Certificate of Approval

This is to certify that the Management System of:

Abbott Laboratories Diagnostics Division

100 Abbott Park Road, Abbott Park, IL, 60064, United States

has been approved by LRQA to the following standards:

ISO 13485:2016

Chris Koci
Issued By: Lloyd's Register Quality Assurance, Inc. for and on behalf of: Lloyd's Register Quality Assurance Ltd

This certificate is valid only in association with the certificate schedule bearing the same number on which the locations applicable to this approval are listed.

Current Issue Date: 7 December 2017
Expiry Date: 30 November 2020
Certificate Issue Number: 10044680

Original Approvals:

ISO 13485 7 December 2017

Approval Certificate Number: ISO 13485 – 0015680

The scope of this approval is applicable to:

Manufacturer, Design, Development, Installation, Service and Support of In Vitro Diagnostic Products including Test Kits, Reagents, Accessories and Instruments.

Digitally signed by Ceaicovschi Tudor
Date: 2021.07.08 16:26:38 EEST
Reason: MoldSign Signature
Location: Moldova

UKAS MANAGEMENT SYSTEMS
001

Certificate Schedule

Certificate Issue Number: 10044680

Location	Activities
100 Abbott Park Road, Abbott Park, IL, 60064, United States	ISO 13485:2016 Manufacturer, Design, Development, Installation, Service and Support of In Vitro Diagnostic Products including Test Kits, Reagents, Accessories and Instruments.
Conway Park, 675 North Field Drive, Schaumburg, Lake Forest, IL, 60045, United States	ISO 13485:2016 Oversight of the Quality Management System for the Abbott Diagnostics Division Sites.

UKAS MANAGEMENT SYSTEMS

001

Certificate of Approval

This is to certify that the Management System of:

Abbott Laboratories Diagnostics Division

100 Abbott Park Road, Abbott Park, IL, 60064, United States

has been approved by LRQA to the following standards:

ISO 13485:2016

Chris Koci
Issued By: Lloyd's Register Quality Assurance, Inc.

This certificate is valid only in association with the certificate schedule bearing the same number on which the locations applicable to this approval are listed.

Effective Date: 13 December 2017
Expiry Date: 30 November 2020
Certificate Identity Number: 10044682

Original Approvals:

ISO 13485 7 December 2017

Approval Certificate Number: CMDCAS – 0015682

The scope of this approval is applicable to:

Design and Manufacture of In Vitro Diagnostic Medical Devices, used in the Screening of Blood Donor Units for Transmissible Diseases. Design and Manufacture of In Vitro Diagnostic Medical Devices used in the Diagnosis, Management and Detection of Cancer, Autoimmune Status, Cardiac Markers, Endocrine Disorders, and for Therapeutic Drug Monitoring. Design, Development, Manufacture, Refurbishment, Distribution, and Post-Market Customer Service and Support of In Vitro Diagnostic Medical Devices (including Diagnostic Instruments) for Immunoassay and Clinical Chemistry Systems. Design and Manufacture of In Vitro Diagnostic Devices for Hematology Systems.

SCC Accredited CB-MS

CMDCAS
RECOGNIZED
REGISTRAR
1009-8/15-6

Certificate Schedule

Certificate Issue Number: 10044682

Location	Activities
100 Abbott Park Road, Abbott Park, IL, 60064, United States	ISO 13485:2016 Design and Manufacture of In Vitro Diagnostic Reagents, Test Kits and Accessories for use in Testing for Cancer, Bacteriological, Cardiovascular, Endocrine, Metabolic, Retroviral, Hepatitis and Other Viral, Parasitic, and Sexually-Transmitted Diseases and for use in Drug Monitoring. Design, Development, Manufacture, Refurbishment, Distribution, and Post-Market Customer Service and Support of In Vitro Diagnostic Medical Devices for Immunoassay and Clinical Chemistry Systems including Instruments for use in testing for Cancer, Bacteriological, Cardiovascular, Endocrine, Metabolic, Retroviral, Hepatitis and Other Viral, Parasitic, and Sexually-Transmitted Diseases and for use in Drug Monitoring. Design and Manufacture of In Vitro Diagnostic Devices for Hematology Systems, including Reagents and Instruments.
Conway Park, 675 North Field Drive, Schaumburg, Lake Forest, IL, 60045, United States	ISO 13485:2016 Oversight of the Quality Management System for the Abbott Diagnostics Division Sites.

SCC Accredited CB-MS™

CMDCAS
RECOGNIZED REGISTRAR
1009-8/15-6

Certificate of Approval

This is to certify that the Management System of:

Abbott Laboratories Diagnostics Division

100 Abbott Park Road, Abbott Park, IL, 60064, United States

has been approved by LRQA to the following standards:

ISO 9001:2015

Chris Koci
Issued By: Lloyd's Register Quality Assurance, Inc. for and on behalf of: Lloyd's Register Quality Assurance Ltd

This certificate is valid only in association with the certificate schedule bearing the same number on which the locations applicable to this approval are listed.

Current Issue Date: 13 December 2017
Expiry Date: 30 November 2020
Certificate Identity Number: 10044681

Original Approvals:
ISO 9001 – 3 December 2017

Approval Number(s): ISO 9001 – 0015681

The scope of this approval is applicable to:
Manufacturer, Design, Development, Installation, Service and Support of In Vitro Diagnostic Products including Test Kits, Reagents, Accessories and Instruments.

UKAS MANAGEMENT SYSTEMS
001

Certificate Schedule

Certificate Identity Number: 10044681

Location	Activities
100 Abbott Park Road, Abbott Park, IL, 60064, United States	ISO 9001:2015 Manufacturer, Design, Development, Installation, Service and Support of In Vitro Diagnostic Products including Test Kits, Reagents, Accessories and Instruments.
Conway Park, 675 North Field Drive, Schaumburg, Lake Forest, IL, 60045, United States	ISO 9001:2015 Oversight of the Quality Management System for the Abbott Diagnostics Division Sites.

UKAS MANAGEMENT SYSTEMS

001

CERTIFICATE OF REGISTRATION

Abbott Laboratories Diagnostic Division

Lake County Site
100 Abbott Park Road
Abbott Park, IL 60064 United States

UL LLC® (UL) issues this certificate to the Firm named above, after assessing the Firm's quality system and finding it in compliance with

ISO 13485:2016
EN ISO 13485:2016

The design, development, manufacture and finishing of In Vitro Diagnostic reagents, test kits and accessories.

With additional Sites located at:

K Complex
Rt. 41 & Martin Luther King Drive
North Chicago, IL 60064 United States

Long Grove Farm Site
6131 RFD Oakwood Road
Long Grove, IL 60047 United States

The Site at Rt. 41 & Martin Luther King Drive performs: QC inspection of incoming materials and products. The storage and distribution of in vitro diagnostic reagents, test kits and accessories.

The Site at 6131 RFD Oakwood Road performs: Antibody production.

File Number	A18075	Cycle Start Date	December 1, 2017
		Effective Date	December 1, 2017
Certificate No.	11957207.PDWS	Expiry Date	November 30, 2020

Authorized by

Michael J. Windler, P.E.
Manager of Global Regulatory Service
Distinguished Member of the Technical Staff
UL Life and Health Sciences
UL LLC

Validate Certificate:
here

This quality system registration is included in UL's Directory of Registered Firms and applies to the provision of goods and/or services as specified in the scope of registration from the address(es) shown above. By issuance of this certificate the firm represents that it will maintain its registration in accordance with the applicable requirements. This certificate is not transferable and remains the property of UL LLC.

