

**The Appendix is an integral part of
Certificate of Accreditation No. 325/202 of 30/06/2022**

Accredited entity according to ČSN EN ISO 15189:2013:

SANATORIUM Helios, spol. s r.o.
Laboratory of Medical Genetics
Štefánikova 75/8, Ponava, 602 00 Brno

The Laboratory has a flexible scope of accreditation permitted as detailed in the Annex. Updated list of activities provided within the flexible scope of accreditation is available from the Laboratory Manager.

Examinations:

Ordinal number	Examination procedure name	Examination procedure identification	Examined object
816 – Medical Genetics Laboratory			
1.	Determination of karyotype by G banding	SOP-LLG-001	Peripheral blood
2.	Detection of chromosomal aberrations by FISH method	SOP-LLG-010	Peripheral blood
3.	Preimplantation genetic testing of monogenic diseases by polymerase chain reaction followed by fragment analysis and Sanger sequencing (PCR)*	SOP-LLG-012	Trophoblast, peripheral blood
4.	Preimplantation genetic testing of chromosomal aberrations by massive parallel sequencing method (NGS)	SOP-LLG-014	Trophoblast

Annex:

Flexible scope of accreditation

Examination procedure ordinal numbers:
3

The Laboratory is allowed to modify the examination procedures listed in the Annex within the specified scope of accreditation provided the measuring principle is observed.

The flexible approach to the scope of accreditation cannot be applied to the examinations not included in the Annex.

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Explanatory notes:

* **Mutations examined:** JAG1 (c.2913_2914delAC), COL4A5 (c.1718G>A), VPS33B (c.357+1G>T), HBB (COD39 C>T, c.93-21 G>A), BRCA1 (300T>G, 5382insC), BRCA2 (c.8537-8538delAG, c.475G>A), CYP21A2 (c.290-13A/C>G, c.1069C>T, p.Q318X), CDH1 (IVS15-6C>G), CFTR (F508del), GJB2 (35delG), FGFR2 (c.1025G>A), HMGCL (c.60+1G>T), DMD, EXT1 (c.1245T→G), GLA (c.511G>C), APC (c.637C>T), FSHD (D4Z4), F8, C1NH (g.16789G>A), HTT, CMT1A, EPB (c.186_188del3, c.455T>C), RYR1 (c.2122G>A, c.6721C>T, c.9047A>C), HADHA (c.1528G>C), MLH1 (c.677G>T, c.1489_1490insC), MSH2 (c.942+3A>T), MSH6 (c.3053delT), FBN1 (c.6148G>T, c.6554T>C, c.7238G>A), DMPK, NF1 (g.253122_7delTAACTT), OTC (c.461-471del), AR (c.1789 G>A), PKD1, SMN1, COL2A1 (c.816+1G>A), TSC1 (C733T), LAMC2 (c.3328+1G>A), EXT2 (c.544C>T), ENPP1 (c.191-92delCG, c.1026-12_1026-61del50), ZNF9, RB1 (c.2416insT), EXT-1 (c.2023A>T), CFTR (c.711+1G>T), GJB2 (c.109G>A), NF1 (c.1297_1300dupTATT), NF1 (c.6756+2T>C), FMR1, CFTR (c.2250 delT), COL1A1 (c.579delT), F9 (c.51277 C>T). SERPINA1 (c.1096G>A), PEX14 (c.319C>T), GCDH (c.1198G>A, c.1262C>T), SURF1 (c.845_846delCT), RS1 (c.575_576insT), CFTR (c.1898+1G>A), ED1 (c.1A>T), BRCA2 (c.7878G>C), PTCH1 (c.403C>T), PTCH1 (c.403C>T), TSC2 (c.103C>T)