

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: **20-12-2023 to 31-12-2025**

Replaces annex dated: **21-07-2022**

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 |
| CH.DON.01 | Donor testing lab | In accordance with permit issued by Farmatec | See permit issued by Farmatec | A1 |

Medical field: Medical Microbiology

| | | | | |
|-----------|--------------------------|---|---|----------------|
| MM.BID.07 | Bacterial identification | Agglutination | Body materials & environmental materials | A1 |
| MM.BID13 | | Antibody determination by means of immunoassay | Body materials & environmental materials | A1 |
| MM.VID.04 | Virus identification | Neutralization | Body materials | A1 |
| MM.VID.08 | | Molecular diagnostics by means of PCR | Body materials | A1 |
| MM.VID.11 | | Antigenic determination by means of immunoassays | Body materials | A1 |
| MM.VID.12 | | Agglutination | Body materials | A1 |
| MM.VID.13 | | Antigenic determination by means of enzymatic assay | Body materials | A1 |
| MM.VID.15 | | Antibody determination by means of enzymatic assay | Body materials | A1 |
| MM.VID.16 | | Antibody determination by means of immunoassay | Body materials | A1 |
| MM.VRS.02 | | Virus resistance determination | Resistance determination by means of PCR and sequencing | Body materials |
| MM.VTP.04 | Virus typing | Genotyping by means of PCR and sequencing | Body materials | A1 |

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

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|-----------|--|--|---|----|
| 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 | Immune deficiencies | Complement / MBL by means of functional testing | All body fluids, culture supernatant | A1 |
| MI.IMD.05 | | Vaccination responses by means of other techniques | All body fluids, culture supernatant | A1 |
| MI.IMD.11 | | DNA / RNA mutation analysis | All body fluids, culture supernatant | A1 |
| 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 |

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|-----------|--|---|---|----------|
| MI.AIA.09 | Autoimmune diseases and inflammatory disorders | 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.11 | | Soluble mediators of the innate and acquired immune system (cytokines, chemokines) by means of other techniques | 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 | A1 |
| MI.MHA.01 | Malignant haematological disorders | Immunoglobulins | All body fluids, punctates, biopsies and tissues | A1 |
| MI.MHA.04 | | 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 |

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| 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 |