

Annex to declaration of accreditation (scope of accreditation)
Normative document: EN ISO 15189:2012
Registration number: **M 005**

of **Sanquin Diagnostiek B.V.**

This annex is valid from: **09-10-2024** to **31-12-2025**

Replaces annex dated: **20-12-2023**

Location(s) where activities are performed under accreditation

Head Office

Plesmanlaan 125
1066 CX
Amsterdam
Nederland

Location	Abbreviation/Location code
Plesmanlaan 125 1066 CX Amsterdam Nederland	A1

Flexibele scope¹

Code	Diagnostic question	Method/Technique	Material or product	Location
Medical field: Clinical Chemistry and Hematology In compliance with the standards in force (NVKC)				
CH.PRE.03	Pre analysis	Sample processing, sample reception, registration, processing, preprocessing for analysis (among other things centrifugation), post-analytic result processing, and progress check/turnaround time	All bodyfluids, blood cells, other body cells, punctures, bone marrow	A1

¹ If no date or version number is mentioned for a normative document, the accreditation concerns the most current version of the document or scheme.

¹ The laboratory shall maintain an up-to-date list of the activities performed under this flexible scope. This list can be requested from the laboratory.

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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Code	Diagnostic question	Method/Technique	Material or product	Location
CH.KCA.01	Clinical Chemistry general	Routine analysis of electrolytes, enzymes, proteins, metabolites, blood gases and their derivatives using standard chemical techniques including all spectrophotometry, colorimetry, binding analysis, nephelometry, turbidimetry, electrophoresis, ion-selective electrodes	All bodily fluids	A1
CH.KCA.04		Immunochemistry / protein chemistry (specific)	All bodily fluids	A1
CH.KCA.05		Nucleic acid diagnostics including PCR and sequencing [technical execution]	Blood cells, plasma, other body cells	A1
CH.KCA.12		Functional tests (including (o)GGT, sugar absorption test, hydrogen breath test)	All bodily fluids, expired air	A1
CH.END.03	Clinical chemistry, endocrinology	Binding analysis (immunoassays)	All bodily fluids	A1
CH.EMZ.03	Clinical chemistry, hereditary metabolic diseases	Chromatography including HPLC, UPLC, GC	All bodily fluids	A1
CH.EMZ.05		Nucleic acid diagnostics including PCR and sequencing	Blood cells, other body cells	A1
CH.EMZ.07		Enzyme diagnostics	Blood cells, other body cells	A1
CH.EMZ.08		Binding analysis (RIA - C/D lab)	All bodily fluids	A1
CH.IMM.03	Clinical chemistry, immunology (including allergy, immunodeficiencies and autoimmune diagnostics)	Immunochemistry	All bodily fluids	A1
CH.BTG.01	Clinical chemistry, hematology, transfusion medicine	Blood cell compatibility testing	Blood, plasma	A1
CH.BTG.02		Blood cell antibody and antigen typing	Blood, plasma	A1

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CH.BTG.04	Clinical chemistry, hematology, transfusion medicine	Nucleic acid diagnostics including PCR and sequencing	Blood cells, plasma	A1
CH.BTG.05		Antibodies against platelets	Blood, plasma	A1
CH.TRH.01	Clinical chemistry, hematology, thrombosis and hemostasis	Clotting tests in plasma (screening and confirming) such as APTT, fib, FVIII, VWF	Plasma	A1
CH.TRH.04		Nucleic acid diagnostics including PCR and sequencing	Blood cells, other body cells	A1

Medical field: Medical Microbiology

MM.BID.07	Bacterial identification	Agglutination	Body materials & environmental materials	A1
MM.BID.13		Antibody determination by means of immunoassay	Body materials & environmental materials	A1
MM.VID.08	Virus identification	Molecular diagnostics by means of PCR	Body materials	A1
MM.VID.11		Antigenic determination by means of immunoassays	Body materials	A1
MM.VID.16		Antibody determination by means of immunoassay	Body materials	A1
MM.DON.01	Donor testing lab	In accordance with permit issued by Farmatec	See permit issued by Farmatec	A1

**Medical field: Medical Immunology
 In compliance with the standards in force (NVVI)**

MI.IMD.01	Immune deficiencies	Immunoglobulins with other techniques	All body fluids, culture supernatant	A1
MI.IMD.03		Complement / MBL by means of other techniques	All body fluids, culture supernatant	A1
MI.IMD.04		Complement / MBL by means of functional testing	All body fluids, culture supernatant	A1
MI.IMD.11		DNA / RNA mutation analysis	All body fluids, culture supernatant	A1

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Code	Diagnostic question	Method/Technique	Material or product	Location
MI.AIA.01	Autoimmune diseases and inflammatory disorders	Immunoglobulins with other techniques	All body fluids, biopsies, punctates, tissues, rinsing fluids and culture supernatant	A1
MI.AIA.04		Autoantibodies with random access analyzer	All body fluids, biopsies, punctates, tissues, rinsing fluids and culture supernatant	A1
MI.AIA.05		Autoantibodies with other (semi) manual techniques	All body fluids, biopsies, punctates, tissues, rinsing fluids and culture supernatant	A1
MI.AIA.06		Autoantibodies by means of (in)direct immunofluorescence	All body fluids, biopsies, punctates, tissues, rinsing fluids and culture supernatant	A1
MI.AIA.07		Autoantibodies by means of multiplex techniques	All body fluids, biopsies, punctates, tissues, rinsing fluids and culture supernatant	A1
MI.AIA.08		Autoantibodies with radionuclide techniques	All body fluids, biopsies, punctates, tissues, rinsing fluids and culture supernatant	A1
MI.AIA.09		Complement by means of other techniques	All body fluids, biopsies, punctates, tissues, rinsing fluids and culture supernatant	A1
MI.AIA.10		Complement by means of functional testing	All body fluids, biopsies, punctates, tissues, rinsing fluids and culture supernatant	A1
MI.AIA.17		Immunological monitoring of antibody therapy (levels and antibodies)	All body fluids, biopsies, punctates, tissues, rinsing fluids and culture supernatant	A1
MI.ALA.03		Allergic disorders	Type III allergy-associated antibodies	All body fluids
MI.MHA.01	Malignant haematological disorders	Immunoglobulins	All body fluids, punctates, biopsies and tissues	A1

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MI.MHA.04	Malignant haematological disorders	M-protein diagnostics	All body fluids, punctates, biopsies and tissues	A1
MI.MHA.05		Immunophenotyping testing	All body fluids, punctates, biopsies and tissues	A1
MI.MHA.07		Molecular clonality testing	All body fluids, punctates, biopsies and tissues	A1
MI.MHA.08		Determination of chromosomal / genomic abnormalities	All body fluids, punctates, biopsies and tissues	A1
MI.MHA.10		Determination of residual disease molecular	All body fluids, punctates, biopsies and tissues	A1
MI.TFG.02	Transfusion medicine	Blood cell antibody and antigen typing	All body fluids	A1
MI.EFI.01	Transplantation immunology	According to EFI standards (Standards for Histocompatibility and Immunogenetics Testing (European Federation for Immunogenetics))	All body fluids	A1
MI.DON.01	Donortestlab	In accordance with license issued by Farmatec	See license issued by Farmatec	A1