



NÁRODNÍ AKREDITAČNÍ ORGÁN

EA MLA Signatory  
Český institut pro akreditaci, o.p.s.  
Olšanská 54/3, 130 00 Praha 3

issues

according to section 16 of Act No. 22/1997 Coll., on technical requirements for products, as amended

## CERTIFICATE OF ACCREDITATION

No. 127/2018

**GENNET, s.r.o.**  
with registered office Kostelní 9/292, 170 00 Praha 7, Company Registration No. 27080234

to the Medical laboratory No. 8068  
GENNET Laboratories

Scope of accreditation:

Cytogenetic and molecular genetic examinations, including preimplantation genetic diagnosis of monogenic diseases (PGM) of embryos, laboratory andrology for IVF and examinations in the field of allergology and clinical immunology to the extent as specified in the appendix to this Certificate.

This Certificate of Accreditation is a proof of Accreditation issued on the basis of assessment of fulfillment of the accreditation criteria in accordance with

ČSN EN ISO 15189:2013

In its activities performed within the scope and for the period of validity of this Certificate, the Body is entitled to refer to this Certificate, provided that the accreditation is not suspended and the Body meets the specified accreditation requirements in accordance with the relevant regulations applicable to the activity of an accredited Conformity Assessment Body.

This Certificate of Accreditation replaces, to the full extent, Certificate No.: 220/2017 of 13. 4. 2017, or any administrative acts building upon it.

The Certificate of Accreditation is valid until: **13. 4. 2022**

Prague: 15. 3. 2018



**Jiří Růžička**  
Director  
Czech Accreditation Institute  
Public Service Company

**The Appendix is an integral part of  
Certificate of Accreditation No. 127/2018 of 15/03/2018**

**Accredited entity according to ČSN EN ISO 15189:2013:**

**GENNET, s.r.o.**  
GENNET Laboratories  
Kostelní 9/292, 170 00 Praha 7

**Medical laboratory locations:**

- |                                             |                                |
|---------------------------------------------|--------------------------------|
| 1. <b>Cytogenetics Laboratory - Letná</b>   | Kostelní 9/292, 170 00 Praha 7 |
| 2. <b>Molecular Genetics Laboratory</b>     | Kostelní 9/292, 170 00 Praha 7 |
| 3. <b>IVF Laboratory – Letná</b>            | Kostelní 9/292, 170 00 Praha 7 |
| 4. <b>Cytogenetics Laboratory – Liberec</b> | Liliová 1, 460 01 Liberec      |
| 5. <b>IVF Laboratory – Liberec</b>          | Liliová 1, 460 01 Liberec      |
| 6. <b>IVF Laboratory – Archa</b>            | Na Poříčí 26, 110 00 Praha 1   |
| 7. <b>Immunology Laboratory</b>             | Na Poříčí 26, 110 00 Praha 1   |

**1. Cytogenetics Laboratory – Letná**

**Examination:**

Ordinal number	Examination procedure name	Examination procedure identification	Examined object
<b>816 - Medical Genetics Laboratory</b>			
1	Examination of karyotype from peripheral blood	SOP-CL-001	Peripheral blood
2	Examination of karyotype from fetal blood	SOP-CL-002	Fetal blood
3	Examination of karyotype from amniotic fluid	SOP-CL-003	Amniotic fluid cells
4	Examination of karyotype from chorionic villi	SOP-CL-004	Chorionic villi
5	Examination of karyotype from solid tissues	SOP-CL-005	Solid tissues
6	Examination of acquired chromosome aberrations from peripheral blood	SOP-CL-006	Peripheral blood
7	Examination of cells by FISH method	SOP-CL-009	Native cytogenetic preparations
8	PGD by FISH (structural aberrations)	SOP-CL-010	Blastomere
9	PGD by FISH (screening)	SOP-CL-011	Blastomeres
10	PGD/PGS by array CGH method	SOP-CL-012	Blastomeres, trophectoderm
11	PGD/PGS by massive parallel sequencing method	SOP-CL-013	Blastomeres, trophectoderm
12	PGD by karyomapping method	SOP-CL-014	Blastomeres, trophectoderm
13	Prenatal /postnatal examination by array CGH method	SOP-CL-015	Peripheral blood, amniotic fluid, chorionic villi, umbilical blood, isolated DNA





