


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

 <p><b>UKAS</b> MEDICAL 9345</p> <p>Accredited to ISO 15189:2012</p>	<h3>HSL (Analytics) LLP</h3> <p>Issue No: 004 Issue date: 03 September 2020</p>	
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<p><b>Testing performed at the above address only</b></p>		

### DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS  Blood (unless otherwise stated)	<p><u>Coagulation</u></p> <p>Haematology examination activities for the purposes of clinical diagnosis. Determination of:</p> <p>Prothrombin time (PT)</p> <p>Activated partial thromboplastin time (APTT)</p> <p>Thrombin time</p> <p>Clauss Fibrinogen</p> <p>Reptilase time</p> <p>APTT Inhibitor Screen</p> <p>Protein S Activity</p> <p>Activated Protein C ratio with Factor V deficient plasma</p> <p>Factor VIII Inhibitor Factor IX Inhibitor</p> <p>Dilute Russell Viper test and confirmation</p> <p>Silica Clot Time and confirmation</p> <p><u>Direct Thrombin Inhibitors</u></p> <p>Dabigatran Level Argatroban Level</p>	<p>In house documented procedures based on equipment manuals and standard methods as specified:</p> <p>Clotting assays using IL ACL TOP Coagulometer with reference to the following procedures:</p> <p>COAG-RFH-060</p> <p>COAG-RFH-075</p> <p>COAG-RFH-073</p> <p>COAG-RFH-061</p> <p>COAG-RFH-074</p> <p>COAG-RFH-078</p> <p>COAG-RFH-077</p>



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<p>HUMAN BODY FLUIDS</p> <p>Blood (unless otherwise stated)</p>	<p><u>Coagulation</u></p> <p>Haematology examination activities for the purposes of clinical diagnosis (cont'd)</p> <p><u>Extrinsic Clotting Factors:</u></p> <p>Factor II Factor V Factor VII Factor X</p> <p><u>Intrinsic Clotting Factors:</u></p> <p>Factor VIII Factor IX Factor XI Factor XII</p> <p><u>Factor IX</u></p> <p>Chromogenic Factor Assays: Factor VIII Factor IX</p> <p>Protein C Activity</p> <p>Plasminogen</p> <p>Plasmin Inhibitor</p>	<p>In house documented procedures based on equipment manuals and standard methods as specified:</p> <p>Clotting assays using IL ACL TOP Coagulometer with reference to the following procedures:</p> <p>COAG-RFH-066</p> <p>COAG-RFH-065</p> <p>Clotting assay using IL ACL TOP Coagulometer with Synthafax APTT reagent with reference to: COAG-RFH-104</p> <p>Chromogenic assays using IL ACL TOP Coagulometer with reference to the following procedures:</p> <p>COAG-RFH-071 COAG-RFH-108</p> <p>COAG-RFH-063</p> <p>COAG-RFH-069</p> <p>COAG-RFH-070</p>



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<p>HUMAN BODY FLUIDS</p> <p>Blood (unless otherwise stated)</p>	<p><u>Coagulation</u></p> <p>Haematology examination activities for the purposes of clinical diagnosis (cont'd)</p> <p><u>Anti-Xa assays:</u></p> <p>Low Molecular Weight Heparin Unfractionated Heparin Fondaparinux levels Danaparoid levels Rivaroxaban levels Apixaban levels Edoxaban levels</p> <p>Protein S Free</p> <p>Fibrinogen Antigen</p> <p>Antithrombin Antigen</p> <p>VWF Antigen</p> <p>VWF Activity</p> <p>Prothrombin time</p> <p>Activated partial thromboplastin time</p> <p>Thrombin time</p> <p>Clauss Fibrinogen</p>	<p>In house documented procedures based on equipment manuals and standard methods as specified:</p> <p>Chromogenic assays using IL ACL TOP Coagulometer with reference to:</p> <p>COAG-RFH-072</p> <p>Latex assays using IL ACL TOP Coagulometer with reference to:</p> <p>HPHLP TOP 006</p> <p>COAG-RFH-076</p> <p>COAG-RFH-064</p> <p>COAG-RFH-067</p> <p>COAG-RFH-068</p> <p>COAG-RFH-029 using Stago KC4 Delta semi-automated analyser by clotting assay</p>



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HUMAN BODY FLUIDS (cont'd)  Blood (unless otherwise stated)	<u>Coagulation</u> (cont'd)  Haematology examination activities for the purposes of clinical diagnosis. Determination of (cont'd)  <u>Contact Factors</u>  HMW Kinninogen (Fitzgerald Trait) Prelallikrein (Fletcher Trait)  Collagen/Epinephrine closure time (seconds)  Collagen/ADP closure time (seconds)	In house documented procedures based on equipment manuals and standard methods as specified:  COAG-RFH-030 using Stago KC Delta by semi-automated mechanical end-point assay by clotting assay  COAG-RFH-031 using Siemens PFA-100 by whole blood shear assay  In house documented procedures based on equipment manuals and standard methods as specified:  Sysmex CS2100i with reference to:  COAG-RFH-056 by chromogenic assay  COAG-RFH-057 by platelet aggregation  COAG-RFH-058 by chromogenic assay  COAG-RFH-034 using BioData PAP-8E by light transmission aggregometry  COAG-RFH-036 using Chronolog Model 700 Aggregometer  COAG-RFH-033 using Matis IMPACT-R by whole blood shear assay  COAG-RFH-032 using Berthold Luminometer Junior by in-house developed method luminescence method
	Antithrombin activity	
	VWF Ristocetin co-factor	
	Factor XIII	
	Platelet Aggregation	
	Platelet Lummiaggregometry	
	Platelet Aggregate Size Surface Coverage	
	Platelet Nucleotides	



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HUMAN BODY FLUIDS (cont'd)  Blood (unless otherwise stated)	<u>Coagulation</u> (cont'd)  Haematology examination activities for the purposes of clinical diagnosis. Determination of (cont'd)  VWF Antigen  VWF Collagen Binding  Protein C Antigen Protein S Total Factor XIII Antigen Factor XI Antigen Factor IX Antigen  Plasminogen Activator Inhibitor-1 antigen  VWF Multimer  Platelet Factor 4 IgG HIT	In house documented procedures based on equipment manuals and standard methods as specified:  COAG-RFH-012 using Grifols Triturus (automated ELISA) and COAG-RFH-007 & COAG-RFH-008 by in-house developed manual ELISA  COAG-RFH-012 using Grifols Triturus (automated ELISA) and COAG-RFH-013 (manual ELISA) using Affinity Biologicals antibodies  COAG-RFH-010 by Stago manual ELISA  COAG-RFH-014 by in-house developed electrophoresis  COAG-RFH-011 using Lifecodes (Immucor GTI Diagnostics) manual ELISA
Citrated whole blood	Factor V Leiden G1691A and Prothrombin (FII) G20210A gene mutations	Real time PCR using Cepheid GeneXpert SOP COAG-RFH-005
END		