UL LLC
333 Pfingsten Road
Northbrook, IL 60062-2096 USA

CERTIFICATE OF REGISTRATION

Abbott Laboratories Diagnostic Division

Lake County Site
100 Abbott Park Road
Abbott Park, IL 60064 United States

D-U-N-S ID No. 001307602

UL Medical Regulatory Services of UL LLC® (UL) issues this certificate to the Firm named above, after auditing the Firm's quality management system and finding it in conformance per the defined scope with respect to

ISO 13485:2016

with additional regulatory requirements listed on final page of this certificate.

Design, development and manufacture of diagnostic test kits and reagents.

The design and manufacture of in-vitro diagnostic medical devices, used in the screening of blood donor units for transmissible diseases. The design and manufacture of in-vitro diagnostic medical devices used in the diagnosis, management and detection of cancer, autoimmune status, cardiac markers, endocrine disorders, and for therapeutic drug monitoring.

With additional locations listed on Addendum 1 of 1

File Number	A18075	Cycle Start Date	December 1, 2017
Certificate No.	11957207.AZBA	Effective Date	December 1, 2017
		Expiry Date	November 30, 2020

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Authorized by

Michael J. Windler, P.E.
Manager of Global Regulatory Service
Distinguished Member of the Technical Staff
UL Medical and Regulatory Services
UL LLC

Validate Certificate:
here

This quality system registration is included in UL's Directory of Registered Firms and applies to the provision of goods and/or services as specified in the scope of registration from the address(es) shown above. By issuance of this certificate the firm represents that it will maintain its registration in accordance with the applicable requirements. This certificate is not transferable and remains the property of UL Medical and Regulatory Services of UL LLC. Certificates may be verified by visiting the Online Certifications Directory on UL.com.

UL Medical and Regulatory Services of UL LLC is an MDSAP Recognized Auditing Organization

UL LLC
333 Pfingsten Road
Northbrook, IL 60062-2096 USA

CERTIFICATE OF REGISTRATION

Abbott Laboratories Diagnostic Division

Lake County Site
100 Abbott Park Road
Abbott Park, IL 60064 United States

D-U-N-S ID No. 001307602

Addendum 1of 1

Off Site 1 located at:

K Complex
Rt. 41 & Martin Luther King Drive
North Chicago, IL 60064 United States

D-U-N-S ID No. 001307602

Performing: QC inspection of incoming materials and products. The storage and distribution of in vitro diagnostic reagents, test kits and accessories.

Manufacturing Site 1 located at:

Long Grove Farm Site
6131 RFD Oakwood Road
Long Grove, IL 60047 United States

D-U-N-S ID No. 001307602

Performing: Antibody production

File Number	A18075	Cycle Start Date	December 1, 2017
		Effective Date	December 1, 2017
Certificate No.	11957207.AZBA	Expiry Date	November 30, 2020

This quality system registration is included in UL's Directory of Registered Firms and applies to the provision of goods and/or services as specified in the scope of registration from the address(es) shown above. By issuance of this certificate the firm represents that it will maintain its registration in accordance with the applicable requirements. This certificate is not transferable and remains the property of UL Medical and Regulatory Services of UL LLC.

UL Medical and Regulatory Services of UL LLC is an MDSAP Recognized Auditing Organization

UL LLC
333 Pfingsten Road
Northbrook, IL 60062-2096 USA

CERTIFICATE OF REGISTRATION

Abbott Laboratories Diagnostic Division

Lake County Site
100 Abbott Park Road
Abbott Park, IL 60064 United States

D-U-N-S ID No. 001307602

Additional Regulatory Requirements

Australia:
- Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure [if design controls are part of the certification];

Brazil:
- RDC ANVISA n. 16/2013
- RDC ANVISA n. 23/2012
- RDC ANVISA n. 67/2009

Canada:
- Medical Devices Regulations – Part 1- SOR 98/282

Japan:
- MHLW Ministerial Ordinance 169, Article 4 to Article 68
- PMD Act (,as applicable)

United States:
- 21 CFR 820
- 21 CFR 803
- 21 CFR 806
- 21 CFR 807 – Subparts A to D

File Number	A18075	Cycle Start Date	December 1, 2017
		Effective Date	December 1, 2017
Certificate No.	11957207.AZBA	Expiry Date	November 30, 2020

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UL Medical and Regulatory Services of UL LLC is an MDSAP Recognized Auditing Organization

UL LLC
333 Pfingsten Road
Northbrook, IL 60062-2096 USA

Carbamazepine
Rubella IgM, IgG
Cyclosporine
BNP
CMV IgG Avidity
ProGRP
Syphilis TP
Troponin-I
Chagas
HE4
HCV Ag
NGAL
Tacrolimus
25-OH Vitamin D
Active B12
2nd Generation
Testosterone
High Sensitive
Troponin I
EBV

ARCHITECT

Immunoassay Menu 2014

Put science on your side.

Abbott
A Promise for Life

ARCHITECT *i*1000SR *i*2000 *i*2000SR *i*4000SR

List Number	Package Insert Revision	Kit Size Tests/Kit	Sample Material	Assay Technology	Time to First Result (minutes)*	Calibration Range	Sensitivity** (Analytical Sensitivity[1] or LOD[2] or LOQ[3])	Interpretation of Results	Automatic Dilution
HEPATITIS/RETROVIRUS									
Anti-HBc II									
8L44-25 8L44-35 8L44-30	G4-3190/R07	1 x 100 1 x 500 4 x 500	Serum, Plasma (E, H, C, L, O, ACD, CPDA-1, CPD), Cadaveric blood specimens	CMIA 2-step	29	qualitative	–	S/CO ≥ 1.0 = reactive	Not applicable
Anti-HBc IgM									
6C33-25 6C33-20	G4-5671/R07	1 x 100 4 x 100	Serum, Plasma (H, E, C, O, ACD, CPDA-1, CPD)	CMIA 2-step	29	qualitative	–	S/CO ≥ 1.0 = reactive	Not applicable
Anti-HBe									
6C34-25 6C34-20	G2-7631/R04	1 x 100 4 x 100	Serum, Plasma (H, E, C, O, ACD-B, CPDA-1, CPD)	CMIA 2-step, competitive	29	qualitative	–	S/CO ≤ 1.0 = reactive	Not applicable
Anti-HBs									
7C18-25 7C18-20 7C18-30	G2-6352/R09	1 x 100 4 x 100 4 x 500	Serum, Plasma (H, E, C, ACD, CPDA-1)	CMIA 2-step	29	0 – 1000 mIU/mL	–	≥ 10.0 mIU/mL = reactive	1:15 1:25
Anti-HCV									
6C37-27 6C37-22 6C37-32	G4-3043/R09	1 x 100 4 x 100 4 x 500	Serum, Plasma (H, L, E, C, O, ACD, CPDA-1, CPD, CP2D), Cadaveric blood specimens	CMIA 2-step	29	qualitative	–	S/CO ≥ 1.0 = reactive	Not applicable
HAVAb-IgG									
6C29-25 6C29-20	G3-0765/R02	1 x 100 4 x 100	Serum, Plasma (E, H, C, ACD, CPDA-1, CPD)	CMIA 2-step	29	qualitative	–	S/CO ≥ 1.0 = reactive	Not applicable
HAVAb-IgM									
6C30-25 6C30-20	G3-0838/R04	1 x 100 4 x 100	Serum, Plasma (H, E, C, ACD, CPDA-1, CPD)	CMIA 2-step	29	qualitative	–	S/CO >1.2 = reactive	Not applicable
HBeAg									
6C32-25 6C32-20	G3-0329/R06	1 x 100 4 x 100	Serum, Plasma (H, E, C, O, ACD-B, CPDA-1, CPD)	CMIA 2-step	29	qualitative	–	S/CO ≥ 1.0 = reactive	Not applicable
HBsAg									
6C36-41 6C36-42	G2-3418/R01	1 x 100 4 x 100	Serum, Plasma (H, L, E, C, O, ACD, CPDA-1, CPD, CP2D)	CMIA 2-step	29	0 – 250 IU/mL	0.15 – 0.29 ng/mL HBsAg ad/ay reference panel	≥ 0.05 IU/mL = reactive	1:500
HBsAg Qualitative II									
2G22-25 2G22-35 2G22-30	G3-4444/R05	1 x 100 1 x 500 4 x 500	Serum, Plasma (H, L, E, C, O/F, ACD, CPDA-1, CPD), Cadaveric blood specimens	CMIA modified 1-step	29	qualitative	–	S/CO ≥ 1.0 = reactive	Not applicable
HBsAg Qualitative II Confirmatory									
2G23-25	G4-3375/R03	50 test results	Serum, Plasma (H, L, E, C, O/F, ACD, CPDA-1, CPD), Cadaveric blood specimens	CMIA modified 1-step with pretreatment	36	–	–	Refer to instructions for use	Manual Dilution
HCV Ag[3,4]									
6L47-27	F5-Y206-2/R03	1 x 100	Serum, Plasma E, H, C, L, CPD	CMIA 2-step with pretreatment	36	0 – 20,000 fmol/L	≤ 3.0 fmol/L	< 3.0 fmol/L = non reactive ≥ 3.0 fmol/L = reactive ≥ 3.0 fmol/L < 10.0 fmol/L = grey zone	1:9
HIV Ag/Ab Combo									
4J27-27 4J27-22 4J27-32	G4-2947/R04	1 x 100 4 x 100 4 x 500	Serum, Plasma (E, H, C, L, O, ACD, CPDA-1, CPD), Cadaveric blood specimens	CMIA 2-step	29	qualitative	–	S/CO ≥ 1.0 = reactive	Not applicable
rHTLV I/II									
6L61-25 6L61-35 6L61-30	G4-3048/R05	1 x 100 4 x 100 4 x 500	Serum, Plasma (E, H, C, L, O, ACD, CPDA-1, CPD), Cadaveric blood specimens	CMIA 2-step with pretreatment	36	qualitative	–	S/CO ≥ 1.0 = reactive	Not applicable

