

Annex to declaration of accreditation (scope of accreditation)
 Normative document: EN ISO/IEC 17043:2010
 Registration number: **R 023**

of **SKML (Stg. Kwaliteitsbewaking Medische Laboratoria)**

This annex is valid from: **27-11-2024 to 01-04-2026**

Replaces annex dated: **18-10-2023**

Location(s) where activities are performed under accreditation

Head Office

Toernooiveld 300
 6525 EC
 Nijmegen
 Nederland

Location	Abbreviation/ location code
Toernooiveld 300 6525 EC Nijmegen Nederland	N

Flexible scope¹⁾

Nr. / HCS code	Material, product or device	Type of activity (parameter)	Concentration range / Measuring range	Frequency	Location
Clinical Chemistry					
1.	frozen serum/plasma	Scheme Clinical Chemistry, blood Contains analytes belonging to basic clinical chemistry ¹⁾	Clinically relevant, physiologically and pathophysiologically	4/year	N
2.	frozen serum/plasma	Scheme Cardiac markers Contains analytes belonging to the cardiac markers ¹⁾	Clinically relevant, physiologically and pathophysiologically	4/year	N

This annex has been approved by the Board of the Dutch Accreditation Council, on its behalf,

J.A.W.M. de Haas

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3.	frozen serum/plasma	Scheme Carbohydrate Deficient Transferrin (CDT) ¹⁾	Clinically relevant, physiologically and pathophysiologically	2/year	N
4.	frozen serum/plasma	Scheme Ethanol in serum ¹⁾	Clinically relevant, physiologically and pathophysiologically	4/year	N
5.	frozen serum/plasma	Scheme Fructosamin ¹⁾	Clinically relevant, physiologically and pathophysiologically	4/year	N
6.	frozen serum/plasma	Scheme Lipids Contains analytes belonging to the lipids ¹⁾	Clinically relevant, physiologically and pathophysiologically	4/year	N
7.	frozen serum/plasma	Scheme Neonatal Bilirubin ¹⁾	Clinically relevant, physiologically and pathophysiologically	4/year	N
8.	lyophilised serum/plasma	Scheme Angiotensine Converting Enzyme (ACE) ¹⁾	Clinically relevant, physiologically and pathophysiologically	2/year	N
9.	lyophilised serum/plasma	Scheme Alkaline Phosphatase isoenzymes ¹⁾	Clinically relevant, physiologically and pathophysiologically	2/year	N
10.	lyophilised serum/plasma	Scheme Bile acid salts ¹⁾	Clinically relevant, physiologically and pathophysiologically	4/year	N
11.	lyophilised serum/plasma	Scheme Homocystein ¹⁾	Clinically relevant, physiologically and pathophysiologically	2/year	N
12.	lyophilised serum/plasma	Scheme Inflammation markers ¹⁾	Clinically relevant, physiologically and pathophysiologically	4/year	N
13.	lyophilised serum/plasma	Scheme Vitamin A, Vitamin E and Beta-carotene ¹⁾	Clinically relevant, physiologically and pathophysiologically	2/year	N

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14.	lyophilised serum/plasma	Scheme Vitamin B1 and Vitamin B6 ¹⁾	Clinically relevant, physiologically and pathophysiologically	2/year	N
15.	fresh whole blood	Scheme HbA1c whole blood ¹⁾	Clinically relevant, physiologically and pathophysiologically	6/year	N
16.	fresh whole blood	Scheme Point of care test (POCT) in whole blood ¹⁾	Clinically relevant, physiologically and pathophysiologically	4/year	N
17.	lyophilised whole blood	Scheme Hemoximetry ¹⁾	Clinically relevant, physiologically and pathophysiologically	2/year	N
18.	aqueous solution with bovine albumin	Scheme Bloodgas Parameters ¹⁾	Clinically relevant, physiologically and pathophysiologically	4/year	N
19.	vaginal fluid	Scheme Fetal fibronectine ¹⁾	Clinically relevant, physiologically and pathophysiologically	2/year	N
20.	urine	Scheme Clinical Chemistry, urine qualitative ¹⁾	Clinically relevant, physiologically and pathophysiologically	4/year	N
21.	lyophilised urine	Scheme Clinical Chemistry, urine quantitative ¹⁾	Clinically relevant, physiologically and pathophysiologically	4/year	
22.	lyophilised urine	Scheme Porphyrines in urine ¹⁾	Clinically relevant, physiologically and pathophysiologically	4/year	N
23.	lyophilised feces suspension	Scheme Occult blood in feces ¹⁾	Clinically relevant, physiologically and pathophysiologically	4/year	N
Parasitology					
24.	human EDTA blood and blood lysate + Giemsa coloured human blood smear	Scheme Blood parasites, Contains clinically relevant blood parasites ¹⁾	Clinically relevant, physiologically and pathophysiologically	4/year	N

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25.	human feces and/or punctate and/or digital image	Scheme Intestinal-, tissue- and ectoparasites Contains clinically relevant intestinal parasites ¹⁾	Clinically relevant, physiologically and pathophysiologically	4/year	N
26.	human feces and/or punctate and/or digital image	Scheme Intestinal Protozoa Molecular Diagnostics Contains clinically relevant intestinal Protozoa for Molecular Diagnostics ¹⁾	Clinically relevant, physiologically and pathophysiologically	3/year	N
27.	Amoebae and purified DNA in stabilisation buffer	Scheme Acanthamoeba External Molecular Quality Assessment ¹⁾	Clinically relevant, physiologically and pathophysiologically	1/year	N
28.	human urine or urogenital swab in stabilisation buffer	Scheme Sexual Transmitted Diseases (STD) External Molecular Quality Assessment ¹⁾	Clinically relevant, physiologically and pathophysiologically	2/year	N
29.	human feces and DNA	Scheme Helminth External Molecular Quality Assessment ¹⁾	Clinically relevant, physiologically and pathophysiologically	1/year	N

Humoral immunology

30.	frozen serum	Scheme Plasma proteins ¹⁾	Clinically relevant, physiologically and pathophysiologically	4/year	N
31.	serum diluted in omniplasma	Allergy Type III antibodies	Clinically relevant, physiologically and pathophysiologically	1/year	N

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32.	pooled serum diluted in omniplasma	Tryptase	Clinically relevant, physiologically and pathophysiologically	1/year	N
33.	lyophilised serum/plasma	Collagen	Clinically relevant, physiologically and pathophysiologically	2/year	N
34.	lyophilised serum/plasma	Rheuma	Clinically relevant, physiologically and pathophysiologically	2/year	N
Bacteriology/ Mycology					
35.	lyophilised micro-organisms obtained from human materials after a culture procedure	Scheme Bacteriology Contains clinically relevant micro-organisms ¹⁾ .	Selected samples from routine diagnostics (determination, qualitative analyses)	5/year	N

1) This flexible scope requires the EQA organiser to maintain a current list of the methods applied under this flexible scope. For an overview of the measurands within each scheme we refer to the SKML website on the subpage of the particular scheme.