

Annex to declaration of accreditation (scope of accreditation)  
 Normative document: EN ISO 15189:2012  
 Registration number: **M 334**

of **Health Care Laboratory Sint Maarten N.V. (HCLS)**

This annex is valid from: **21-03-2024** to **31-12-2025**

Replaces annex dated: **N.v.t.**

**Location(s) where activities are performed under accreditation**

**Head Office**

Orange Grove Mall, units 12 &13, Union road Cole Bay

Philipsburg  
 Sint Maarten

Location	Abbreviation/ location code
Orange Grove Mall, units 12 &13, Union road Cole Bay Philipsburg Sint Maarten	P1

**Flexible scope<sup>1</sup>**

Code	Diagnostic question	Method/Technique	Material or product	Location
<b>Medical field: Clinical Chemistry and Hematology In compliance with the standards in force (NVKC)</b>				
CH.PRE.01	Pre analysis	Blood collection (extra-mural)	Blood	P1
CH.PRE.02		Blood collection (intra-mural)	Blood	P1
CH.PRE.03		Sample processing, sample reception, registration, processing, preprocessing for analysis (among other things centrifugation), post-analytic result processing, and progress check/turnaround time	Blood	P1

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

J.A.W.M. de Haas

<sup>1</sup> If no date or version number is mentioned for a normative document, the accreditation concerns the most current version of the document or scheme.  
<sup>1</sup> This flexible scope requires the laboratory to maintain a current list of the methods applied under this flexible scope.

of **Health Care Laboratory Sint Maarten N.V. (HCLS)**

This annex is valid from: **21-03-2024** to **31-12-2025**

Replaces annex dated: **N.v.t.**

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 body fluids, blood cells	P1
CH.KCA.02		Binding analysis (specific immunoassays)	All body fluids	P1
CH.KCA.04		Immunochemistry/protein chemistry (special)	All body fluids	P1
CH.END.03	Clinical chemistry, endocrinology	Binding analysis (immunoassays)	All body fluids	P1
CH.IMM.03	Clinical chemistry, immunology (including allergy, immunodeficiencies and autoimmune diagnostics)	Immunochemistry	All body fluids	P1
CH.IMM.05		Total IgE, specific IgE	All body fluids	P1
CH.IMM.06		Autoantibodies using (in)direct immunofluorescence	All body fluids	P1
CH.BTG.01	Clinical chemistry, hematology, transfusion medicine	Blood cell compatibility testing	Blood, plasma	P1
CH.BTG.02		Blood cell antibody and antigen typing	Blood, plasma	P1
CH.HCO.01	Clinical chemistry, hematology, hemocytometry incl haemato-oncology	hematology and microscopy	Blood	P1
CH.HCO.02		Erythrocyte sedimentation rate	Blood	P1
CH.HCO.04		Immunoflow cytometry	Blood	P1
CH.HCO.05		M protein diagnostics	All body fluids	P1

Annex to declaration of accreditation (scope of accreditation)  
 Normative document: EN ISO 15189:2012  
 Registration number: **M 334**

of **Health Care Laboratory Sint Maarten N.V. (HCLS)**

This annex is valid from: **21-03-2024** to **31-12-2025**

Replaces annex dated: **N.v.t.**

Code	Diagnostic question	Method/Technique	Material or product	Location
CH.HBP.02	Clinical chemistry, hematology, Hb-pathy	Electrophoresis	Blood	P1
CH.TRH.01	Clinical chemistry, hematology, thrombosis and hemostasis	Plasma coagulation tests (screening and confirmatory) such as APTT, fib, FVIII, VWF	Plasma	P1
<b>Medical field: Medical Microbiology</b>				
MM.PRE.01	Pre analysis	Pre analysis	Body materials & Environmental materials	P1
MM.BID Fixed element 01	Bacterial identification	Antibody determination by immunoassays: - Helicobacter pylori IgG [technical performance]	Serum	P1
MM.BID Fixed element 02		Antigenic determination by immunoassays: - Helicobacter pylori [technical performance]	Feaces	P1
MM.VID Fixed element 01	Virus identification	Antigenic determination by immunoassays: - SARS-CoV-2 [technical performance]	Nasal swab	P1
MM.VID Fixed element 02		Antigenic determination by immunoassays: - Hepatitis B Surface [technical performance]	Serum	P1

Annex to declaration of accreditation (scope of accreditation)  
 Normative document: EN ISO 15189:2012  
 Registration number: **M 334**

of **Health Care Laboratory Sint Maarten N.V. (HCLS)**

This annex is valid from: **21-03-2024** to **31-12-2025**

Replaces annex dated: **N.v.t.**

Code	Diagnostic question	Method/Technique	Material or product	Location
MM.VID Fixed element 03	Virus identification	Antibody determination by immunoassays: <ul style="list-style-type: none"> <li>- CMV IgG/IgM</li> <li>- Epstein Bar Virus (EBV)</li> <li>- Hepatitis A (HAV)</li> <li>- Hepatitis B Core antibodies</li> <li>- Hepatitis B Surface antibodies</li> <li>- Hepatitis C antibodies</li> <li>- HIV 1 + 2</li> <li>- HSV 1 + 2 (IgG + IgM)</li> <li>- Measles IgG</li> <li>- Mumps IgG</li> <li>- Rubella IgG</li> <li>- Syphilis Screening</li> <li>- Toxoplasma IgG/IgM</li> <li>- Varicella Zoster Virus IgG (VZV)</li> </ul> [technical performance]	Serum	P1