

Date

Reference

2026-04-15

2025/1792

Scope of accreditation

Testing according to SS-EN ISO/IEC 17025:2018

RISE Research Institutes of Sweden AB

Borås

Accreditation number

1002

Medicinteknik och diagnostik

A002626-004

Biological examinations

<i>Method</i>	<i>Parameter</i>	<i>Technique</i>	<i>Material</i>	<i>Flex</i>	<i>Type of flex</i>	<i>Field</i>
SS-EN ISO 10993-12	Cytotoxicity		Medical devices	Yes	2	No
SS-EN ISO 10993-5	Cytotoxicity	Spectrophotometry	Medical devices	Yes	2	No

Functional testing

Genetics

<i>Method</i>	<i>Parameter</i>	<i>Technique</i>	<i>Material</i>	<i>Flex</i>	<i>Type of flex</i>	<i>Field</i>
Inhouse method; RISE method 5739 (kit-based), ed 3.0	Telomere length of human DNA	Real-time PCR	PBMC	No		No
Inhouse method; RISE method 5767 (kit-based), ed 4.0	Methylation level of human DNA	ELISA	PBMC	No		No
Inhouse method; RISE metod 5738	Extraction of genomic DNA	Extraction	Human body fluids	Yes	2	No

Functional testing

Immunology

<i>Method</i>	<i>Parameter</i>	<i>Technique</i>	<i>Material</i>	<i>Flex</i>	<i>Type of flex</i>	<i>Field</i>
Inhouse method; RISE method 5717 (kit-based), ed 3.0	Blood type microcolumn technology (gel cards) (ABO, Rh, Kell, Kidd, Duffy)	Visual reading	Whole blood	No		No

Functional testing

Immunology

<i>Method</i>	<i>Parameter</i>	<i>Technique</i>	<i>Material</i>	<i>Flex</i>	<i>Type of flex</i>	<i>Field</i>
Inhouse method; RISE method 5722 (kit-based), ed 5.0	Blood type (ABO, RH, KEL, JK, FY)	Real-time PCR	Whole blood	No		No
Inhouse method; RISE method 5809 (kit-based), ed 4.0	Blood type microcolumn technology (gel cards) (ABO, Rh, Kell, Kidd, Duffy)	Photometry	Whole blood	No		No
Inhouse method; RISE method 5813 (kit-based), ed 2.0	Cytokines, chemokines and growth factors	Luminex	Serum	No		No

Microbiological analysis

Molecular biology

<i>Method</i>	<i>Parameter</i>	<i>Technique</i>	<i>Material</i>	<i>Flex</i>	<i>Type of flex</i>	<i>Field</i>
European Pharmacopeia EP 2.6.14 Bacterial endotoxin	Endotoxin	Spectrophotometry	Medical devices, biological samples	Yes	2	No

Changes in the scope of accreditation are in bold.

The scope of accreditation is flexible as specified in this decision. The accredited body must always retain a current list of the scope for which it is accredited.

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