*ci*4100 *ci*8200 *ci*16200 Immunoassay Menu

List Number	Package Insert Revision	Kit Size Tests/Kit	Sample Material	Assay Technology	Time to First Result (minutes)*	Calibration Range	Sensitivity** (Analytical Sensitivity[1] or LOD[2] or LOQ[3])	Interpretation of Results	Automatic Dilution
CONGENITALS AND OTHER INFECTIOUS DISEASES									
Chagas									
2P25-25 2P25-35	G4-2946/R04	1 x 100 1 x 500	Serum, Plasma (H, L, E, C, O, CPD, CPDA-1, APD), Cadaveric blood specimens	CMIA 2-step	29	qualitative	–	S/CO ≥ 1.0 = reactive	Not applicable
CMV IgG									
6C15-25 6C15-30	G3-4609/R07	1 x 100 1 x 500	Serum, Plasma (H, L, E, C, O, ACD, CPDA-1, CPD)	CMIA 2-step with predilution	36	0 – 250 AU/mL	–	≥ 6.0 AU/mL = reactive	1:10
CMV IgG Avidity									
3L46-25	G3-0041/R05	50 test results	Serum, Plasma (H, L, E, C)	CMIA 2-step with pretreatment	43	qualitative	–	≥ 60% Avi = high avidity	Not applicable
CMV IgM									
6C16-25 6C16-30	G2-6298/R02	1 x 100 1 x 500	Serum, Plasma (H, L, E, C)	CMIA 2-step with predilution	36	qualitative	–	Index ≥ 1.0 = reactive	Not applicable
EBV EBNA-1 IgG									
3P67-25 3P67-35	G3-3877/R1	1 x 100 1 x 500	Serum, Plasma (E, H, L, C)	CMIA 2-step	29	qualitative	–	S/CO ≥ 1.0 = reactive	Not applicable
EBV VCA IgG									
3P65-25 3P65-35	G3-3887/R1	1 x 100 1 x 500	Serum, Plasma (E, H, L, C)	CMIA 2-step	29	qualitative	–	S/CO ≥ 1.0 = reactive	Not applicable
EBV VCA IgM									
3P66-25 3P66-35	G3-3876/R1	1 x 100 1 x 500	Serum, Plasma (E, H, L, C)	CMIA 2-step	36	qualitative	–	S/CO ≥ 1.0 = reactive	Not applicable
Rubella IgG									
6C17-28 6C17-38	840627/R3	1 x 100 1 x 500	Serum, Plasma (H, L, E, C)	CMIA 2-step with predilution	36	0 – 500 IU/mL	–	≥ 10.0 IU/mL = positive	1:10
Rubella IgM									
6C18-25	34-8771/R3	1 x 100	Serum, Plasma (H, L, E, C)	CMIA 2-step with predilution	36	qualitative	–	Index ≥ 1.6 = reactive S/CO ≥ 1.0 = reactive	Not applicable
Syphilis TP									
8D06-28 8D06-38	G2-0439/R1	1 x 100 1 x 500	Serum, Plasma (H, E, CPD, C, L)	CMIA 2-step	29	qualitative	–	S/CO ≥ 1.0 = reactive	Not applicable
Toxo IgG									
6C19-25 6C19-35	G3-0569/R04	1 x 100 1 x 500	Serum, Plasma (H, L, E, C)	CMIA 2-step with predilution	36	0 – 200 IU/mL	–	≥ 3.0 IU/mL = reactive	1:10
Toxo IgG Avidity									
6L37-25	G3-0450/R05	50 test results	Serum, Plasma (H, L, E, C)	CMIA 2-step with pretreatment	43	qualitative	–	≥ 60.0% Avi = high avidity	Not applicable
Toxo IgM									
6C20-25 6C20-35	G3-0550/R02	1 x 100 1 x 500	Serum, Plasma (H, L, E)	CMIA 2-step with predilution	29	qualitative	–	Index ≥ 0.6 = reactive S/CO ≥1.0 = reactive	Not applicable

List Number	Package Insert Revision	Kit Size Tests/Kit	Sample Material	Assay Technology	Time to First Result (minutes)*	Calibration Range	Sensitivity** (Analytical Sensitivity[1] or LOD[2] or LOQ[3])	Expected Values**	Automatic Dilution
CARDIOLOGY									
BNP									
8K28-27 8K28-35	260-737 10/08 R2	1 x 100 1 x 500	Plasma (E)	CMIA 2-step	Routine: 29 STAT***: 18	0 – 5000 pg/mL 0 – 1444 pmol/L	≤ 10 pg/mL[1] ≤ 2.89 pmol/L[1]	< 100 pg/mL < 28.9 pmol/L (Suggested diagnostic threshold)	1:5
STAT* CK-MB **									
2K42-28 2K42-38	JL840740/R05 JL840825/R06	1 x 100 1 x 500	Serum, Plasma (H, L, E)	CMIA 2-step	STAT***: 18	0 – 300 ng/mL	≤ 0.1 ng/mL[1]	H, L: 4,7 ng/mL (99th percentile) E: 5.0 ng/mL (99th percentile) Serum: 4.0 ng/mL (99th percentile)	1:2
Galectin-3									
5P03-25	306-351 10/12	1 x 100	Serum, Plasma (E)	CMIA-2 step	Routine 29 STAT*** 18	0 – 114 ng/mL	1.0 ng/mL[2]	Apparently Healthy Population (97.5th percentile) 27.5 ng/mL	1:2

