

Deutsche Akkreditierungsstelle GmbH

Annex to the Accreditation Certificate D-PL-13424-01-00 according to DIN EN ISO/IEC 17025:2005

Indefinite since: 05.12.2018

Date of issue: 02.07.2018

Holder of certificate:

CSL Behring GmbH

Plasma Product Development Marburg, Central laboratory for clinical testing

Emil von Behring Straße 76, 35041 Marburg

Tests in the fields:

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

Testing area:

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 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:

medical laboratory testing in the context of clinical studies (clinical chemistry)

Testing field: coagulation tests**

Analyte (test parameter)	Matrix (testing material)	Type of examination (technique)
factor II	citrate plasma	coagulation test
factor VII	citrate plasma	coagulation test
factor VIIa	citrate plasma	coagulation test
factor VII-INH	citrate plasma	coagulation test
factor VIII	citrate plasma	coagulation test
factor VIII-INH	citrate plasma	coagulation test
factor IX	citrate plasma	coagulation test
factor IX-INH	citrate plasma	coagulation test
factor X	citrate plasma	coagulation test
fibrinogen	citrate plasma	coagulation test
vWF-RiCoF	citrate plasma	agglutination test
PT/INR	citrate plasma	coagulation test
MCF	citrate plasma	thrombelastography

Testing field: ligand assays**

Analyte (test parameter)	Matrix (testing material)	Type of examination (technique)
protein S	citrate plasma	ELISA
fibrinogen	citrate plasma	ELISA
prothrombin fragment F 1+2	citrate plasma	ELISA
thrombin antithrombin III complex	citrate plasma	ELISA
factor IX	citrate plasma	ELISA
factor XIII	citrate plasma	ELISA
vWF-CBA	citrate plasma	ELISA
vWF-INH	citrate plasma	ELISA

Testing field: spectrometry (photometry)**

Analyte (test parameter)	Matrix (testing material)	Type of examination (technique)
factor VIII	citrate plasma	chromogen
protein C	citrate plasma	chromogen
C1 inhibitor activity	citrate plasma	chromogen
C1 inhibitor-INH	citrate plasma	chromogen
ATIII	citrate plasma	chromogen
factor XIII	citrate plasma	chromogen
Thrombin Generation Assay (TGA)	citrate plasma	fluorogen
FVII	citrate plasma	chromogen

Testing field: spectrometry (turbidimetry)**

Analyte (test parameter)	Matrix (testing material)	Type of examination (technique)
D-Dimer	citrate plasma	immunoturbidimetry

Testing area:

medical laboratory testing in the context of clinical studies (immunology)

Testing field: ligand assays**

Analyte (test parameter)	Matrix (testing material)	Type of examination (technique)
interleukin 1 β (IL-1 β)	heparin plasma	ELISA
interleukin 6 (IL-6)	heparin plasma	ELISA
FXIII antibody, isotype IgG	citrate plasma	ELISA
Tumor Nekrosis Factor alpha (TNFa)	heparin plasma	ELISA
C1 Inhibitor auto-antibody/ Screening	citrate plasma, serum	ELISA
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

Analyte (test parameter)	Matrix (testing material)	Type of examination (technique)
human albumin antibody	citrate plasma	ELISA
human FIX antibody	citrate plasma	ELISA
rFVIIa-fusion protein antibody	citrate plasma	ELISA
rFVIII antibody	citrate plasma	ELISA
CHO antibody (rIX-FP)	citrate plasma	ELISA
CHO antibody (rVIIa-FP)	citrate plasma	ELISA
CHO antibody (rVIII sc)	citrate plasma	ELISA
CHO antibody (rVIIa-FP)	citrate plasma	ELISA
FVII antigen	citrate plasma	ELISA
C3a antigen	citrate plasma, serum	ELISA
C5a antigen	EDTA plasma, citrate plasma, serum	ELISA
Determination of rD'D3-FP antibodies	citrate plasma	ECLIA

Testing field: spectrometry (turbidimetry)**

Analyte (test parameter)	Matrix (testing material)	Type of examination (technique)
vWF antigen	citrate plasma	immunoturbidimetry
vWF-INH	citrate plasma	immunoturbidimetry
Free Protein S antigen	citrate plasma	immunoturbidimetry

Testing field: spectrometry (surface plasmon resonance)**

Analyte (test parameter)	Matrix (testing material)	Type of examination (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

Testing field: spectrometry (nephelometry)**

Analyte (test parameter)	Matrix (testing material)	Type of examination (technique)
C1 inhibitor antigen	citrate plasma	nephelometry
IgG level	serum, sputum, BAL	nephelometry
C3 antigen	serum	nephelometry
C4 antigen	citrate plasma, serum	nephelometry
C5 antigen	serum	nephelometry

Abbreviations used:

DIN	Deutsches Institut für Normung e.V.
EN	European Standard
ISO	International Organization for Standardization
IEC	International Electrotechnical Commission