



ACCREDITATION DOCUMENT

TEST 229

St. Olavs hospital HF, Laboratoriemedisinsk klinikk, Avdeling for medisinsk biokjemi
Erling Skjalgssons gt.1
7006 Trondheim

The scope of accreditation is in accordance with the specifications on the following pages in this document.

The accreditation was initially granted 21.11.2008. The accreditation is given according to "Law on the free exchange of goods in the European Economic Area" of 14.04.2013.
The organisation complies with the requirements in NS-EN ISO 15189 (2012)

The accreditation requires regular surveillance, and is valid until 19.10.2028.

The decision of accreditation made by Norwegian Accreditation implies that the organisation has been found to fulfil the requirements for accreditation within the scope.
The organisation itself is responsible for the results of performed measurements.

NORWEGIAN ACCREDITATION

19.10.2023

Date


Norwegian Accreditation



Accreditation document
Accreditation no. TEST 229

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Administrative/geographical unit:

Avd. for medisinsk biokjemi, St. Olav - Orkdal sjukehus
Sjukehusvegen 3
7300 Orkanger

Permanent facility

M30 **Sample collection**

Object	Parameter	Reference standard	Identity of internal method	Comments
Patient	Venous and capillary samples	Internal method	13358, 1756, 18398, 21149, 2423	

19.10.2023

Date

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Administrative/geographical unit:
Avd. for medisinsk biokjemi, St. Olav - Røros sykehus
7374 Røros

Permanent facility

M30 **Sample collection**

Object	Parameter	Reference standard	Identity of internal method	Comments
Patient	Venous and capillary samples	Internal method	13358, 1756, 18398, 21149, 2423	

19.10.2023

Date

B. Hellerød

Norwegian Accreditation

Administrative/geographical unit:

Avd. for medisinsk biokjemi, St. Olav - Trondheim

Erling Skjalgssongt 1

7006 Trondheim

Permanent facility

M12 Medical biochemistry

Object	Parameter	Reference standard	Identity of internal method	Comments
Serum	17-OH-progesteron	Internal method	2242	LC-MS-MS
Serum	25-OH vitamin D	Internal method	1023	LC-MS-MS
Plasma	ADAMTS 13 antibody, IgG	Internal method	43484	ELISA
Plasma	ADAMTS 13 antibody, IgG	Internal method	43484	ELISA
Plasma	Adrenocorticotrophic hormone (ACTH)	Internal method	1002	ECLIA, cobas pro e801
Plasma, serum	Alanin aminotransferase (ALAT)	Internal method	1787	Enzymatic photometry IFCC Atellica CH930
Plasma, serum	Albumin	Internal method	2007	Photometry BCG Atellica CH930
Urin	Albumin	Internal method	1012	Immunoturbidimetry Atellica CH930
Plasma, serum	Alcaline phosphatase (ALP)	Internal method	4619	Enzymatic photometry IFCC Atellica CH930
Serum	Aldosteron	Internal method	1003	LC-MS-MS
Serum	Alpha 1-antitrypsin	Internal method	355	Nephelometry Atellica NEPH
Serum	Alpha1-Fetoprotein (AFP)	Internal method	1506	ECLIA Cobas pro e801
Plasma	Ammonium	Internal method	1785	Enzymatic photometry Atellica CH930
Plasma, serum, urine	Amylase	Internal method	2511, 12853	Enzymatic photometry IFCC Atellica CH930
Serum	Androstenedione	Internal method	2242	LC-MS-MS
Plasma	Antifactor Xa	Internal method	20430	Cromogenic substrate Sysmex CS-5100
Plasma	Antithrombin	Internal method	1536	Cromogenic substrate Sysmex CS-5100
Serum	Apolipoprotein A1 (ApoA1)	Internal method	448	Nephelometry Atellica NEPH
Serum	Apolipoprotein B (ApoB)	Internal method	448	Nephelometry Atellica NEPH
Plasma	APTT (activated partial thromboplastin time)	Internal method	326	Optical clot detection Sysmex CS-5100

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B. Hellerud
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7006 Trondheim