ARCHITECT *i*1000SR *i*2000 *i*2000SR *i*4000SR

List Number	Package Insert Revision	Kit Size Tests/Kit	Sample Material	Assay Technology	Time to First Result (minutes)*	Calibration Range	Sensitivity** (Analytical Sensitivity[1] or LOD[2] or LOQ[3])	Expected Values**	Automatic Dilution
Homocysteine									
1L71-25	ABBL268/R08	1 x 100	Serum, Plasma (L, E)	CMIA 1-step	Routine: 29	0 – 50 µmol/L 0 – 6.76 µg/mL	≤ 1.0 µmol/L[2] ≤ 0.14 µg/mL[2]	Male: ≤ 16.2 µmol/L Male: ≤ 2.19 µg/mL Female: ≤ 13.56 µmol/L Female: ≤ 1.83 µg/mL (97.5th percentile)	1:10
STAT* High sensitive Troponin-I **									
3P25-25 3P25-35	G4-5454/R03	1 x 100 1 x 500	Serum, Plasma (L, E)	CMIA 2-step	STAT***: 18	0 – 50,000 pg/mL	≤ 10 pg/mL[5]	Apparently Healthy Population (99th percentile) Female: 15.6 pg/mL Male: 34.2 pg/mL Overall: 26.2 pg/mL	1:10
STAT* Troponin-I **									
2K41-28 2K41-38	840653/R08	1 x 100 1 x 500	Serum, Plasma (H, E)	CMIA 2-step	STAT***: 18	0 – 50 ng/mL	≤ 0.01 ng/mL[1]	0.028 ng/mL (99th percentile) 0.032 ng/mL (10 % CV [Precision])	1:9
STAT* Myoglobin **									
2K43-25 2K43-20	840268/R4	1 x 100 4 x 100	Serum, Plasma (H, L, E)	CMIA 2-step	STAT***: 18	0 – 1200 ng/mL	≤ 1.0 ng/mL[1]	140.1 ng/mL (99th percentile)	1:10
RENAL									
NGAL									
1P37-25	G4-2989/R06	1 x 100	Urine	CMIA 2-step	Routine: 36	0 – 1500 ng/mL	≤ 0.7 – 1.0 ng/mL[2] ≤ 1.5 – 3.0 ng/mL[5]	131.7 ng/mL (95th percentile)	1:4
ANEMIA/METABOLIC									
Active B12									
3P24-25 3P24-35	ABBL331/R07	1 x 100 1 x 500	Serum	CMIA 2-step	29	0 – 128 pmol/L	1.9 pmol/L[2] 5.0 pmol/L[5]	25.1 – 165.0 pmol/L (95 %)	1:2
Anti CCP									
1P65-25 1P65-35	ABBL174/R2	1 x 100 1 x 500	Serum, Plasma (L, E)	CMIA 2-step with pretreatment	36	0 – 200 U/mL	≤ 0.11 U/mL[2]	≥ 5.0 U/mL = Positive < 5.0 U/mL = Negative	1:6
B12									
7K61-25 7K61-35	G3-0916/R08	1 x 100 1 x 500	Serum, Plasma (H, L, E)	CMIA 2-step with pretreatment	36	0 – 2000 pg/mL 0 – 1476 pmol/L	125 pg/mL[2, 5] 92 pmol/L[2, 5]	187 – 833 pg/mL 138 – 652 pmol/L	1:3
C-Peptide									
3L53-25	G2-7566/R05	1 x 100	Serum, Plasma (E, H, A, L, F), 24-h urine	CMIA 2-step	29	0 – 30 ng/mL 0 – 10,000 pmol/L	0.01 ng/mL[2] 3.33 pmol/L[2]	Serum: 5.19 ng/mL Serum: 1730 pmol/L 24-h urine: 116.28 ng/mL 24-h urine: 38760 pmol/L (97th percentile)	Serum: Manual dilution Urine: 1:10
Cortisol									
8D15-25 8D15-35	JL840685/R06	1 x 100 1 x 500	Serum, Plasma (H, L, E), direct urine	CMIA delayed 1-step	29	0 – 59.8 µg/dL 0 – 1650 nmol/L	0.4 µg/dL[2] 11.03 nmol/L[2]	Serum AM: 3.7 – 19.4 µg/dL Serum AM: 101.2 – 535.7 nmol/L Serum PM: 2.9 – 17.3 µg/dL Serum PM: 79.0 – 477.8 nmol/L Urine: 4.3 – 176.0 µg/24 h Urine: 11.8 – 485.6 nmol/24 h (95th percentile)	1:2
Ferritin									
7K59-25 7K59-35 7K59-30	G4-5568/R07	1 x 100 1 x 500 4 x 500	Serum, Plasma (L, E)	CMIA 2-step	29	0 – 1000 ng/mL	≤ 1 ng/mL[1]	Male: 21.81 – 274.66 ng/mL Female: 4.63 – 204.0 ng/mL (Central 95 % interval)	1:20
Folate									
1P74-25 1P74-35	G2-7444/R04	1 x 100 1 x 500	Serum, Plasma (L), Whole blood (E)	CMIA 2-step with pretreatment	43	0 – 20 ng/mL 0 – 45.3 nmol/L	0.5 ng/mL[2] 1.1 nmol/L[2] 1.5 ng/mL[5] 3.4 nmol/L[5]	Serum: 3.1 – 20.5 ng/mL 7.0 – 46.4 nmol/L RBC: 126.0 – 651.1 ng/mL 285.4 – 1474.7 nmol/L	1:2
HbA1c									
4P72-25 4P72-35	ABBL343/R05	1 x 100 1 x 500	Whole Blood (E, F, O)	CMIA 2-step with pretreatment	36	4.0 – 14.5 % HbA1c	–	4.0 – 5.6 % HbA1c 20 – 42 mmol/mol	Manual dilution
Insulin									
8K41-27	F5-Y302-2/R02	1 x 100	Serum, Plasma (H, E, F)	CMIA 1-step	29	0 – 300 µU/mL 0 – 2153 pmol/L	≤ 0.28 µU/mL[1] ≤ 2.01 pmol/L[1]	Not defined designed ≤ 1.0 µU/mL	1:2

