

ACCREDITATION DOCUMENT

TEST 099

Oslo universitetssykehus HF, Aker, Hormonlaboratoriet
0514 OSLO

The scope of accreditation is M12, M31 and M32 in accordance with the specifications on the following pages in this document.

The accreditation was first time granted 12.11.1997 and given according to Parliamentary Proposition no. 106 (1989/1990) and the Statutes of Norwegian Accreditation , established by Royal Decree of 7 October 1993

The organisation complies with the requirements in NS-EN ISO/IEC 17025 (2005)

The accreditation requires regular surveillance, and is valid until 21.12.2014.
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

Administrative/geographical unit:

Oslo universitetssykehus HF, Aker, Hormonlaboratoriet
0514 OSLO

Permanent facility

M12

Object	Parameter	Reference standard	Identity of internal method	Comments
Serum	17-OH-Progesterone		MI 12	Method based on immuno assay (RIA)
Serum	Estradiol		ML 18	Method based on immuno assay (FIA)
Plasma	Adrenocorticotropin (ACTH)		ML 38	Method based on immuno assay (ILMA)
Plasma/ serum	Aldosterone		MI 01	Method based on immuno assay (RIA)
Urine	Aldosterone		MI 02	Method based on immuno assay (RIA)
Serum/ urine	Chorionic gonadotropin (hCG)		ML 08	Method based on immuno assay (ILMA)
Serum	C-terminal telopeptide type 1 collagen (ICTP)		MI 05	Method based on immuno assay (RIA)
Serum	Dehydroepiandrosterone sulphate (DHEA-SO ₄)		ML 04	Method based on immuno assay (LIA)
Urine	Deoxypyridinium collagen crosslinks (DPYD)		ML 41	Method based on immuno assay (LIA)
Serum	Follicle stimulating hormone (FSH)		ML 06	Method based on immuno assay (IFMA)
Plasma	Glucagon		MI 11	Method based on immuno assay (RIA)
Serum	Insulin		ML 43	Method based on immuno assay (IFMA)
Serum	C-peptide (Pro-insulin C-peptide)		ML 42	Method based on immuno assay (IFMA)
Serum	Insulin-like growth factor 1 (IGF-1)		ML 37	Method based on immuno assay (ILMA)
Serum	IGF-binding protein 3 (IGFBP-3)		ML 36	Method based on immuno assay (ILMA)
Serum	Cortisol		ML 28	Method based on immuno assay (LIA)
Urine	Free cortisol		ML33	Method based on immuno assay (LIA)
Serum/ urine	Luteinizing hormone (LH)		ML 10	Method based on immuno assay (IFMA)
Serum	Osteocalcin		ML 44	Method based on immuno assay (ILMA)
Serum	Progesterone		ML 35	Method based on immuno assay (FIA)
Serum	Proinsulin		MI 16	Method based on immuno assay (ELISA)
Serum	Prolactin (PRL)		ML 13	Method based on immuno assay (IFMA)

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Object	Parameter	Reference standard	Identity of internal method	Comments
Plasma	Renin activity (PRA)		MI 18	Method based on immuno assay (RIA)
Serum	Sex hormone-binding globulin (SHBG)		ML 31	Method based on immuno assay (ILMA)
Serum	Testosterone		MI 20	Method based on immuno assay (RIA)
Serum	Thyroid stimulating hormone (TSH)		ML 17	Method based on immuno assay (IFMA)
Serum	Thyroxine (T4)		ML 16	Method based on immuno assay (FIA)
Serum	Free thyroxine (FT4)		ML 07	Method based on immuno assay (FIA)
Serum	Thyroxine-binding globulin (TBG)		ML 14	Method based on immuno assay (LIA)
Serum	Triiodothyronine (T3)		ML 15	Method based on immuno assay (FIA)
Serum	Growth hormone (GH)		ML 32	Method based on immuno assay (IFMA)
Fat (animal)	Acetyl gestagens		MD 01	Method based on GC-MS
Urine (animal)	Anabolic steroids/ stilbenes		MD 03	Methods based on GC-MS and LC-MS/MS. Confirmation
Liver (animal), muscular tissue (bovine, bird)	Beta-agonists		MD 29	Method based on LC-MS/MS
Serum	Free triiodothyronine (FT3)		ML 24	Method based on immuno assay (FIA)
Urine	Doping agents		MD 14	Method based on GC-MS and LC-MS/MS. Confirmation. (Parameter: defined in LD08)
Urine	Ephedrines		MD 15	Method based on GC-NPD. Quantification
Urine	Doping agents (non-conjugated)		MD 11	Method based on GC-NPD. Screening I (Parameter: defined in LD02)
Urine	Doping agents		MD 12	Method based on GC-MS. Screening II (Parameter: defined in LD05)
Urine	Doping agents		MD 10	Method based on GC-MS and LC-MS/MS. Screening IV (Parameter: defined in LD03 and LD04)
Urine	Testosterone, epitestosterone and T/E-ratio		MD 34	Method based on GC-MS. Quantification
Urine	Creatinine		MI 08	Method based on photometry
Urine	Doping agents (non-conjugated)		MD 18	Method based on GC-MS. Screening III (Parameter: defined in LD33)

