

Deutsche Akkreditierungsstelle GmbH

Annex to the Accreditation Certificate D-K-15117-01-00 according to DIN EN ISO/IEC 17025:2018 und DIN EN ISO 15195:2004

Valid from: 03.06.2020

Date of issue: 03.09.2021

Holder of certificate:

Stiftung für Pathobiochemie und Molekulare Diagnostik

with its Calibration Laboratory

**Referenzinstitut für Bioanalytik
Kalibrierlaboratorium I
Nattermannallee 1, 50829 Köln**

Calibration in the fields:

Medical reference measurement laboratories
- Amount of substance concentration
- Amount of substance fraction

The management system requirements of DIN EN ISO/IEC 17025 are written in the language relevant to the operations of calibration 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 the annex reflects the status as indicated by the date of issue.
The current status of any given scope of accreditation may be found respectively in the database of accredited bodies of Deutsche Akkreditierungsstelle GmbH <https://www.dakks.de/en/content/accredited-bodies-dakks>.*

Abbreviations used: see last page

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This document is a translation. The definitive version is the original German annex to the accreditation certificate.

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Measurement quantity / Calibration item	Range	Measurement conditions / procedure	Expanded uncertainty of measurement ¹⁾	Remarks
Amount of substance concentration of creatinine in serum or material similar to serum	50 µmol/L to 1 mmol/L	Online combination of chromatography / isotope dilution mass spectrometry (IDMS) In house procedure 13_Creatinine in serum Edition: 3 Status: 2019-09-04	1.0 %	
Amount of substance concentration Creatinine of urine	0.4 mmol/L to 40 mmol/L	Online combination of chromatography / isotope dilution mass spectrometry (IDMS) In house procedure 14_Creatinine in urine Edition: 3 Status: 2019-09-05	1.0 %	
Amount of substance concentration Cholesterol in serum or material similar to serum	1 mmol/L to 10 mmol/L	Online combination of chromatography / isotope dilution mass spectrometry (IDMS) In house procedure 15_Cholesterin in serum Edition: 3 Status: 2019-09-05	1.0 %	
Amount of substance concentration Total glycerol in serum or material similar to serum	0.5 mmol/L to 20 mmol/L	Online combination of chromatography / isotope dilution mass spectrometry (IDMS) In house procedure 16_Glycerol in Serum Edition: 3 Status: 2019-10-09	1.0 %	
Amount of substance concentration Urea in serum or material similar to serum	0.5 mmol/L to 50 mmol/L	Online combination of chromatography / isotope dilution mass spectrometry (IDMS) In house procedure 17_Urea in serum Edition: 3 Status: 2019-10-09	1.0 %	

¹⁾ The expanded uncertainties according to EA-4/02 M:2013 are part of CMC and are the best measurement uncertainties within accreditation. They have a coverage probability of approximately 95 % and have a coverage factor of $k = 2$ unless stated otherwise. Uncertainties without unit are relative uncertainties referring to the measurement value unless stated otherwise.

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Measurement quantity / Calibration item	Range	Measurement conditions / procedure	Expanded uncertainty of measurement ¹⁾	Remarks
Amount of substance concentration Urea in urine	0.5 mmol/L to 1 mol/L	Online combination of chromatography / isotope dilution mass spectrometry (IDMS) In house procedure 18_Urea in urine Edition: 3 Status: 2019-10-09	1.0 %	
Amount of substance concentration Uric acid in serum or material similar to serum	50 µmol/L to 1 mmol/L	Online combination of chromatography / isotope dilution mass spectrometry (IDMS) In house procedure 19_Uric acid in serum Edition: 3 Status: 2019-10-09	1.0 %	
Amount of substance concentration Uric acid in urine	0.1 mmol/L to 10 mmol/L	Online combination of chromatography / isotope dilution mass spectrometry (IDMS) In house procedure 20_Uric acid in urine Edition: 3 Status: 2019-10-09	1.0 %	
Amount of substance concentration Progesterone in serum or material similar to serum	0.1 nmol/L to 100 nmol/L	Online combination of chromatography / isotope dilution mass spectrometry (IDMS) In house procedure 21_Progesterone in serum Edition: 1 Status: 2019-10-09	1.0 %	
Amount of substance concentration Estradiol in serum or material similar to serum	10 pmol/L to 7.5 nmol/L	Online combination of chromatography / isotope dilution mass spectrometry (IDMS) In house procedure 22_Estradiol in serum Edition: 1 Status: 2019-11-30	1.0 %	
Amount of substance concentration Estriol in serum or material similar to serum	1 nmol/L to 500 nmol/L	Online combination of chromatography / isotope dilution mass spectrometry (IDMS) In house procedure 23_Estriol in serum Edition: 3 Status: 2019-10-10	1.0 %	

¹⁾ The expanded uncertainties according to EA-4/02 M:2013 are part of CMC and are the best measurement uncertainties within accreditation. They have a coverage probability of approximately 95 % and have a coverage factor of $k = 2$ unless stated otherwise. Uncertainties without unit are relative uncertainties referring to the measurement value unless stated otherwise.

