

Deutsche Akkreditierungsstelle GmbH

Annex to the Accreditation Certificate D-PL-21873-01-00 according to DIN EN ISO/IEC 17025:2018

Valid from: 13.07.2021

Date of issue: 13.07.2021

Holder of certificate:

CSL Behring Innovation GmbH

Central Laboratory Marburg, Research and Clinical Bioanalytics

Emil von Behring Straße 76, 35041 Marburg

Tests in the field:

Health Care (medical laboratory testing in the context of clinical studies)

Testing areas:

Clinical chemistry

Immunology

Within the given testing field marked with **, the technical laboratory is permitted, without being required to inform and obtain prior approval from Deutsche Akkreditierungsstelle GmbH (DAkkS), the modification, development and refinement of testing methods.

The listed testing methods are exemplary. The testing laboratory maintains a current list of all testing methods within the flexible scope of accreditation.

The management system requirements of DIN EN ISO/IEC 17025 are written in the language relevant to the operations of testing laboratories. Laboratories that conform to the requirements of this standard, operate generally in accordance with the principles of DIN EN ISO 9001.

The certificate together with its annex reflects the status at the time of the date of issue. The current status of the scope of accreditation can be found in the database of accredited bodies of Deutsche Akkreditierungsstelle GmbH.

<https://www.dakks.de/en/content/accredited-bodies-dakks>

Testing area: Clinical chemistry

Type of testing: Agglutination

Analyte (test parameter)	Test material (matrix)	Test technique
vWF-RiCoF	citrate plasma	agglutination test

Type of testing: Chromatography (liquid chromatography (LC))**

Analyte (test parameter)	Test material (matrix)	Test technique
Hemopexin	serum	LC-MS/MS

Type of testing: Coagulometry**

Analyte (test parameter)	Test material (matrix)	Test technique
aPTT	citrate plasma	coagulation test
factor II	citrate plasma	coagulation test
factor IX	citrate plasma	coagulation test
factor IX-INH	citrate plasma	coagulation test
factor VII	citrate plasma	coagulation test
factor VIIa	citrate plasma	coagulation test
factor VIII	citrate plasma	coagulation test
factor VIII-INH	citrate plasma	coagulation test
factor VII-INH	citrate plasma	coagulation test
factor X	citrate plasma	coagulation test
fibrinogen	citrate plasma	coagulation test
MCF	citrate plasma	thrombelastography
naPTT	citrate plasma	coagulation test
PT/INR	citrate plasma	coagulation test

Type of testing: Ligand assays**

Analyte (test parameter)	Test material (matrix)	Test technique
Faktor IX	citrate plasma	ELISA
Faktor XIII	citrate plasma	ELISA
Fibrinogen	citrate plasma	ELISA
Protein S	citrate plasma	ELISA
Prothrombinfragment F 1+2	citrate plasma	ELISA
Thrombin Antithrombin III Komplex	citrate plasma	ELISA
vWF-CBA	citrate plasma	ELISA
vWF-INH	citrate plasma	ELISA

Type of testing: Spectrometry (photometry)**

Analyte (test parameter)	Test material (matrix)	Test technique
AAT activity	serum, citrate plasma	chromogen
ATIII	citrate plasma	chromogen
C1 inhibitor activity	citrate plasma	chromogen
C1 inhibitor-INH	citrate plasma	chromogen
factor VIII	citrate plasma	chromogen
factor XIII	citrate plasma	chromogen
FVII	citrate plasma	chromogen
protein C	citrate plasma	chromogen
Thrombin Generation Assay (TGA)	citrate plasma	fluorogen
total protein by Bradford assay	citrate plasma, sputum	colorimetric
Urea	serum, sputum	colorimetric

Type of testing: Spectrometry (immunoturbidimetry)**

Analyte (test parameter)	Test material (matrix)	Test technique
D-Dimer	citrate plasma	immunoturbidimetric

Testing area:
immunology

Type of testing: Ligand assays**

Analyte (test parameter)	Test material (matrix)	Test technique
CSL312 antibodies	citrate plasma	ECL Immunoassay
CSL312 antibodies (BEAD assay)	citrate plasma	ECL Immunoassay
C1 inhibitor auto-antibody/ Isotype IgA	citrate plasma, serum	ELISA
C1 inhibitor auto-antibody/ Isotype IgG	citrate plasma, serum	ELISA
C1 inhibitor auto-antibody/ Isotype IgM	citrate plasma, serum	ELISA
C1 Inhibitor auto-antibody/ Screening	citrate plasma, serum	ELISA
C3a antigen	citrate plasma, serum	ELISA
C5a antigen	EDTA plasma, citrate plasma, serum	ELISA

Analyte (test parameter)	Test material (matrix)	Test technique
CHO antibody (rIX-FP)	citrate plasma	ELISA
CHO antibody (rVIIa-FP)	citrate plasma	ELISA
CHO antibody (rVIII-FP)	citrate plasma	ELISA
FVII antigen	citrate plasma	ELISA
FXIII antibody, isotype IgG	citrate plasma	ELISA
human albumin antibody	citrate plasma	ELISA
human FIX antibody	citrate plasma	ELISA
IgG level	Sputum	ECL immunoassay
IgM level	Sputum	ECL immunoassay
interleukin 6 (IL-6)	heparin plasma	ELISA
Determination of CSL312	citrate plasma	ELISA
rFIX-fusion protein antibody	citrate plasma	ELISA
rFVIIa-fusion protein antibody	citrate plasma	ELISA
rFVIII antibody	citrate plasma	ELISA
Tumor Nekrosis Factor alpha (TNFa)	heparin plasma	ELISA

Type of testing: Spectrometry (immunturbidimetry)**

Analyte (test parameter)	Test material (matrix)	Test technique
Free Protein S antigen	citrate plasma	immunturbidimetric
vWF antigen	citrate plasma	immunturbidimetric
vWF-INH	citrate plasma	immunturbidimetric

Type of testing: Spectrometry (surface plasmon resonance)**

Analyte (test parameter)	Test material (matrix)	Test technique
Determination of rIX-FP CHO HCP antibodies	citrate plasma	SPR
Determination of rVIII CHO HCP antibodies	citrate plasma	SPR
Determination of rVIIa-FP CHO HCP antibodies	citrate plasma	SPR

Type of testing: Spectrometry (nephelometry)**

Analyte (test parameter)	Test material (matrix)	Test technique
AAT Antigen	serum, citrate plasma	nephelometric
Albumin antigen	serum, citrate plasma	nephelometric
APA antigen	citrate plasma	nephelometric
C1 inhibitor antigen	citrate plasma	nephelometric
C3 antigen	serum	nephelometric
C4 antigen	citrate plasma, serum	nephelometric
C5 antigen	serum	nephelometric
IgA level	serum	nephelometric
IgG level	serum, BAL, citrate plasma	nephelometric
IgM level	serum	nephelometric