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Object	Parameter	Reference standard	Identity of internal method	Comments
Urine	19-Norandrosterone		MD 22	Method based on GC-MS. Quantification
Plasma/ serum	Parathyroid hormone (PTH)		ML 12	Method based on immuno assay (ILMA)
Serum	25-hydroxyvitamin D (25-OH-Vit.D)		MI 51	Method based on immuno assay (RIA)
Muscular tissue (bovine, pig, sheep, bird, fish)	Anabolic steroids/ stilbenes		MD 26	Method based on GC-MS and LC-MS/MS.
Urine	Hydroxyethyl starch (HES)		MD 23	Method based on GC-MS. Screening VI
Urine (animal)	Anabolic steroids/ stilbenes		MD 02	Method based on GC-MS and LC-MS/MS. Screening
Urine	Doping agents		MD 28	Method based on LC-MS/MS. Screening VII (Parameter: defined in LD44)
Urine (animal)	Beta-agonists		MD 30	Method based on LC-MS/MS
Kidney (animal)	Neuroleptics		MD 31	Method based on LC-MS/MS
Urine	Erythropoietin (EPO)		MD 25	Method based on isoelectric focusing and chemiluminescence
Urine	Doping agents		MD 27	Method based on LC-MS/MS. Screening V (Parameter: defined in LD43)
Serum	Erythropoietin		ML 05	Method based on immuno assay (ILMA)
Serum	1,25-(OH) ² -Vit.D (1,25-dihydroxyvitamin D)		MI 50	Method based on immuno assay (RIA)
Serum	Anti-thyroglobulin antibodies (Anti-Tg)		ML 01	Method based on immuno assay (ILMA)
Serum	Anti-thyroid peroxidase antibodies (Anti-TPO)		ML 03	Method based on immuno assay (ILMA)
Urine	Cannabis metabolite (THC acid)		MD 32	Method based on GC-MS. Quantification
Serum	Androstendion		ML 45	Method based on LIA
EDTA-blood	Laktase genotyping (C-13910T, rs4988235 C/T)		MF 11	Method based on Real-Time PCR
EDTA-blood	Hemokromatose genotyping (HFE C282Y, rs1800562 G/A)		MF 12	Method based on Real-Time PCR

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Object	Parameter	Reference standard	Identity of internal method	Comments
Urine	Morphine		MD 33	Method based on GC-MS. Quantification.
EDTA blood	Haematological parameters		MD 35	Sysmex. Quantification.
Urine	Endogenous steroids		MD 36	Method based on GC-MS and GC-C-IRMS. Quantification
Serum	Recombinant growth hormone		MD 37	Method based on immuno assay (ILMA). Quantification.
Urine	Chorionic gonadotropin (hCG)		ML 09	Method based on immuno assay (IFMA). Confirmation

Permanent facility

M31

Object	Parameter	Reference standard	Identity of internal method	Comments
Urine	Doping analysis			Method based on judgement of competence and procedures for method validation. Flexibility for reference standard for all methods with internal identity MD. Flexibility for parameter (analyte) for qualitative methods with internal identity MD (except for MD 15, MD 22, MD 32, MD 33, MD 34, MD 35 and MD 37). Flexibility for object for method MD26 and 29.
Urine, blood, serum, plasma	Hormone Laboratory's routine analyses			Method based on judgement of competence and procedures for method validation. Flexibility for object and reference standard for all methods with internal identity MI and ML

Permanent facility

M32

Object	Parameter	Reference standard	Identity of internal method	Comments
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M32

Object	Parameter	Reference standard	Identity of internal method	Comments
Urine, blood, serum, plasma	Hormone Laboratory's routine analyses			The quality manual chapter 13.4.2. Method based on judgement of competence and documentation forming the basis for the opinions and interpretations. Methods with internal identity MF, MI and ML

Personnel responsible for validation: Peter Hemmersbach, Randi Aarsand and John A. Henninge and Ingunn R. Hullstein in "Norwegian Doping Control Laboratory".
Peter Torjesen in "Sections for Isotopeimmuno Assay and Luminescence Immuno Assay".

Abbreviations:

ELISA Enzyme linked immunosorbent assay
EIA Enzymeimmuno assay
FIA Fluoroimmuno assay
GC-MS Gas chromatography- mass spectrometry
GC-NPD Gas chromatography- nitrogen phosphorus detector
HPLC High performance liquid chromatography
HPLC-DAD High performance liquid chromatography- diode array detector
IFMA Immunofluorometric assay
ILMA Immunoluminometric assay
IRMA Immunoradiometric assay
LC-MS/MS Liquid chromatography- tandem mass spectrometry
LIA Luminescence immuno assay
RIA Radioimmuno assay
RRA Radioreceptor assay
PCR-RFLP Polymerase chain reaction- restriction fragment length polymorphism