

**issued by**

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



**Issue No: 006      Issue date: 28 June 2023**

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## DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS	<u>Haematology examination activities for the purposes of clinical diagnosis</u>	Documented in-house methods based on manufacturer's operating instructions, where relevant, to support clinical diagnosis
	<u>Haematology</u>	
EDTA Whole Blood	Full blood counts and automated differential: Haemoglobin (Hb) Total white cell count (WBC) Red cell count (RBC) Platelet count (PLT) MCV MCH MCHC Nucleated Red Cell Count (NRBC) Neutrophil count Lymphocyte count Monocyte count Eosinophil count Haematocrit (HCT) Red Cell Distribution Width (RDW) Reticulocyte Count (RET)	Sysmex XN2000 Analyser SLS-HGB method- Absorbance at 555nm, Fluorescence flow cytometry, Hydrodynamic focussing DC detection (impedance method), and calculated red cell parameters HAJ-184
EDTA Whole Blood	Erythrocyte Sedimentation Rate (ESR)	StarrSed Autocompact Blood Sedimentation Instrument based on Westergren method. HAJ-100
EDTA Whole Blood	Detection of normal and abnormal morphologies, white blood cell differential	Manual Thin film slide preparation and automated staining with Wright's stain using Siemens Hematek 3 and examination by light microscopy HAJ-170, HAJ176



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ISO 15189:2012

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HUMAN BODY FLUIDS (cont'd)	<u>Haematology examination activities (cont'd)</u>	Documented in-house methods
Bone Marrow aspirate	Detection of normal and abnormal morphology	Automated Wrights using Siemens Hematek 3 & Manual staining with Giemsa stains and examination by light microscopy. HAJ-188, HAJ-SOP-15
Bone Marrow aspirate	Assessment of iron storage	Manual staining with Perls' stain and examination by light microscopy. HAJ-188, HAJ-SOP-15
EDTA Whole Blood	Detection of Malarial antigens of: P. falciparum Pan-detection for P. falciparum, P. malariae, P. ovale & P. vivax	CareStart™ Malaria HRP2/pLDH Combo Immunoassay HAJ-156
EDTA Whole Blood	Detection and identification of malarial parasites P.falciparum, P.vivax, P.ovale, P.malariae and P.knowlesi	Thin film slide preparation and manual staining with Giemsa stain and examination by light microscopy HAJ-156
EDTA Whole Blood	Detection of malarial parasites (P.falciparum, P.vivax, P.ovale, P.malariae and P.knowlesi	Thick film slide preparation and manual staining with Field's A&B stain and examination by light microscopy HAJ-156
EDTA Whole Blood	Infectious Mononucleosis (Paul Bunnell/ PB): qualitative detection of heterophile antibodies	Alere Clearview IM II test using mobilised/immobilised bovine erythrocyte glycoprotein. HAJ-161



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HUMAN BODY FLUIDS (cont'd)  Blood Citrated plasma	<u>Haematology examination activities (cont'd)</u>  <u>Coagulation</u>  Prothrombin Time (PT)  INR  Activated Partial Thromboplastin Time (APTT)  Fibrinogen (FIB)  D-dimer (DD)  Lupus Anticoagulant Screening  Anti-Xa assay	Documented in-house methods  Sysmex CS2500 using in house documented procedures based on standard methods and incorporating manufacturers' instructions as relevant:  Sysmex clotting detection method – change in optical density of sample/reagent mixture over time. INR HAJ-198  Calculated from mean normal PT and ISI value. HAJ-198  Sysmex clotting detection method – change in optical density of sample/reagent mixture over time. HAJ-199  Sysmex clotting detection method – change in optical density of sample/reagent mixture over time. Result calculated from reference curve. HAJ-200  Immuno-turbidometric assay using reagents containing monoclonal antibody specific to D-dimer. Result calculated from reference curve. HAJ-201  Detection of Lupus anticoagulant by activated partial thromboplastin time and direct Russell's Viper Venom test on Sysmex CS2500. HAC-83  Chromogenic assay on Sysmex CS2500 for level of anti-Xa activity in patients undergoing LMW Heparin therapy. HAC-90



