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: 18-10-2023 to 01-04-2026

Replaces annex dated: 17-03-2022

Location(s) where activities are performed under accreditation

Head Office							
Toernoo 6525 EC Nijmeger Nederlar	า						
	Locati	ion		Abbr	eviation/ location	code	
6525 EC Nijmege	Toernooiveld 300 6525 EC Nijmegen Nederland						
Flexible scope ¹⁾							
Nr. / HCS code	Material, product or device	Type of activity (parameter)		entration range easuring 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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Nr. / HCS code	Material, product or device	Type of activity (parameter)	Concentration range / Measuring range	Frequency	Location
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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Nr. / HCS code	Material, product or device	Type of activity (parameter)	Concentration range / Measuring range	Frequency	Location
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
	1	I	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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Nr. / HCS code	Material, product or device	Type of activity (parameter)	Concentration range / Measuring range	Frequency	Location		
25.	human feces and/or punctate and/or digital image	Scheme Intestinal- , tissue- and ectoparasites	Clinically relevant, physiologically and pathophysiologically	4/year	N		
		Contains clinically relevant intestinal parasites ¹⁾					
26.	human feces and/or punctate and/or digital image	Scheme Intestinal Protozoa Molecular Diagnostics Contains clinically	Clinically relevant, physiologically and pathophysiologically	3/year	N		
		relevant intestinal Protozoa for Molecular Diagnostics ¹⁾					
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 urogental 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		
	1	Hum	oral immunology	<u> </u>	J		
30.	frozen serum	Scheme Plasma proteins ¹⁾	Clinically relevant, physiologically and pathophysiologically	4/year	N		
Bacteriology/ Mycology							

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Nr. / HCS code	Material, product or device	Type of activity (parameter)	Concentration range / Measuring range	Frequency	Location
31.	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

 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.