SWEDAC
Styrelsen för ackreditering och teknisk kontroll
Swedish Board for Accreditation and Conformity Assessment

Appendix 1

Date	Reference
2023-11-03	2022/1065

Scope of accreditation

Medical testing according to SS-EN ISO 15189:2012

iCellate Medical AB Solna Accreditation number 10473

A014501-001

Genetics

Technical area	*Parameter*	*Method*	*Technique*	*Material*	*Flex*	*Type of flex*	*Field*
Molecular biology	**GeneMate**	**Internal method; P-901 GeneMate**	**Next Generation Sequencing (NGS)**	**DNA**	**Yes**	**2**	**No**

Changes in the scope of accreditation are in bold.

Type of flexible scope
1: - Introduce new version of standard method and make editorial changes to non-standard method
2: - Introduce new version of standard method and make editorial changes to non-standard method - Introduce new version and modifications of non-standard method. The procedure must be equivalent - Introduce new parameter/component/characteristics - Introduce new measurement range - Introduce new material/new products/matrices - Introduce new method equivalent to methods already in the accreditation decision