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HUMAN BODY FLUIDS (cont'd)	<u>Haematology examination activities (cont'd)</u>	Documented in-house methods
Blood	<u>Coagulation (cont'd)</u>	Sysmex CS2500 using in house documented procedures based on standard methods and incorporating manufacturers' instructions as relevant:
Citrated plasma (cont'd)	Factor Assays (Factors 8 and 9)	Single step APTT based assays on Sysmex CS2500, using specific factor deficient plasmas to measure factors 8 and 9. HAJ-SOP-16
Blood (whole)	Sickle Solubility test	Streck Sickledex Reduced HbS solubility HAJ-162
EDTA Whole Blood	<u>Thalassaemia and Abnormal Haemoglobin Screening:</u>	Documented in-house methods to meet the requirements of the SCT screening programme as defined in the 27th July 2018 'NHS Sickle Cell and Thalassaemia Screening Programme: laboratory quality assurance evidence requirements.' HPLC method using Biorad Variant II analyser HAC-SOP-2
	Assay of HbA2 and HbF levels	
	Identification of presence of HbA and HbS	
	Screening for Hb variants	
EDTA Whole Blood	Glucose-6-Phosphate Dehydrogenase (G6PD) Screening	Trinity Biotech G6PD Screening Kit. Sample incubated with Glucose-6-Phosphate and nicotinamide adenine dinucleotide phosphate (NADP) reagent and examination under UV light. HAC-102



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HUMAN BODY FLUIDS (cont'd)	<u>Blood Transfusion examination activities for the purpose of clinical diagnosis</u>	Documented in-house procedures based on manufacturers' instructions
EDTA Whole Blood	Blood Grouping: • ABO blood groups • Rh D antigen:	<u>Automated method</u> Using Ortho cassettes and using Ortho Vision analyser BTJ-SOP-25 & BTJ-SOP-22  <u>Manual method</u> Using Ortho cassettes and centrifugation BTJ-SOP-25 & BTJ-SOP-22
EDTA Whole Blood	Red cell phenotyping: D,C,E,c,e,Cw,K,k,Fya,Fyb, Jka,Jkb,Lea,Leb,P1,M,N,S,s, Lua,Lub  <u>Jka, Jkb, N</u>	<u>Manual method</u> Using Ortho cassettes and centrifugation BTJ-SOP-14  Manual method Using tube agglutination and Lorne reagents BTJ-SOP-14
EDTA Whole Blood	Red cell antibody detection: Anti- D,C,E,c,e,Cw,K,k,Fya,Fyb, Jka,Jkb,Kpa,Kpb,Lea,Leb,P1,M,N, S,s,Lua,Lub	<u>Automated method</u> Using Ortho cassettes and using Ortho Vision analyser BTJ-SOP-25 & BTJ-SOP-22  <u>Manual method</u> Using Ortho cassettes and centrifugation BTJ-SOP-25 & BTJ-SOP-22
EDTA Whole Blood	Direct Antiglobulin Test (DAT)	<u>Automated method</u> Using Ortho cassettes and using Ortho Vision analyser BTJ-SOP-23  <u>Manual method</u> Using Ortho cassettes and centrifugation BTJ-SOP-23



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HUMAN BODY FLUIDS (cont'd)	<u>Blood Transfusion examination activities (cont'd)</u>	Documented in-house methods
Blood (whole)	Compatibility Testing: Serological Crossmatch- serological compatibility test between donor red cell antigens and patient plasma	<u>Automated Method</u> Documented in-house procedures based on Ortho manufacturer's instructions for glass bead column technology and Ortho Vision analyser BTJ-SOP-26  <u>Manual Method</u> Documented in-house procedures based on Ortho manufacturer's instructions for glass bead column technology and centrifugation.  <u>Manual method</u> Using tube and centrifugation SOP-BTE-13 BTJ-SOP-26
Blood (whole)	Detection and estimation of Foetal Maternal Haemorrhage (Kleihauer test)	Clini-tech Foetal Cell Detection Kit. Acid elution and microscopic examination. BTJ-112
END		