Permanent facility

M12 Medical biochemistry

Object	Parameter	Reference standard	Identity of internal method	Comments
Plasma, serum	Aspartate aminotransferase (ASAT)	Internal method	1789	Enzymatic photometry IFCC Atellica CH930
Serum, cerebrospinal fluid	Beta-2-microglobulin	Internal method	1467	Nephelometry Atellica NEPH
Plasma, serum	Bilirubin, conjugated	Internal method	258	Photometry Atellica CH930
Plasma, serum	Bilirubin, total	Internal method	334	Photometry Atellica CH930
Plasma, serum	Bilirubin, unconjugated	Internal method	258	Calculated
Plasma, serum, urine	Calcium	Internal method	3377, 970	Photometry Atellica CH930
Serum	Cancer antigen 125 (CA 125)	Internal method	1507	ECLIA Cobas pro e801
Serum	Cancer antigen 15-3 (CA 15-3)	Internal method	2618	ECLIA Cobas pro e801
Serum	Cancer antigen 19-9 (CA 19-9)	Internal method	2333	ECLIA Cobas pro e801
Plasma, serum, urine	Carbamid	Internal method	4630, 12888	Enzymatic photometry Atellica CH930
Serum	Carcino embryonic antigen (CEA)	Internal method	2448	ECLIA Cobas pro e801
Serum	Ceruloplasmin	Internal method	349	Nephelometry Atellica NEPH
Plasma, serum, urine	Chloride	Internal method	291, 971	Indirect potentiometry Atellica CH930
Plasma, serum	Cholesterol	Internal method	2829	Enzymatic photometry Atellica CH930
Serum	Chromogranin A	Internal method	6294	FIA Kryptor
Plasma, serum	Copper	Internal method	1014	Atomic absorption
Plasma, serum	Cortisol	Internal method	297	Chemiluminescence Atellica IM1600
Saliva, urine	Cortisol	Internal method	9313	LC-MS-MS
Serum	C-peptid (connecting peptide of insulin)	Internal method	6714	ECLIA Cobas pro e801
Plasma, serum	C-reactive protein (CRP)	Internal method	328	Immunoturbidimetry Atellica CH930
Plasma, serum	C-reactive protein (CRP), high sensitivity	Internal method	8821	Immunoturbidimetry Atellica CH930

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M12 Medical biochemistry

Object	Parameter	Reference standard	Identity of internal method	Comments
Plasma, serum	Creatine kinase-MB (CK-MB)	Internal method	1792	Chemiluminescence Atellica IM1600
Plasma, serum, urine	Creatinine	Internal method	4632, 968	Enzymatic Photometry Atellica CH930
Plasma, serum	Creatinkinase, total (CK)	Internal method	2275	Enzymatic photometry IFCC Atellica CH930
Serum	CTX-1, (Beta-Crosslaps)	Internal method	31044	ECLIA Cobas pro e801
Plasma, serum	Cystatine C	Internal method	43104	Immunoturbidimetry Atellica CH930
Plasma	D-dimer (fibrin degradation products)	Internal method	1604	Immunoturbidimetry Sysmex CS-5100
Serum	Dehydroepiandrosterone sulfate (DHEAS)	Internal method	6522	ECLIA Cobas pro e801
Serum	Electrophoresis of serum proteins	Internal method	1018	Capillary elektroforesis
Blood	Erythrocyte indices: MCV, MCH, MCHC	Internal method	34723	Calculated value, Sysmex XN, Sysmex XP-300, Advia 2120i, Celldyn Sapphire, ABX Micros
Blood	Erythrocytes	Internal method	272	Flowcytometry/Impedance Sysmex XN, Advia 2120i, Celldyn Sapphire, ABX Micros
Serum	Erythropoietin, (EPO)	Internal method	15826	Chemiluminescence Atellica IM1600
Plasma, serum	Estradiol	Internal method	5650	ECLIA Cobas pro e801
Serum	Estradiol	Internal method	38003	LC/MS-MS
Plasma, serum	Ethanol (ethyl alcohol)	Internal method	994	Enzymatic photometry Atellica CH930
Blood	EVF (Erythrocyte volume fraction)	Internal method	2479	Calculated value, Sysmex XN, Sysmex XP-300, Advia 2120i, Celldyn Sapphire, ABX Micros
Plasma	Factor VIII	Internal method	13601	Cromogenic substrate ACL Top 550
Plasma, serum	Ferritin	Internal method	1032	Chemiluminescence Atellica IM1600
Plasma	Fibrinogen	Internal method	327	Optical clot detection Sysmex CS-5100
Serum	Folate	Internal method	1033	Chemiluminescence Atellica IM1600