*ci*4100 *ci*8200 *ci*16200 Immunoassay Menu

List Number	Package Insert Revision	Kit Size Tests/Kit	Sample Material	Assay Technology	Time to First Result (minutes)*	Calibration Range	Sensitivity** (Analytical Sensitivity[1] or LOD[2] or LOQ[3])	Expected Values**	Automatic Dilution
Intact PTH									
8K25-25 8K25-20	84-6434/R5	1 x 100 4 x 100	Serum, Plasma (H, L, E)	CMIA 2-step	Routine: 29 STAT***: 18	Routine: 0 – 3000 pg/mL Routine: 0 – 318 pmol/L STAT: 0 – 2500 pg/mL STAT: 0 – 265 pmol/L	Routine: 0.23 pg/mL[1] STAT: 0.31 pg/mL[1]	68.3 pg/mL 7.2 pmol/L (97.5th percentile)	Manual dilution
25-OH Vitamin D									
3L52-25 3L52-35	49-8941/R02	1 x 100 1 x 500	Serum, Plasma (H, L, E)	CMIA delayed 1-step with pretreatment	36	0 – 160 ng/mL 0 – 400 nmol/L	3.1 ng/mL[2] 7.8 nmol/L[2] 8.0 ng/mL[5] 20 nmol/L[5]	Observed: Summer: 15.7 – 60.3 ng/mL 39.3 – 150.7 nmol/L Winter: 8.8 – 46.3 ng/mL 22 – 115.7 nmol/L Sufficiency: > 30 – 40 ng/mL (97.5th percentile)	Manual dilution
TRANSPLANT									
Cyclosporine									
1L75-25	301-514 12/11	1 x 100	Whole blood (E)	CMIA 2-step with pretreatment	29	0 – 1500 ng/mL	4.7 ng/mL[2] Functional Sensitivity: 20.7 ng/mL	Individual patient ranges	Not applicable
Sirolimus									
1L76-25	290-514 12/11	1 x 100	Whole blood (E)	CMIA delayed 1-step with pretreatment	29	0 – 30 ng/mL	0.3 ng/mL[2] Functional Sensitivity: 0.7 ng/mL	Individual patient ranges	Not applicable
Tacrolimus									
1L77-25	300-349 12/11	1 x 100	Whole blood (E)	CMIA delayed 1-step with pretreatment	29	0 – 30 ng/mL	0.3 ng/mL[2] Functional Sensitivity: 0.8 ng/mL	Individual patient ranges	Not applicable
THERAPEUTIC DRUG MONITORING									
i*Carbamazepine									
1P36-25	G2-6210/R02	1 x 100	Serum, Plasma (L, E, H)	CMIA 1-step	STAT***: 18	0 – 20 µg/mL 0 – 84.6 µmol/L	0.13 µg/mL[2] 0.55 µmol/L[2] 0.3 µg/mL[5] 1.27 µmol/L[5]	4 – 12 µg/mL 16.9 – 50.8 µmol/L	Manual dilution
i*Digoxin									
1P32-25	48-1968/R3	1 x 100	Serum, Plasma (L, E, H)	CMIA 1-step	STAT***: 18	0 – 4 ng/mL 0 – 5.12 nmol/L	0.09 ng/mL[2] 0.11 nmol/L[2]	0.8 – 2.0 ng/mL 1.02 – 2.56 nmol/L	Manual dilution
i*Gentamicin									
1P31-25	G2-6097/R06	1 x 100	Serum, Plasma (L, E, H)	CMIA 1-step	STAT***: 18	0 – 10 µg/mL 0 – 20.9 µmol/L	0.05 µg/mL[2] 0.1 µmol/L[2] 0.2 µg/mL[5] 0.42 µmol/L[5]	5 – 10 µg/mL 10.5 – 20.9 µmol/L	Manual dilution
i*Phenobarbital									
1P33-25	F5-0204-2/R2	1 x 100	Serum, Plasma (L, E, H, O)	CMIA 1-step	STAT***: 18	0 – 80 µg/mL 0 – 344.8 µmol/L	0.34 µg/mL[2] 1.47 µmol/L[2]	15 – 40 µg/mL 64.7 – 172.4 µmol/L	Manual dilution
i*Phenytoin									
1P34-25	F5-0205-2/R3	1 x 100	Serum, Plasma (L, E, C, H, O)	CMIA 1-step	STAT***: 18	0 – 40 µg/mL 0 – 158.4 µmol/L	0.05 µg/mL[2] 0.2 µmol/L[2]	10 – 20 µg/mL 39.6 – 79.2 µmol/L	Manual dilution
i*Theophylline									
1P29-25	56-7932/R2	1 x 100	Serum, Plasma (L, E, C, F, H)	CMIA 1-step	STAT***: 18	0 – 40 µg/mL 0 – 222 µmol/L	0.05 µg/mL[2] 0.28 µmol/L[2]	10 – 20 µg/mL 55.5 – 111 µmol/L	Manual dilution
i*Valproic Acid									
1P35-25	F5-0207-2/R3	1 x 100	Serum, Plasma (L, E, H)	CMIA 1-step	STAT***: 18	0 – 150 µg/mL 0 – 1039.5 µmol/L	0.51 µg/mL[2] 3.53 µmol/L[2]	50 – 100 µg/mL 346.5 – 693 µmol/L	Manual dilution
i*Vancomycin									
1P30-27	G3-0864/R03	1 x 100	Serum, Plasma (L, E, C, F, H, O)	CMIA 1-step	STAT***: 18	0 – 100 µg/mL 0 – 69 µmol/L	0.42 µg/mL[2] 0.29 µmol/L[2] 2.45 µg/mL[5] 1.69 µmol/L[5]	Peak level: 20 – 40 µg/mL Peak level: 13.8 – 27.6 µmol/L Through level: 5 – 10 µg/mL Through level: 3.45 – 6.9 µmol/L	Manual dilution

ARCHITECT *i*1000SR *i*2000 *i*2000SR *i*4000SR

List Number	Package Insert Revision	Kit Size Tests/Kit	Sample Material	Assay Technology	Time to First Result (minutes)*	Calibration Range	Sensitivity** (Analytical Sensitivity[1] or LOD[2] or LOQ[3])	Expected Values**	Automatic Dilution
FERTILITY/PREGNANCY									
DHEA-S									
8K27-25 8K27-20	G2-6144/R06	1 x 100 4 x 100	Serum, Plasma (E, H, C)	CMIA 1-step	29	0 – 1500 µg/dL 0 – 40.7 µmol/L	≤ 3.0 µg/dL[1] ≤ 0.08 µmol/L[1]	Dependent upon application	Manual dilution
Estradiol									
7K72-25 7K72-20	G4-3058/R05	1 x 100 4 x 100	Serum, Plasma (L, E)	CMIA 1-step	29	0 – 1000 pg/mL 0 – 3.67 nmol/L	≤ 10 pg/mL[1] ≤ 0.037 nmol/L[1]	Dependent upon application	1:5
FSH									
7K75-25 7K75-20 7K75-30	G2-7883/R08	1 x 100 4 x 100 4 x 500	Serum, Plasma (H, L, E)	CMIA 2-step	29	0 – 150 mIU/mL	< 0.05 mIU/mL[1]	Dependent upon application	1:5
LH									
2P40-25 2P40-35	G3-0641/R04	1 x 100 1 x 500	Serum, Plasma (E, H)	CMIA 2-step	29	0 – 250 mIU/mL	0.03 mIU/mL[2]	Dependent upon application	1:4
Progesterone									
7K77-25 7K77-20	G2-7955/R05	1 x 100 4 x 100	Serum, Plasma (H, L, E)	CMIA 1-step	29	0 – 40 ng/mL 0 – 127 nmol/L	≤ 0.1 ng/mL[1] ≤ 0.32 nmol/L[1]	Dependent upon application	1:10
Prolactin									
7K76-25 7K76-20 7K75-30	G3-0273/R03	1 x 100 4 x 100 4 x 500	Serum, Plasma (H, L, E)	CMIA 2-step	29	0 – 200 ng/mL 0 – 4200 mIU/L	< 0.6 ng/mL[1] < 12.6 mIU/L[1]	Male: 3.46 – 19.4 ng/mL 72.7 – 407.4 mIU/mL Female: 5.18 – 26.53 ng/mL 108.8 – 557.1 mIU/L	1:10
SHBG									
8K26-25 8K26-20	G3-0703/R05	1 x 100 4 x 100	Serum, Plasma (H, L, A, E)	CMIA 2-step	29	0 – 250 nmol/L 0 – 23.8 µg/mL	≤ 0.1 nmol/L[1] ≤ 0.0095 µg/mL[1]	Male: 13.5 – 71.4 nmol/L 1.3 – 6.8 µg/mL Female: 19.8 – 155.2 nmol/L 1.9 – 14.7 µg/mL	1:5
Total β-hCG									
7K78-25 7K78-20 7K78-30	G3-0464/R05	1 x 100 4 x 100 4 x 500	Serum, Plasma (L, E, H)	CMIA 2-step	Routine: 29 STAT***: 18	0 – 15,000 mIU/mL	≤ 1.2 mIU/mL [1]	Non-pregnant women: < 5 mIU/mL Early pregnancy: 5 – 25 mIU/mL Pregnant women: > 25 mIU/mL	1:15
2nd Gen Testosterone									
2P13-25 2P13-20	ABBL311/R07	1 x 100 4 x 100	Serum, Plasma (H, E, L)	CMIA 1-step delayed	29	0 – 30 nmol/L 0 – 865.2 ng/dL	1.44 ng/mL[2] 0.05 nmol/L[2] 0.08 nmol/L[5] 2.3 ng/dL[5]	Dependent upon application	Dependent upon protocol
THYROID									
Anti-Tg									
2K46-25 2K46-20	840240/R4	1 x 100 4 x 100	Serum, Plasma (H, L, E)	CMIA 2-step	29	0 – 1000 IU/mL	≤ 1.0 IU/mL[2]	< 4.11 IU/mL	1:10
Anti-TPO									
2K47-25 2K47-20	840242/R2	1 x 100 4 x 100	Serum, Plasma (H, L, E)	CMIA 2-step with predilution	36	0 – 1000 IU/mL	≤ 1.0 IU/mL[1]	< 5.61 IU/mL	1:2
Free T3									
7K63-25 7K63-35 7K63-30	G4-5567/R06	1 x 100 1 x 500 4 x 500	Serum, Plasma (H, L, E)	CMIA 2-step	29	0 – 30 pg/mL 0 – 46.1 pmol/L	≤ 1.0 pg/mL[1] ≤ 1.54 pmol/L[1]	1.71 – 3.71 pg/mL 2.63 – 5.7 pmol/L	Not applicable
Free T4									
7K65-27 7K65-35 7K65-32	G2-3136/R01	1 x 100 1 x 500 4 x 500	Serum, Plasma (H, L, E)	CMIA 2-step	29	0 – 6 ng/dL 0 – 77.2 pmol/L	0.4 ng/dL[5] 5.15 pmol/L[5] 0.28 ng/mL[2] 3.6 pmol/L[2]	0.7 – 1.48 ng/dL 9.0 – 19.0 pmol/L	Not applicable
T3									
7K64-25 7K64-35 7K64-30	G2-7947/R05	1 x 100 1 x 500 4 x 500	Serum, Plasma (H, L, E)	CMIA 2-step	29	0 – 8 ng/mL 0 – 12.3 nmol/L	≤ 0.25 ng/mL[1] ≤ 0.38 nmol/L[1]	0.58 – 1.59 ng/mL 0.89 – 2.44 nmol/L	Manual dilution
T4									
7K66-25 7K66-35 7K66-30	G3-0051/R04	1 x 100 1 x 500 4 x 500	Serum, Plasma (H, L, E)	CMIA 2-step	29	0 – 24 µg/dL 0 – 308.9 nmol/L	≤ 1.0 µg/dL[1] ≤ 12.9 nmol/L[1]	4.87 – 11.72 µg/dL 62.7 – 150.8 nmol/L	Manual dilution

