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



HSL (Analytics) LLP

Issue No: 009 Issue date: 18 February 2025

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DETAIL OF ACCREDITATION

Assessment Manager: KW1



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Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS Blood (unless otherwise stated)	<u>Coagulation</u> Haematology examination activities for the purposes of clinical diagnosis (cont'd) <u>Extrinsic Clotting Factors:</u> Factor II Factor V Factor VII Factor X <u>Intrinsic Clotting Factors:</u> Factor VIII Factor IX Factor XI Factor XII <u>Factor IX</u> Chromogenic Factor Assays: Factor VIII Factor IX Protein C Activity Plasminogen Plasmin Inhibitor	In house documented procedures based on equipment manuals and standard methods as specified: Clotting assays using IL ACL TOP Coagulometer with reference to the following procedures: COAG-RF1-64 COAG-RF1-63 Clotting assay using IL ACL TOP Coagulometer with Synthafax APTT reagent with reference to: COAG-RF1-101 Chromogenic assays using IL ACL TOP Coagulometer with reference to the following procedures: COAG-RF1-69 COAG-RF1-104 COAG-RF1-61 COAG-RF1-67 COAG-RF1-68



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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-RF1-70</p> <p>Latex assays using IL ACL TOP Coagulometer with reference to:</p> <p>COAG-RF1-60</p> <p>COAG-RF1-74</p> <p>COAG-RF1-62</p> <p>COAG-RF1-65</p> <p>COAG-RF1-66</p> <p>COAG-RF1-28 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) Antithrombin activity VWF Ristocetin co-factor Factor XIII Platelet Aggregation Platelet Lummiaggregometry Platelet Aggregate Size Surface Coverage Platelet Nucelotides	<p>In house documented procedures based on equipment manuals and standard methods as specified:</p> <p>COAG-RF1-28 using Stago KC Delta by semi-automated mechanical end-point assay by clotting assay</p> <p>COAG-RF1-115 using Siemens PFA-200 by whole blood shear assay</p> <p>In house documented procedures based on equipment manuals and standard methods as specified:</p> <p>Sysmex CS2100i with reference to:</p> <p>COAG-RF1-54 by chromogenic assay</p> <p>COAG-RF1-55 by platelet aggregation</p> <p>COAG-RF1-56 by chromogenic assay</p> <p>COAG-RF1-33 using BioData PAP-8E by light transmission aggregometry</p> <p>COAG-RF1-35 using Chronolog Model 700 Aggregometer</p> <p>COAG-RF1-32 using Matis IMPACT-R by whole blood shear assay</p> <p>COAG-RF1-31 using Berthold Luminometer Junior by in-house developed method luminescence method</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) 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: In-house developed manual ELISA with absorbance values read on Thermoscientific Multiskan FC Plate reader SOPs COAG-RF1-10, COAG-RF1-1 & COAG-RF1-122 Manual ELISA using Affinity Biologicals antibodies with absorbance values read on Multiskan FC Microplate Photometer SOPs COAG-RF1-13 & COAG-RF1-122 COAG-RF1-3 by Stago manual ELISA COAG-RF1-14 by in-house developed electrophoresis COAG-RF1-11 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-RF1-8
Citrated Blood	Factor VIII	Chromogenic FVIII assay using Coamatic kit (Bovine Clotting Factors) on Werfen ACL TOP 750 SOP COAG-RF1-1000
Citrated Blood	Emicizumab Assay	Modified one stage APTT clotting based Factor VIII assay on Werfen ACL TOP 750 SOP COAG-RF1-108



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HUMAN BODY FLUIDS (cont'd)	<u>Coagulation</u> (cont'd)	
Blood (unless otherwise stated)	Haematology examination activities for the purposes of clinical diagnosis. Determination of (cont'd)	In house documented procedures based on equipment manuals and standard methods as specified:
Citrated Blood	Dabigatran Assay	HemosIL Dilute thrombin time assay using Werfen ACL TOP 750 SOP COAG-RF1-116
Citrated Blood	Chromogenic Bethesda	Chromogenic Nijmegen Bethesda using Werfen ACL TOP 750 SOP COAG-RF1-99
Citrated Blood	Collagen/Epinephrine Closure times and Collagen/ADP Closure times	Whole blood shear assay using PFA-200 SOP COAG-RF1-115
Citrated Blood	Antithrombin activity	Chromogenic assay using Sysmex CS2100i SOP COAG-RF1-54
Citrated Blood	VWF Ristocetin co-factor	Platelet Aggregation using Sysmex CS2100i SOP COAG-RF1-55
Citrated Blood	Factor XIII activity	Chromogenic assay using Sysmex CS2100i SOP COAG-RF1-56
Citrated Blood	Platelet Aggregation	Light transmission aggregometry using BioData PAP-8E SOP COAG-RF1-33
Citrated Blood	Platelet Lumiaggregometry	Lumi-Aggregometry Adenosine Triphosphate Release Assay using Chronolog Model 700 Aggregometer SOP COAG-RF1-35
Citrated Blood	Platelet Aggregate Size Surface Coverage	Whole blood shear assay using Matis IMPACT-R SOP COAG-RF1-32
END		