# The Appendix is an integral part of Certificate of Accreditation No. 29/2025 of 23/01/2025

## Accredited entity according to ČSN EN ISO 15189 ed. 3:2023:

## FertiCare SE

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

The laboratory applies a flexible approach to the scope of accreditation.

The current "List of activities within the flexible scope" is available on the website <a href="http://www.genetikakv.cz/akreditace.html">http://www.genetikakv.cz/akreditace.html</a>

#### **Examinations**

Ordinal Number	Analyte/ parameter/diagnostics	Principle of examination	Identification of procedure/equipment	Examined material	Degrees of freedom
		816 – Medica	l Genetics Laboratory		
1.	Examination of constitutional karyotype	Conventional cytogenetic analysis	Published procedure	Biological material containing nucleic DNA	A, B, D
2.	Examination of constitutional chromosomal aberrations	FISH	Commercial procedure	Biological material containing nucleic DNA	A, B, D
3.	Examination of germline genome variants	Real -Time PCR	Commercial procedure	Biological material containing nucleic DNA	A, B, C
4.	Examination of unbalanced chromosomal aberrations #	aCGH	Commercial procedure	Biological material containing nucleic DNA	A, B, D
5.	Examination of germline genome variants	MLPA	Commercial procedure	Biological material containing nucleic acid	A, B, C
6.	Examination of germline genome variants	PCR with fragment analysis	Commercial procedure	Biological material containing nucleic acid	A, B, C



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### **Explanatory notes:**

- 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

aCGH

Array Comparative Genome Hybridization

FISH

Fluorescence in situ hybridization

**MLPA** 

Multiplex Ligation-Dependent Probe Amplification

PCR

Polymerase Chain Reaction

Real-Time PCR

Polymerase Chain Reaction in real time



<sup>&</sup>quot;This document is an appendix to the certificate of accreditation. In case of any discrepancies between the English and Czech versions, the Czech version shall prevail, both for the certificate appendix and the certificate itself."