

**The Appendix is an integral part of
Certificate of Accreditation No. 622/2023 of 15/11/2023**

Accredited entity according to ČSN EN ISO 15189:2013:

FertiCare SE

CAB Number 8164, Location Karlovy Vary, Medical Genetics Laboratory
Bělehradská 1042/14, 360 01 Karlovy Vary

Examinations:

Ordinal number	Analyte/parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom ¹
816 – Medical Genetics Laboratory					
1.	Examination of constitutional karyotype	Conventional cytogenetic analysis – chromosome banding	SOP – 01, Issue 14.	Fetal and peripheral blood, amniotic fluid	-
2.	Examination of constitutional chromosomal aberrations	FISH	SOP – 02, Issue 17.	Fetal and peripheral blood, blastomere, amniotic fluid, fetus tissue	-
3.	Examination of germline genome variants	Real-Time PCR	SOP – 04, Issue 13.; SOP – 10, Issue 7.; Rotorgene	Peripheral blood, buccal smear, amniotic fluid, fetus tissue	-
4.	Examination of germline genome variants	aCGH	SOP – 15, Issue 10.; SOP – 10, Issue 7.; SOP – 11, Issue 7.; SurePrint G3 ISCA V2 CGH Kit 8X60K; GenetiSure Pre-Screen Array Kit 8x60K	Fetal and peripheral blood, buccal smear, amniotic fluid, fetus tissue, trophoctoderm	-
5.	Examination of germline genome variants	MLPA	SOP – 17, Issue 4.; SOP – 10, Issue 7.; ABI3130	Fetal and peripheral blood, buccal smear, amniotic fluid, fetus tissue	-
6.	Examination of germline genome variants	PCR fragment analysis	SOP – 18, Issue 4.; SOP – 20, Issue 3.; SOP – 21, Issue 4.; SOP – 22, Issue 3.; SOP – 10, Issue 7.; ABI3130	Fetal and peripheral blood, buccal smear, amniotic fluid, fetus tissue	-

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Specification of the scope of accreditation:

Field of expertise / ordinal number	Detailed information on activities within the scope of accreditation
816/3	<p>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)</p>
816/5	genes <i>GJB2</i> , <i>SMN1</i>
816/6	<p>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</p> <p>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</p> <p>MDY sY14, ZFY, sY1841, sY86, sY625, sY84, M259 (AZFa), sY90, sY127, sY131, sY134 (AZFb), sY254, sY255, sY157 (AZFc)</p>

Explanatory notes:

¹ The laboratory does not apply a flexible approach to the scope of accreditation.

aCGH – array Comparative Genome Hybridization

CFTR – Cystic Fibrosis Transmembrane Conductance Regulator gene

CNV – Copy Number Variation

FISH – Fluorescence In Situ Hybridization

FMRI – Fragile Mental Retardation gene

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