*ci*4100 *ci*8200 *ci*16200 Immunoassay Menu

List Number	Package Insert Revision	Kit Size Tests/Kit	Sample Material	Assay Technology	Time to First Result (minutes)*	Calibration Range	Sensitivity** (Analytical Sensitivity[1] or LOD[2] or LOQ[5])	Expected Values**	Automatic Dilution
TSH									
7K62-25 7K62-35 7K62-30	G4-5947/R05	1 x 100 1 x 500 4 x 500	Serum, Plasma (H, L, E)	CMIA 2-step	29	0 – 100 µIU/mL	≤ 0.0025 µIU/mL[1]	0.35 – 4.94 µIU/mL	1:5
T-Uptake									
2K48-25 2K48-20	840610/R4	1 x 100 4 x 100	Serum, Plasma (H, L, E)	CMIA 1-step	29	0 – 1.9 T-Uptake Units	Not applicable	0.69 – 1.41 T-Uptake units	Not applicable
TUMOR MARKER									
AFP									
3P36-25 3P36-20 3P36-30	G4-3210/R04	1 x 100 4 x 100 4 x 500	Serum, Plasma (E, H, L), Amniotic fluid	CMIA 2-step	29	0 – 2000 ng/mL 0 – 1660 IU/mL	0.04 ng/mL[2] 0.033 IU/mL[2] 0.5 mg/mL[5] 0.42 IU/mL[5]	Serum: 0.89 to 8.78 ng/mL 0.74 to 7.3 IU/mL (central 95% interval) Amniotic fluid: Depends on pregnancy week	Serum 1:10 Amniotic fluid 1:40
CA 15-3									
2K44-25 2K44-20 2K44-35	016-513 4/09	1 x 100 4 x 100 1 x 500	Serum, Plasma (E, H, L)	CMIA 2-step	29	0 – 800 U/mL	≤ 0.5 U/mL[1]	< 31.3 U/mL (99th precentile)	1:5
CA 19-9XR									
2K91-28 2K91-23 2K91-38	604-030 11/12	1 x 100 4 x 100 1 x 500	Serum, Plasma (E, H, L)	CMIA 2-step	29	0 – 1200 U/mL	< 2.0 U/mL[1]	< 37 U/mL (94.4th percentile)	1:10
CA 125 II									
2K45-28 2K45-23 2K45-38	500-040 9/11	1 x 100 4 x 100 1 x 500	Serum, Plasma (E, H, L)	CMIA 2-step	29	0 – 1000 U/mL	≤ 1.0 U/mL[1]	< 35 U/mL (94.4th percentile)	1:10
CEA									
7K68-27 7K68-22 7K68-32	G4-3208/R03	1 x 100 4 x 100 4 x 500	Serum, Plasma (E, H, L)	CMIA 2-step	29	0 – 500 ng/mL	< 0.5 ng/mL[1]	< 5 ng/mL (93.5th precentile)	1:10
CYFRA 21-1									
2P55-25	304-480 4/10	1 x 100	Serum, Plasma (E)	CMIA 2-step	29	0 – 100 ng/mL	≤ 0.09 ng/mL[2]	Healthy Subjects: ≤ 2.08 ng/mL	1:5
Free PSA									
7K71-25 7K71-20	G2-7497/R04	1 x 100 4 x 100	Serum	CMIA 2-step	29	0 – 30 ng/mL	< 0.008 ng/mL[1]	Not available	Not applicable
HE4									
2P54-25	305-488 12/11	1 x 100	Serum	CMIA 2-step	29	0 – 1500 pmol/L	≤ 15 pmol/L[2]	Premenopausal: < 70 pmol/L Postmenopausal: < 140 pmol/L	1:10
ProGRP									
1P45-27	F5-Y308-2/R04	1 x 100	Serum, Plasma (E, H, L)	CMIA 2-step	29	0 – 5000 pg/mL	≤ 3 pg/mL[2]	< 65 pg/mL	1:10
SCC									
8D18-27	F5-Y301-2/R03	1 x 100	Serum, Plasma (E, H)	CMIA 2-step	29	0 – 70 ng/mL	< 0.1 ng/mL[1]	≤ 1.5 ng/mL	Manual dilution
Total PSA									
7K70-25 7K70-20 7K70-30	G2-7463/R03	1 x 100 4 x 100 4 x 500	Serum	CMIA 2-step	29	0 – 100 ng/mL	< 0.008 ng/mL[1]	Age dependent reference ranges	1:10

Please refer to the latest version of the Package Insert, available on www.abbottdiagnostics.com, for the most up to date information.

