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, trophectoderm	-
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	**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 *PAI-1* gene (Plasminogen Activator Inhibitor-1)
816/5	genes *GJB2*, SMN1
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, sY1841, sY86, sY625, sY84, M259 (AZFa), sY90, sY127, sY131, sY134 (AZFb), sY254, sY255, sY157 (AZFc)

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
FMR1 – 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