

List of activities within the flexible scope of accreditation

Accredited Body: FertiCare SE
CAB Name: Location Karlovy Vary, Medical Genetics Laboratory
CAB Number: 8164
Certificate of Accreditation No.: 29/2025
Field of Accreditation: Medical Laboratory - ČSN EN ISO 15189 ed. 3:2023
Updated: 23. 1. 2025

Examinations:

Ordinal Number	Analyte/parameter/diagnostics	Principle of examination	Identification of method procedure/ equipment	Examined material	Degrees of freedom ¹
816 – Medical Genetics Laboratory					
1.	Examination of constitutional karyotype	Conventional cytogenetic analysis	SOP – 01, Issue 15.	Fetal and peripheral blood, amniotic fluid	A, B, D
2.	Examination of constitutional chromosomal aberrations	FISH	SOP – 02, Issue 18.	Fetal and peripheral blood, blastomere, amniotic fluid, fetus tissue	A, B, D
3.	Examination of germline genome variants	Real-Time PCR	SOP – 04, Issue 13.; P – 10, Issue 7.	Biological material containing nucleic acid	A, B, C
4.	Examination of unbalanced chromosomal aberrations [#]	aCGH	SOP – 15, Issue 12.; P – 10, Issue 7.; P – 11, Issue 8.; Roche Nimble Gen MS200; SurePrint G3 CGH ISCA v2, 8x60K (Agilent Technologies); GenetiSure Pre-Screen Array 8x60K (Agilent Technologies)	Fetal and peripheral blood, buccal smear, amniotic fluid, fetus tissue, trophoctoderm	A, B, D
5.	Examination of germline genome variants	MLPA	SOP – 17, Issue 4.; P – 10, Issue 7.; ABI3130	Biological material containing nucleic acid	A, B, C

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6.	Examination of germline genome variants	PCR with fragment analysis	SOP – 18, Issue 4.; SOP – 20, Issue 4.; SOP – 21, Issue 4.; SOP – 22, Issue 4.; P – 10, 7.; ABI3130	Biological material containing nucleic acid	A, B, C

Specification of the scope of accreditation:

Field Nr. / Ordinal Number	Detailed information on activities within the scope of accreditation
816/3	TM A1298C mutation in MTHFR gene C677T mutation in MTHFR gene Factor V G1691A Leiden mutation 20210A mutation in Prothrombin gene (Factor II) 4G/5G mutation in <i>PAI-1</i> gene (Plasminogen Activator Inhibitor-1)
816/5	genes <i>GJB2</i> , <i>SMN1</i>
816/6	STR markers (QF-PCR) D13S742, D13S252, D13S305, D13S1492, D13S634, D13S800, D13S628, GATA178F11, D18S976, D18S1002, D18S535, D18S978, D18S386, D18S1364, D21S11, D21S1435, D21S1442, D21S1444, D21S2055, D21S1411, D21S1446, DXYS218, AMELX, ZFX, T1, DXS981, T3, DXYS267, DXS1187, XHPRT, DXS2390, SRY, AMELY, ZFY CFTR 3120+1G>A, 711+1G>T, 621+1G>T, 1717-1G>A, CFTRdele2,3(21kb), 3849+10kbC>T, 2789+5G>A, 1898+1G>A, G542X, G85E, Y1092X(C>A), G551D, R553X, 3659delC, N1303K, R560T, R117H, R1162X, L1077P, R117C, R1066C, L1065P, W1282X, R347H, R347P, I507del, T338I, F508del, I336K, 1677delTA, R334W, 3272-26A>G, 1078delT, 2183AA>G, 2184insA, 2143delT, IVS8 5T/7T/9T, 9-13TG MDY sY14, ZFY, sY86, sY84, sY127, sY134, sY254, sY255

Explanatory notes:

¹ Established degrees of freedom according to MPA 00-09-...:

A – Flexibility concerning the documented examination/ sample collection procedure

B – Flexibility concerning the technique

C – Flexibility concerning the analytes / parameters

D – Flexibility concerning the examined material

If no degree of freedom is specified, the laboratory cannot apply a flexible approach to the scope of accreditation for this examination.

The chip scanning is performed as an external service provided by another legal entity.

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aCGH	array Comparative Genome Hybridization
CFTR	Cystic Fibrosis Transmembrane Conductance Regulator gene
FISH	fluorescence <i>in situ</i> hybridization
GJB2	Gap Junction Beta-2 protein gene
MDY	Chromosome Y microdeletion
MLPA	Multiplex Ligation-Dependent Probe Amplification
PCR	Polymerase Chain Reaction
QF-PCR	Quantitative Fluorescence Polymerase Chain Reaction
SMN1	Survival of Motor Neuron gene
TM	Thrombophilic Mutation
STR	short tandem repet
Real-Time PCR	Polymerase Chain Reaction in real time