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M12 Medical biochemistry

Object	Parameter	Reference standard	Identity of internal method	Comments
Serum	Follicle stimulating hormone (FSH)	Internal method	1537	Chemiluminiscence Atellica IM1600
Serum	Free kappa chains	Internal method	9319	Nephelometry Atellica NEPH
Serum	Free lambda chains	Internal method	9319	Nephelometry Atellica NEPH
Plasma, serum	Gamma glutamyl transferase (GT, gamma-GT)	Internal method	1971	Enzymatic photometry IFCC Atellica CH930
Plasma, serum	Gentamicin	Internal method	4590	Immunoturbidimetri Atellica CH930
Plasma, serum	GFR, estimated (creatinine)	Internal method	9377	Calculated
Plasma, serum	GFR, estimated (Cystatine C)	Internal method	43104	Calculated
Plasma, serum, cerebrospinal fluid	Glucose	Internal method	2023, 6552	Enzymatic photometry Atellica CH930
Blood	Glycosylated hemoglobin (HbA1c)	Internal method	122	HPLC Tosoh G8
Serum	Growth hormone (hGH)	Internal method	6836	ECLIA Cobas pro e801
Serum	Haptoglobin	Internal method	449	Nephelometry Atellica NEPH
Plasma, serum	HDL-cholesterol	Internal method	1466	Enzymatic photometry Atellica CH930
Blood	Hemoglobin	Internal method	273	Photometry Sysmex XN, Sysmex XP-300, Advia 2120i, Celldyn Sappihre, ABX Micros
Plasma	Homocysteine	Internal method	986	CMIA Alinity
Plasma, serum	Human choriongonadotropin (hCG, beta-hCG)	Internal method	1849	ECLIA Cobas pro e801
Serum	IGF-1 insulin like growth factor 1, (somatomedin C)	Internal method	1004	ECLIA Cobas pro e801
Plasma, serum	Immunglobulins, quantitation (IgA)	Internal method	348	Immun turbidimetry Atellica CH930
Plasma, serum	Immunglobulins, quantitation (IgG)	Internal method	11825	Immunoturbidimetry Atellica CH930
Plasma, serum	Immunglobulins, quantitation (IgM)	Internal method	450	Immunoturbidimetry Atellica CH930

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B. Hellestad
Norwegian Accreditation

Administrative/geographical unit:

Avd. for medisinsk biokjemi, St. Olav - Trondheim
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7006 Trondheim

Permanent facility

M12 Medical biochemistry

Object	Parameter	Reference standard	Identity of internal method	Comments
Plasma, serum	Interleukine 6	Internal method	43456	ECLIA Cobas pro e801
Plasma, serum	Iron	Internal method	331	Photometry Atellica CH930
Plasma, serum	Iron binding capacity (TIBC)	Internal method	4634	Calculated Atellica CH930
Plasma	Lactate	Internal method	2000	Enzymatic photometry Atellica CH930
Plasma, serum	Lactate dehydrogenase (LD)	Internal method	2110	Enzymatic photometry IFCC Atellica CH930
Plasma, serum	LDL-cholesterol	Internal method	978	Enzymatic photometry Atellica CH930
Blood	Leukocytes	Internal method	10015	Flowcytometry Sysmex XN, Advia 2120i, Celldyn Sapphire
Plasma, serum	Lipase	Internal method	1412	Enzymatic photometry Atellica CH930
Plasma, serum	Lipoprotein Lp(a)	Internal method	354	Immunoturbidimetry Atellica CH930
Plasma	Lupus anticoagulant	Internal method	17169	Clot ALC Top 550
Serum	Luteinizing hormone (LH)	Internal method	1538	Chemiluminescence Atellica IM1600
Plasma, serum, urine	Magnesium	Internal method	4631, 12837	Photometry Atellica CH930
Serum	Methylmalonic acid	Internal method	2230	GC-MS
Serum	Neuron specific enolase (NSE)	Internal method	2480	ECLIA Cobas pro e801
Plasma, serum	Nt-proBNP	Internal method	7106	ECLIA Cobas pro e801
Serum	Orosomuroid	Internal method	443	Nephelometry Atellica NEPH
Serum	Osmolal Gap	Internal method	18498	Calculated
Plasma, serum, urine	Osmolalitet	Internal method	2022	Freezing point depression
Plasma, serum	Paracetamol	Internal method	4708	Photometry Atellica CH930
Plasma og serum	Parathyroid hormon (PTH)	Internal method	2320	Chemiluminescence Atellica IM1600