**The Appendix is an integral part of  
Certificate of Accreditation No. 127/2018 of 15/03/2018**

**Accredited entity according to ČSN EN ISO 15189:2013:**

**GENNET, s.r.o.**  
GENNET Laboratories  
Kostelní 9/292, 170 00 Praha 7

Ordinal number	Examination procedure name	Examination procedure identification	Examined object
14	Prenatal /postnatal examination by SNP array method	SOP-CL-016	Peripheral blood, amniotic fluid, chorionic villi, umbilical blood, isolated DNA

Explanations:

PGS - preimplantation genetic screening

PGD - preimplantation genetic diagnostics



**The Appendix is an integral part of  
Certificate of Accreditation No. 127/2018 of 15/03/2018**

**Accredited entity according to ČSN EN ISO 15189:2013:**

**GENNET, s.r.o.**  
GENNET Laboratories  
Kostelní 9/292, 170 00 Praha 7

**2. Molecular Genetics Laboratory**

*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 at the Laboratory and at [www.gennet.cz](http://www.gennet.cz).*

**Examination:**

Ordinal number	Examination procedure name	Examination procedure identification	Examined object
<b>816 - Medical Genetics Laboratory</b>			
1	Examination of 13, 18, 21, X and Y chromosome aneuploidies by QF-PCR method	SOP-MGL-001	Amniotic fluid, blood, chorionic villi
2	Examination of G20210A, G1691A thrombophilic mutations and C677T and A1298C polymorphisms in MTHFR gene by Real-Time PCR method	SOP-MGL-002	Amniotic fluid, blood
3	Examination of microdeletions in AZFa, AZFb and AZFc areas of Y chromosome long arm by fragment analysis method using a diagnostic kit	SOP-MGL-017	Amniotic fluid, blood
4	Examination of CFTR gene mutations by ARMS method using a diagnostic kit *	SOP-MGL-004	Amniotic fluid, blood, chorionic villi
5	Examination of HFE gene C282Y, H63D and S65C mutations by fragment analysis method using a diagnostic kit	SOP-MGL-018	Blood
6	Examination of the most common aneuploidies by QF-PCR method using a diagnostic kit	SOP-MGL-016	Amniotic fluid, blood, chorionic villi, fetus tissue
7	Determination of parentage by the analysis of STR markers by multiplex PCR method using a diagnostic kit	SOP-MGL-007	Amniotic fluid, blood, chorionic villi



**The Appendix is an integral part of  
Certificate of Accreditation No. 127/2018 of 15/03/2018**

**Accredited entity according to ČSN EN ISO 15189:2013:**

**GENNET, s.r.o.**  
GENNET Laboratories  
Kostelní 9/292, 170 00 Praha 7

Ordinal number	Examination procedure name	Examination procedure identification	Examined object
8	Preimplantation genetic examination of monogenic diseases by indirect linkage analysis**	SOP-MGL-008	Embryonic cells
9	Examination of GJB2 gene (CX26) by PCR amplification method and sequence analysis	SOP-MGL-009	Amniotic fluid, blood, chorionic villi
10	Examination of gene mutations by MLPA method using a diagnostic kit***	SOP-MGL-010	Blood
11	Examination of fragile X chromosome syndrome (Fraxa X) by fragment analysis method using a diagnostic kit	SOP-MGL-011	Amniotic fluid, blood, chorionic villi
12	Determination of HLA markers associated with coeliac disease by reverse hybridization strip assay using a diagnostic kit	SOP-MGL-012	Blood, buccal smear
13	Examination of genetic mutations by massive parallel sequencing method****	SOP-MGL-013	Blood
14	Non-invasive prenatal test of chromosome aneuploidies 13, 18, 21 by massive parallel sequencing method (NIPT)	SOP-MGL-014	Blood
15	Examination of N680S polymorphism of FSH gene by Real-Time PCR method	SOP-MGL-015	Blood
16	Examination of F508del mutation in CFTR gene by fragment analysis method	SOP-MGL-019	Amniotic fluid, blood, chorionic villi