* Abbott data on file ** Representative data; results in individual laboratories may vary from these data. *** available on ARCHITECT i-SR and ci systems

[1] Analytical Sensitivity [2] LOD (Limit of Detection) [3] HCV Ag availability depends on country regulatory/registration [4] not available on *i*1000SR [5] LOQ (Limit of Quantitation)

CMIA = Chemiluminescence Immunoassay

Plasma: **E** = EDTA, **A** = Ammonium Heparin, **H** = Sodium Heparin, **L** = Lithium Heparin, **C** = Citrate, **O** = Oxalate, **ACD** (-A, -B) = Acid Citrate Dextrose, **F** = Sodium Fluoride, **CPD** = Citrate Phosphate Dextrose, **CPDA-1** = Citrate Phosphate Dextrose Adenine, **S/CO** = Sample/cut-off

Committed to Continuous Menu Expansion

ARCHITECT Immunoassays in Development:

NSE

Thyroglobulin

Methotrexate

PIVKA

Brahms PCT

*i*1000SR

*i*2000SR

*i*4000SR

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*ci*4100

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DIAGNOSTICS

ARCHITECT *i*1000SR

Maximizing productivity for labs like yours

- Equivalent results across all ARCHITECT *i*Systems
- Testing handled with ease
- STATs prioritized fast

CHOOSE TRANSFORMATION

Advanced patented technology. Improved patient safety.

TRUE FAMILY COMMONALITY

- The ARCHITECT *i*1000SR exemplifies the design philosophy of the ARCHITECT family of analyzers
- Identical CHEMIFLEX technology, 100 test kit reagents, assay protocols and consumables
- Identical ARCHITECT software
- Identical ARCHITECT Universal Sample Carrier

The benefits: equivalent patient results across all ARCHITECT immunoassay instruments and a simple, consistent user experience

ARCHITECT *i*1000SR Reagent Carrier

ENHANCED SYSTEM AND ASSAY DYNAMICS

- CHEMIFLEX technology with flexible assay protocols provides excellent low-end sensitivity and expanded dynamic ranges
- New patented wash cup design and wash algorithm effectively control sample carryover (< 0.1 ppm tube to tube)
- Pressure differential technology enables detection of clots, bubbles and insufficient sample volume to reduce analytical error and improve patient safety

The benefits: certainty and confidence in the clinical results

INTEGRATION WITHOUT COMPROMISE

- Designed for integration with the *c*4000 chemistry analyzer ➔ *ci*4100
- Fast STATs: The ARCHITECT Robotic Sample Handler (RSH) provides "load on the fly" continuous access to both reagents and samples and allows the lab to prioritize tests through customizable priority bays

The benefits: handle the most urgent samples first without compromising your routine testing

ARCHITECT *c*4000
can be integrated with ARCHITECT *i*1000SR to consolidate clinical chemistry and immunoassay on a single platform.

ARCHITECT *c*4000

ARCHITECT *i*1000SR

ARCHITECT *ci*4100

Refer to the Operations Manual for operational precautions, limitations and hazards. Manuals can be found on www.abbottdiagnostics.com.

See where it will take you at AbbottDiagnostics.com/Transform

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Anexa 14. Analizator automat, cu chemoluminiscenta

Specificatia tehnica solicitata	Specificatia tehnica ofertata **Architect i1000 (ABBOTT/USA)**
Analizator automat, cu chemoluminiscență Cod 150300 Parametru Specificație Descriere- Analizator automat care utilizează tehnici imunologice care implică interacțiunea unui anticorp cu un antigen și hapten Tip sistem- complet automat Tip probă urină ser plasmă sînge integru Capacitate de lucru ≥ 60 probe/h Posibilitatea integrării într-un sistem informational centralizat (LIS) da Posibilitatea sincronizării cu un analizator de chemoluminiscență de o capacitate mai mare da Randoom acces da Metoda chemoluminiscență amplificată enzimatic Nr. Probe ≥ 60 probe la bord Reagenți ≥ 25 la bord Stabilitate reagent ≥ 28 zile Afișaj alfanumeric, color Printer da Cititor cod bare da Interfață PC bidirecțională Analizatorul va fi livrat cu reagenți comform listelor de reagent solicitați da Sistem de purificare și deionizare a apei cu productivitatea comform cerințelor analizatorului (să se indice prețul separate) Teste anti CPP -TSH FT4 T4 FT3 Free PSA PSA total CEA AFP CA 19-9 CA 125 CA 15-3 Prolactina Progesteronul FSH LH Estradiol	Analizor automat de imunologie care permite efectuarea tuturor etapelor de lucru complet automat folosind ca tehnologie de detectie chemiluminiscenta, utilizate pentru a detecta și/sau cuantifica reacții imunologice. Tehnologie chemiluminiscenta in unu si doi pasi (constituie un avantaj testele utilizand tehnologia in 2 pasi)- pentru reducerea interferentelor si a fenomenului hook effect cu rezultate corecte, care coreleaza cu clinica. Tip sistem- complet automat Tip probă urină, ser, plasmă, singe integru. Analizor automat cu viteza de lucru minim 100 teste/ora Tip probă urină ser plasmă sînge integral si urina Acces imediat pentru probele care au fost pipetate permitand utilizarea lor in alte departemente ale laboratorului Autonomie de functionare (fara reincarcare cu consumabile si evacuare reziduuri) min. 3 ore Acces in timpului lucrului la containerele pentru reziduuri.. Capacitate incarcare reactivi: 25 de pozitii cu racire; Capacitate de procesare simultana a cel putin 25 de tipuri diferite de teste, si de a mentine reactivii la o temperatura stabila (refrigerat). Capacitate incarcare probe la bord: 65 probe incluzand cel putin 35 pozitii STAT Afișaj alfanumeric, color Printer da Cititor cod bare da Interfață PC bidirecțională Analizatorul va fi livrat cu reagenți comform listelor de reagent solicitați da Sistem de purificare și deionizare a apei inclus Tehnologie de detectie chemiluminiscenta este metoda cea mai sensibila care permite cea mai buna specificitate pentru testele de imunologie, hormonale, cardiace. marker tumorali si infectiosi. Compania Abbott este lider Mondial in testarea virusologica prin metode imunologice, cu acoperire si expertiza globala in domeniile , cu cele mai inovatoare solutii de laborator. Design compact cu computer incorporat (monitor color+touchscreen), cititor de cod de bare intern si extern,imprimanta, UPS, manual de utilizare,

Cortizol Testosteron Alergeni specifici IgE Alergeni specifici IgG Anti- TG Ab Anti-TPO Ab Produse degradabile țesut osos (β cross lass au Pyrilink-D) Calcitonina Osteocalcina Hormonul paratiroid Hormoni reproductive (de indicat) Alergeni Limba de comunicare rom/rus Alimentarea 220 V, 50 Hz	instructiuni pentru operatori incluse in soft, cu posibilitate de accesare in orice moment Sistem de control al temperaturii separat pentru reactia imunologica si pentru reactivii de la bord. Tehnologie de spalare acelor pipetoare care optimizeaza timpii de lucru si inlatura contaminarea de la proba la proba ; fara varfuri de unica folosinta, cee ace inseamna numar minim de consumabile si deci costuri mai mici. Sistem cu Interfață PC bidirecțională si cu monitorizare permanenta cu posibilitate de configurari si interventii tehnice tip remote Sistemul sa permit monitorizarea eventualelor defectiuni. Meniu de teste anexat. Limba de comunicare rusa/engleza. Alimentarea 220 V, 50 Hz Certificat de la producător- anexate Manuale de operare anexate- in limba romana si in limba engleza si limba rusa Catalogul producătorului/prospecte/document e tehnice, pe suport hîrtie sau în format electronic- anexate