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M12 Medical biochemistry

Object	Parameter	Reference standard	Identity of internal method	Comments
Plasma, serum, urine	Phosphate	Internal method	2828, 1788	Photometry Atellica CH930
Serum	PINP	Internal method	31867	ECLIA Cobas pro e801
Serum	Placental growth factor (PIGT)	Internal method	45221	FIA Kryptor
Plasma, Serum, urine	Potassium	Internal method	1603, 972	Indirect potentiometry Atellica CH930
Serum	Prealbumin	Internal method	442	Nephelometry Atellica NEPH
Serum	Progesterone	Internal method	7080	Chemiluminescence Atellica IM1600
Serum	Prolactin	Internal method	7245	Chemiluminescence Atellica IM1600
Serum	Prostate specific antigen (PSA)	Internal method	1036	Chemiluminescence Atellica IM1600
Plasma	Protein C	Internal method	2109	Cromogenic substrate Sysmex CS-5100
Plasma	Protein S, free	Internal method	344	Immunoturbidimetry Sysmex CS-5100
Plasma, serum, cerebrospinal fluid, urine	Protein, total	Internal method	4633, 995, 6963	Photometry Atellica CH930
Plasma	PT-INR	Internal method	347	Optical clot detection Sysmex CS-5100
Blood	Reticulocytes	Internal method	1474	Flowcytometry Sysmex XN
Serum	Retinol Binding Protein	Internal method	451	Nephelometry Atellica NEPH
Plasma, serum	Salicylate	Internal method	257	Photometry Atellica CH930
Serum	Sex hormone binding globulin (SHBG)	Internal method	7277	Chemiluminescence Atellica IM1600
Plasma, serum, urine	Sodium	Internal method	1602, 976	Indirect potentiometry Atellica CH930
Serum	Soluble fms-like tyrosine kinase 1 (sFlt-1)	Internal method	45221	FIA Kryptor
Serum	Testosterone, total	Internal method	2242	LC-MS-MS
Plasma, serum	Thyroid stimulating hormone (TSH)	Internal method	1031	Chemiluminescence Atellica IM1600

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M12 Medical biochemistry

Object	Parameter	Reference standard	Identity of internal method	Comments
Plasma, serum	Thyroxine, free (FT4)	Internal method	1035	Chemiluminiscense Atellica IM1600
Plasma, serum	Tobramycin	Internal method	4593	Photometry Atellica CH930
Plasma, serum	Transferrin	Internal method	4634	Immunoturbidimetry Atellica CH930
Plasma, serum	Triglycerides	Internal method	335	Enzymatic photometry Atellica CH930
Serum	Triiodothyronine, free (FT3)	Internal method	5258	Chemiluminiscense Atellica IM1600
Blood	Trombocytes	Internal method	2430	Flowcytometry/Impedance Sysmex XN, Advia 2120i, Celldyn Sapphire
Plasma, serum	Troponin T, cardiac specific	Internal method	2274	ECLIA Cobas pro e801
Plasma, serum, urine	Urate	Internal method	2826, 7194	Enzymatic photometry Atellica CH930
Plasma, serum	Vancomycin	Internal method	4592	Immunoturbidimetry Atellica CH930
Serum	Vitamin A	Internal method	1605	HPLC
Plasma, serum	Vitamin B12	Internal method	1030	Chemiluminiscense Atellica IM1600
Blood	Vitamin B2 (FAD)	Internal method	1469	HPLC
Plasma	Vitamin B6	Internal method	870	HPLC
Serum	Vitamin E	Internal method	1605	HPLC
Plasma, serum	Zinc	Internal method	1013	Atomic absorption

Permanent facility

M15 Medical genetics

Object	Parameter	Reference standard	Identity of internal method	Comments
Blood	Alfa1-antitrypsin, gene test	Internal method	1865	Real time PCR LightCycler
Blood	ApoE, gene test	Internal method	4278	Real time PCR LightCycler

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Administrative/geographical unit:

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7006 Trondheim

Permanent facility

M15 Medical genetics

Object	Parameter	Reference standard	Identity of internal method	Comments
Blood	Factor V Leiden, gene test	Internal method	35262	Real time PCR LightCycler
Blood	Gilbert's syndrome, gene test	Internal method	7872	Real time PCR LightCycler
Blood	Hemokromatose, gene test	Internal method	35120	Real time PCR LightCycler
Blood	JAK2, gene test mutation	Internal method	34865	Real time PCR, quantitative Lightcycler
Blood	Lactose intolerance, gene test	Internal method	34888	Real tyime PCR LightCycler
Blood	Protrombin, gene test	Internal method	35262	Real time PCR LightCycler

Permanent facility

M30 Sample collection

Object	Parameter	Reference standard	Identity of internal method	Comments
Patient	Venous and capillary samples	Internal method	13358, 1756, 18398, 21149, 2423	

Permanent facility

M31 Flexible accreditation

Object	Parameter	Reference standard	Identity of internal method	Comments
Blood	Gene analyses	Internal method	Measurement principle/analysis platforms that are accredited under medical genetics (M15), Method ID: 17990	An updated list of methods included in the flexible scope of accreditation, is available with the organization.

19.10.2023

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Norwegian Accreditation

Administrative/geographical unit:
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Permanent facility

M31 Flexible accreditation

Object	Parameter	Reference standard	Identity of internal method	Comments
body fluids	Hematological analytes Clinical - chemical analytes Coagulation analyses Proteins Pharmacological analyses	Internal method	Measurement principle/analysis platforms that are accredited under medical biochemistry (M12), MethodID: 17990	An updated list of methods included in the flexible accreditation is available from the organisation.

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