marrow failure syndromes (cont'd)	incorporating manufacturer's instructions (where relevant)
Peripheral blood	Hereditary spherocytosis screening	Esoin-5-Malemide binding assay flow cytometry using Flow cytometry 8 colour BD Bioscience FACSCanto II flow cytometer using SOPs HODS.SOP.FLOW 32444 Flow cytometry screening for Hereditary spherocytosis- Canto
END		