

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 UKAS MEDICAL 9839 Accredited to ISO 15189:2022	The Royal Marsden NHS Foundation Trust Issue No: 008 Issue date: 17 June 2026 <table border="1"> <tr> <td data-bbox="395 439 842 790"> Immunophenotyping Department Specialist Integrated Haematological Malignancy Diagnostic Service (SIHMDS) The Centre for Molecular Pathology 10 Oakleaf Avenue SUTTON SM2 5PT </td><td data-bbox="842 439 1493 790"> Contact: Zanell Lategan Tel: +44 (0)20 8661 3354 E-Mail: Zanell.Lategan@rmh.nhs.uk </td></tr> </table>	Immunophenotyping Department Specialist Integrated Haematological Malignancy Diagnostic Service (SIHMDS) The Centre for Molecular Pathology 10 Oakleaf Avenue SUTTON SM2 5PT	Contact: Zanell Lategan Tel: +44 (0)20 8661 3354 E-Mail: Zanell.Lategan@rmh.nhs.uk
Immunophenotyping Department Specialist Integrated Haematological Malignancy Diagnostic Service (SIHMDS) The Centre for Molecular Pathology 10 Oakleaf Avenue SUTTON SM2 5PT	Contact: Zanell Lategan Tel: +44 (0)20 8661 3354 E-Mail: Zanell.Lategan@rmh.nhs.uk		

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 SAMPLES Blood Bone Marrow CSF Biopsies including fine needle aspirates and other body fluids: Pericardial fluid Peritoneal fluid Pleural fluid Ascitic fluid Vitreous fluid BAL fluid EBUS.	<u>SIHMDS Immunophenotyping activities for the purpose of clinical diagnosis</u> Diagnosis and monitoring of Acute Leukaemia, MDS and Chronic Lymphoid Neoplasms using the following antibodies: <u>ALOT tube</u> MPO, CD79a, CD34, CD7, CD19, CytCD3, MembraneCD3, CD45 AML Tube 1 CD7, CD56, CD13, CD117, CD34, CD33, CD38, CD11b, HlaDr, CD45, CD19, CD123 <u>AML Tube 2</u> CD16, CD300e, CD117, CD13, CD105, CD34, CD14, CD33, CD36, CD45, CD64, CD71, CD10 <u>B-ALL tube</u> CD81, CD66c, CD20, CD123, CD73, CD34, CD10, CD19, CD38, CD45, CD304, CD22 <u>T-ALL tubes</u> TCR gamma/delta, CD4, CD2, CD56, CD5, CD34, CD7, CD8, CD3, CD45, CD33, CD99, CD1a, TDT, CytCD3, CD45 <u>Mast cell tubes</u> CD9, CD203c, CD25, CD30, CD34, CD2, CD117, HlaDr, CD45	Manufacturer's instructions for the Beckman Coulter DxFlex Flow Cytometers, using either Cellmek automated cell preparation analysers or manual red cell lysis sample preparation and in-house methods. Immuno No. 11 Immuno No. 18 Immuno No. 22 Immuno No. 88 Immuno No. 89 Immuno No. 92 Immuno No. 94



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HUMAN BODY SAMPLES	<u>SIHMDS Immunophenotyping activities for the purpose of clinical diagnosis</u>	
Blood Bone Marrow CSF Biopsies including fine needle aspirates and other body fluids: Pericardial fluid Peritoneal fluid Pleural fluid Ascitic fluid Vitreous fluid BAL fluid EBUS.	Diagnosis and Monitoring of Plasma cell dyscrasia: CD38,CD138,CD45,CD19,CD117, CD27,CD81,CD56,Kappa,Lambda	Manufacturer's instructions for the Beckman Coulter DxFlex Flow Cytometers, using either Cellmek automated cell preparation analysers or manual red cell lysis sample preparation and in-house methods. Immuno No. 10 Immuno No. 18 Immuno No. 22 Immuno No. 88 Immuno No. 89 Immuno No. 94
Blood Bone Marrow CSF Biopsies including fine needle aspirates and other body fluids: Pericardial fluid Peritoneal fluid Pleural fluid Ascitic fluid Vitreous fluid BAL fluid EBUS.	MRD assessment in AML <u>AML Tube 1</u> CD7, CD56, CD13, CD117, CD34, CD33, CD38, CD11b, HlaDr, CD45, CD19, CD123 <u>AML Tube 2</u> CD16, CD300e, CD117, CD13, CD105, CD34, CD14, CD33, CD36, CD45, CD64, CD71, CD10	Manufacturer's instructions for the Beckman Coulter DxFlex Flow Cytometers, using manual red cell lysis sample preparation and in-house methods. Immuno No. 18 Immuno No. 22 Immuno No. 86 Immuno No. 88 Immuno No. 89
Peripheral Blood (EDTA)	Diagnosis and monitoring of PNH: <u>WBC</u> FLAER,CD157,CD64,CD15,CD45 <u>RBC</u> CD59,CD235a,CD71	Manufacturer's instructions for the Beckman Coulter DxFlex Flow Cytometers, using manual red cell lysis sample preparation and in-house methods. Immuno No. 22 Immuno No. 66 Immuno No. 86 Immuno No. 88 Immuno No. 89



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HUMAN BODY SAMPLES	<u>SIHMDS Immunophenotyping activities for the purpose of clinical diagnosis</u>	
Blood Bone Marrow CSF Biopsies including fine needle aspirates and other body fluids: Pericardial fluid Peritoneal fluid Pleural fluid Ascitic fluid Vitreous fluid BAL fluid EBUS.	MRD Assessment in T and B ALL: <u>B-ALL tube</u> CD81, CD66c, CD20, CD123, CD73, CD34, CD10, CD19, CD38, CD45, CD304, CD22 <u>T-ALL tubes</u> TCR gamma/delta, CD4, CD2, CD56, CD5, CD34, CD7, CD8, CD3, CD45, CD1a, CD33, CD99	Manufacturer's instructions for the Beckman Coulter DxFlex Flow Cytometers, using manual red cell lysis sample preparation and in-house methods. Immuno No. 17 Immuno No. 18 Immuno No. 22 Immuno No. 86 Immuno No. 88 Immuno No. 89
Blood Bone Marrow CSF Biopsies including fine needle aspirates and other body fluids: Pericardial fluid Peritoneal fluid Pleural fluid Ascitic fluid Vitreous fluid BAL fluid EBUS.	MRD assessment in CLL CD81, ROR1, CD5, CD23, CD10, CD79b, CD19, CD200, CD43, CD20, CD45	Manufacturer's instructions for the Beckman Coulter DxFlex Flow Cytometers, using manual red cell lysis sample preparation and in-house methods. Immuno No. 13 Immuno No. 18 Immuno No. 22 Immuno No. 86 Immuno No. 88 Immuno No. 89
Peripheral Blood Peripheral Blood Stem Cell Harvest (PBSCH) Bone Marrow	CD34 enumeration for the purposes of stem cell transplant. CD45, CD34, 7AAD	Manufacturer's instructions for the Beckman Aquios CL Flow Cytometers Immuno No.93
Peripheral Blood	Immune Monitoring (CD3, CD4, CD8, CD19 and CD56 percentage and absolute counts)	Manufacturer's instructions for the Beckman Aquios CL Flow Cytometers Immuno No. 93
Peripheral Blood Stem Cell Harvest (PBSCH) Bone Marrow	CD3 enumeration for the purposes of stem cell transplant. CD45, CD3, 7AAD	Beckman DX Flex Immuno No. 64



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