**The Appendix is an integral part of  
Certificate of Accreditation No. 127/2018 of 15/03/2018**

**Accredited entity according to ČSN EN ISO 15189:2013:**

**GENNET, s.r.o.**  
GENNET Laboratories  
Kostelní 9/292, 170 00 Praha 7

Annex:

Flexible scope of accreditation

Examination procedure ordinal numbers
8, 13

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.

**\*Examined mutations:**

S549N, S549R, R553X, G551D, V520F, delI507, delF508, 1717-1G→A, G542X, R560T, 3120+1G→A, A455E, R117H, 394delTT, 2184delA, 2789+5G→A, 1898+1G→A, 621+1G→T, 711+1G→T, G85E, R347P, R347H, W1282X, R334W, 1078delT, 3849+10kbC→T, R1162X, N1303K, 3659delC, 3905insT, CFTRdele2,3(21kb), polymorphism 5/7/9 T in intron 8, 3876delA and 2183AA→G. Elucigene CF-EU2v2 tests also the following mutations: E60X, P67L, 444delA, R117C, Y122X, L206W, 1811+1,6kbA→G, 2143delT, 2347delG, W846X, Q890X, 3272-26A→G, R1066C, Y1092X(C→A), M1101K, D1152H, 1677delTA, R1158X, S1251N.

**\*\*List of examined genes:**

PMP22, CFTR, FBN1, IT15, RhD, DMPK, FMR1, IL2RG, Factor VIII, PKHD1, GJB2, SPTLC1, FGFR2, BRCA1, Dystrophin, NF1, SMN1, HLXB9, TCOF1, FECH, FOXP3, PCCB, JAG1, KRT14, MLH1, PLP1, GJB1, Factor V, GLA, PKD1, Factor IX, LAMB3, BRCA2, HADHA, COL4A5, ADSL, VHL, ADA, IDUA, NEMO, MYH9, FRG1, DHCR7, CYP21, SGSH, SERPINA1, RET, PCCD1 (locus 20p11.2), PAX3, FLG1, ALPL, OCRL, MSH2, MYH7, TSC1, ZNF9, PAH, COL7A1, TGM1, PHF, CC2D2A, ASPM, ABCD1, PTHLH, UMOD, AARS2, MTM1, IDS, L1CAM, duplication 15q11.1-q13.1 (8,3Mb-PW/AS), HADH2, ATXN2, RS1, TGFB1, FBLN5, MUC1, EXOSC3, PKD2, GNPTAB, NOTCH3, AR gen, MPZ, SHOX+ PAR1 area, translocation 6q25-6q27, COL1A1, AFM1, TP53, RAG2, RBM8A, PRRT2, FAP (APC gene), FOXL2, OTC, SPG4 (SPAST gene), HMRS (PIGV gene), sickle cell anaemia (HBB), MECP2 duplication (SLC6A8), Deletion 17q12, duplication 3p26, KRT15, SPG3A (ATL1), MSH6, DFNB3 (MYO15A), WDR35, RB1, 1q21-deletion-duplication, deletion Xq21.31, KCNQ1.