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Measurement quantity / Calibration item	Range	Measurement conditions / procedure	Expanded uncertainty of measurement ¹⁾	Remarks
Amount of substance concentration Aldosterone in serum or material similar to serum	50 pmol/L to 3.5 nmol/L	Online combination of chromatography / isotope dilution mass spectrometry (IDMS) In house procedure 24_Aldosterone in serum Edition: 4 Status: 2019-10-10	1.0 %	
Amount of substance concentration Cortisol in serum or material similar to serum	10 nmol/L to 2 µmol/L	Online combination of chromatography / isotope dilution mass spectrometry (IDMS) In house procedure 25_Cortisol in serum Edition: 3 Status: 2019-10-10	1.0 %	
Amount of substance concentration 17-hydroxyprogesterone in serum or material similar to serum	1 nmol/L to 2,5 µmol/L	Online combination of chromatography / isotope dilution mass spectrometry (IDMS) In house procedure 26_17-hydroxyprogesterone in serum Edition: 3 Status: 2019-10-07	1.0 %	
Amount of substance concentration Testosterone in serum or material similar to serum	1 nmol/L to 50 nmol/L	Online combination of chromatography / isotope dilution mass spectrometry (IDMS) In house procedure 27_Testosterone in serum Edition: 1 Status: 2019-11-30	1.0 %	
Amount of substance concentration Thyroxine in serum or material similar to serum	20 nmol/L to 350 nmol/L	Online combination of chromatography / isotope dilution mass spectrometry (IDMS) In house procedure 28_Thyroxine in serum Edition: 3 Status: 2019-10-10	1.0 %	

¹⁾ The expanded uncertainties according to EA-4/02 M:2013 are part of CMC and are the best measurement uncertainties within accreditation. They have a coverage probability of approximately 95 % and have a coverage factor of $k = 2$ unless stated otherwise. Uncertainties without unit are relative uncertainties referring to the measurement value unless stated otherwise.

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Measurement quantity / Calibration item	Range	Measurement conditions / procedure	Expanded uncertainty of measurement ¹⁾	Remarks
Amount of substance concentration Digoxin in serum or material similar to serum	0.1 nmol/L to 40 nmol/L	Online combination of chromatography / isotope dilution mass spectrometry (IDMS) In house procedure 29_Digoxin in serum Edition: 3 Status: 2019-10-10	1.0 %	
Amount of substance concentration Digitoxin in serum or material similar to serum	0.5 nmol/L to 100 nmol/L	Online combination of chromatography / isotope dilution mass spectrometry (IDMS) In house procedure 30_Digitoxin in serum Edition: 3 Status: 2019-10-10	1.0 %	
Amount of substance concentration Triiodo-L-thyronine in serum or material similar to serum	0.5 nmol/L to 8,0 nmol/L	Online combination of chromatography / isotope dilution mass spectrometry (IDMS) In house procedure 31_Triiodothyronine in serum Edition: 3 Status: 2019-10-10	1.0 %	
Amount of substance fraction of HbA1c in material similar to whole blood or hemolysate	29 mmol/mol to 150 mmol/mol	High pressure liquid chromatography-mass spectrometry (LC-MS / MS) according to the IFCC reference measurement method Clin. Chem., 2008, 54: 6, 1018-1022	2.0 %	

¹⁾ The expanded uncertainties according to EA-4/02 M:2013 are part of CMC and are the best measurement uncertainties within accreditation. They have a coverage probability of approximately 95 % and have a coverage factor of $k = 2$ unless stated otherwise. Uncertainties without unit are relative uncertainties referring to the measurement value unless stated otherwise.

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Abbreviations used:

CMC	Calibration and measurement capabilities
IDMS	Isotope dilution mass spectrometry
In-house procedure	In-house procedure of the calibration laboratory

¹⁾ The expanded uncertainties according to EA-4/02 M:2013 are part of CMC and are the best measurement uncertainties within accreditation. They have a coverage probability of approximately 95 % and have a coverage factor of $k = 2$ unless stated otherwise. Uncertainties without unit are relative uncertainties referring to the measurement value unless stated otherwise.