**\*\*\*List of examined genes:**

BRCA2, BRCA1, CHEK2, MLH1, MSH2, VHL, SMN1, SMN2

**\*\*\*\*List of examined genes:**

APC; ATM; BAP1; BARD1; BLM; BMPR1A; BRCA1; BRCA2; BRIP1; CDH1; CDK4; CDKN2A; CHEK2; DICER1; DPYD; EPCAM; EXT1; EXT2; FANCA; FANCB; FANCC; FANCD2; FANCE; FANCF; FANCG; FANCI; FANCL; FANCM; FH; FLCN; GATA2; KIT; MEN1; MET; MLH1; MLH3; MRE11A; MSH2; MSH6; MUTYH; NBN; NF1; NF2; PALB2; POLD1; POLE; PRKAR1A; PTCH1; PTEN; RAD50; RAD51; RAD51C; RAD51D; RB1; RECQL; RET; SDHB; SMAD4; SMARCA4; SMARCB1; STK11; SUFU; TERT; TMEM127; TP53; TSC1; TSC2; VHL; WT1.



**The Appendix is an integral part of  
Certificate of Accreditation No. 127/2018 of 15/03/2018**

**Accredited entity according to ČSN EN ISO 15189:2013:**

**GENNET, s.r.o.**  
GENNET Laboratories  
Kostelní 9/292, 170 00 Praha 7

**3. IVF Laboratory – Letná**

**Examination:**

Ordinal number	Examination procedure name	Examination procedure identification	Examined object
<b>Laboratory examination for IVF</b>			
1	Macro- and microscopic examination of spermiogram	SOP-IVF-001	Ejaculate

**4. Cytogenetics Laboratory – Liberec**

**Examination:**

Ordinal number	Examination procedure name	Examination procedure identification	Examined object
<b>816 - Medical Genetics Laboratory</b>			
1	Examination of karyotype from peripheral blood	SOP-CL-001	Peripheral blood

**5. IVF Laboratory – Liberec**

**Examination:**

Ordinal number	Examination procedure name	Examination procedure identification	Examined object
<b>Laboratory examination for IVF</b>			
1	Macro- and microscopic examination of spermiogram	SOP-IVF-001	Ejaculate

**6. IVF Laboratory – Archa**

**Examination:**

Ordinal number	Examination procedure name	Examination procedure identification	Examined object
<b>Laboratory examination for IVF</b>			
1	Macro- and microscopic examination of spermiogram	SOP-IVF-001	Ejaculate





**Accredited entity according to ČSN EN ISO 15189:2013:**

**GENNET, s.r.o.**  
GENNET Laboratories  
Kostelní 9/292, 170 00 Praha 7

**7. Immunology Laboratory**

**Examination:**

Ordinal number	Examination procedure name	Examination procedure identification	Examined object
<b>813 - Allergy and Immunology Laboratory</b>			
1	Determination of immunoglobulins by immunoturbidimetric method [IgA, IgG, IgM]	SOP-IML-101	Serum
2	Determination of acute phase reactants by immunoturbidimetric method [Alpha -1 antitrypsin, Prealbumin, Transferrin, Ceruloplasmin, CRP]	SOP-IML-102	Serum
3	Determination of antibodies against tissue transglutaminase, gliadin and deamidated gliadin by Elia method [Anti - deamidated gliadin IgG (EliA), Anti - deamidated gliadin IgA (EliA)]	SOP-IML-051	Serum, plasma
4	Determination of total IgE by FEIA method [Total IgE]	SOP-IML-401	Serum, plasma
5	Determination of specific IgE by FEIA method [sIgE - allergen (CAP code)]	SOP-IML-402	Serum, plasma
6	Determination of subpopulations of lymphocytes by flow cytometry [T lymphocytes CD3+, Th lymphocytes CD3+CD4+, Tc lymphocytes CD3+CD8+, B lymphocytes CD19+, NK lymphocytes CD3-CD16+56+]	SOP-IML-301	Peripheral blood
7	Determination of autoantibodies to nuclear and cytoplasmic antigens by indirect immunofluorescence method (ANA) [ANA IgG (IF), ANA final titre, ANA nuclear fluorescence, ANA cytoplasmatic fluorescence]	SOP-IML-201	Serum, plasma

Names in parentheses [ ] are the names of examinations shown in the reports.