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CLINICAL CHEMISTRY

GENERAL CHEMISTRIES

Acid Phosphatase
Albumin BCG
Albumin BCP
Alkaline Phosphatase
ALT
ALT (activated)
Amylase
Amylase (pancreatic)
AST
AST (activated)
Bilirubin, Direct
Bilirubin, Total
Calcium
Cholesterol
CK
CO_2
Creatinine
Enzymatic Creatinine
Direct LDL
GGT
Glucose
HDL, Ultra
ICT Cl^- (Chloride)
ICT K^+ (Potassium)
ICT Na^+ (Sodium)
Iron
LDH (Lactate Dehydrogenase)
Lactic Acid
Lipase
Magnesium (Arsenazo)
Magnesium (Enzymatic)
Phosphorous
Total Protein
Triglyceride
UIBC
Urea Nitrogen
Uric Acid
Urine/CSF Protein

CARDIAC

CK-MB
Myoglobin

SPECIAL CHEMISTRIES

Ammonia
Bile Acids
Cholinesterase
Cholinesterase/Dibucaine
Copper
Cystatin C
D-Dimer
Fructosamine
HbA1c
HBDH

SPECIFIC PROTEINS

Alpha-1 Antitrypsin
Alpha-1 Glycoprotein
Apolipoprotein A1
Apolipoprotein B
ASO
Beta 2-Microglobulin
Ceruloplasmin
Complement C3
Complement C4
CRP Vario (High Sensitivity, Standard, Wide Range)
Ferritin
Haptoglobin
IgA
IgE
IgG
IgM
Lp(a)
Microalbumin
Prealbumin
RF
Transferrin
κ Light Chains
λ Light Chains

THERAPEUTIC DRUGS

Amikacin
Carbamazepine
Digitoxin
Digoxin
Gentamicin
Lithium
Phenobarbital
Phenytoin
Quinidine
Theophylline
Tobramycin
Valproic Acid
Vancomycin

DRUGS OF ABUSE/ TOXICOLOGY

Acetaminophen
Amphetamine/ Methamphetamine
Barbiturates
Benzodiazepines
Benzodiazepines Serum
Cannabinoids
Cocaine
Ecstasy
Ethanol
Methadone
Opiates
Phencyclidine (PCP)
Propoxyphene
Salicylate
Tricyclic Antidepressants

IMMUNOASSAY

CANCER

AFP
CA 125 II
CA 15-3
CA 19-9 (CA 19-9 XR)
CEA
CYFRA 21-1
HE-4
Pepsinogen I
Pepsinogen II
PIVKA-II
ProGRP
PSA, Free
PSA, Total
ROMA (HE4/CA125)
SCC

CARDIAC

BNP
CK-MB
Galectin-3
Homocysteine
Myoglobin
NT-proBNP
Troponin-I (high sensitive)

FERTILITY/PREGNANCY

DHEA-S
Estradiol
FSH
hCG (total beta-hCG)
LH
Progesterone
Prolactin
SHBG
Testosterone 2nd Generation

INFLAMMATORY DISORDERS

Procalcitonin (BRAHMS)

HEPATITIS

Anti-HAV IgG
Anti-HAV IgM
Anti-HBc
Anti-HBc IgM
Anti-HBe
HBeAg Qualitative/Quantitative
Anti-HBs
HBsAg Qualitative
HBsAg Qualitative Confirmatory
HBsAg Quantitative
Anti-HCV
HCVAg

RETROVIRUS

HIV Ag/Ab Combo
Anti-HTLV I/II

CONGENITALS

CMV IgG
CMV IgG Avidity
CMV IgM
Rubella IgG
Rubella IgM
Toxo IgG
Toxo IgG Avidity
Toxo IgM

OTHER INFECTIOUS DISEASE

Chagas
EBV EBNA-1 IgG
EBV VCA IgG
EBV VCA IgM
Syphilis TP

METABOLIC

Active-B12
Anti-CCP
B12
C-Peptide
Cortisol
Ferritin
Folate
HbA1c
Insulin
Intact PTH
Vitamin D

RENAL

NGAL

THERAPEUTIC DRUG MONITORING

Carbamazepine
Digoxin
Gentamicin
Methotrexate
Phenobarbital
Phenytoin
Theophylline
Valproic Acid
Vancomycin

THYROID

Anti-Tg
Anti-TPO
Free T3
Free T4
Total T3
Total T4
TSH
T-Uptake

TRANSPLANT

Cyclosporine
Sirolimus
Tacrolimus

ARCHITECT

ARCHITECT SYSTEM FAMILY

CONSISTENT USER EXPERIENCE

CLINICAL CHEMISTRY	IMMUNOASSAY	INTEGRATION
		
*c*16000	*i*4000SR	*ci*16200
		
*c*8000	*i*2000SR	*ci*8200
		
*c*4000	*i*1000SR	*ci*4100

INCREASING VOLUME

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Declaration of Conformity

Certificate Identification: 1L86
Legal Manufacturer's Name: Abbott Laboratories Diagnostics Division
Legal Manufacturer's Address: Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
01L86-01	56701	ARCHITECT i1000$_{SR}$ PROCESSING MODULE	**Self-declared**
01L86-40	56701	ARCHITECT i1000$_{SR}$ INTEGRATED MODULE	**Self-declared**

Authorized European Representative (Name and Address)	Abbott Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott 1921 Hurd Drive Irving, TX 75038 Department - Regulatory Affairs
Harmonized Standards	Listed in the Technical Documentation

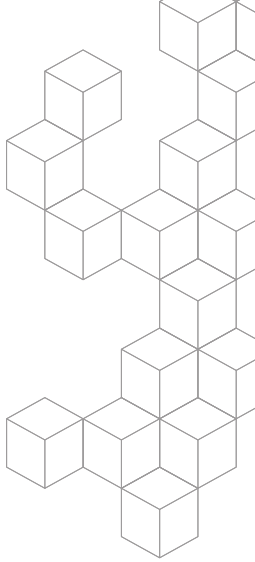
We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states, and Directive 2011/65/EU the restriction of the use of certain hazardous substances in electrical and electronic equipment(ROHS) .

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: Diana Romero
Full Name: Diana Romero
Position: Site Director, Quality Assurance
Date of Approval: 7-6-2016
Date Issued: 7-6-2016
Supersedes: March 28, 2016

Signature: Mark Littlefield
Full Name: Mark Littlefield
Position: Associate Director, Regulatory Affairs
Date of Approval: 7-6-2016
Place Issued: Abbott Laboratories, 1921 Hurd Drive, Irving, TX 75038
Effective (Date or Lot Number): 7-22-2016

DIAGNOSTICS



Clinical Chemistry, Immunoassay Traceability, Uncertainty of Measurement

Alinity ci-series / ARCHITECT *ci* System

Second Edition, June 2018

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TABLE OF CONTENTS

Welcome to the Abbott Calibrator Traceability and Uncertainty of Measurement document.

This document provides information about the metrological traceability of calibrators used by the Abbott Clinical Chemistry and Immunoassay tests and the uncertainty of measurement (MU), commonly known as uncertainty, for these methods. The uncertainty data have been calculated following the International Organization for Standardization (ISO) Guide to the Expression of Uncertainty in Measurement (GUM) and the Eurachem Guide for Quantitative Uncertainty in Analytical Measurement (Eurachem/CITAC Guide).[1,2]

The available reference materials and reference measurement procedures of the highest metrological order for each calibrator are listed. An internationally recognized reference material or procedure may not be available for some analytes. For other analytes, there may be two or more materials or procedures. Those materials and procedures listed in the database of the Joint Committee for Traceability in Laboratory Medicine (JCTLM) are preferentially used. For the large number of analytes lacking a reference material and/or procedure, manufacturers anchor assays by preparing calibrators using the materials and/or procedures considered most appropriate. Therefore, the actual target value of a calibrator may vary from lot to lot. The values given in this document represent target concentrations, and calibrator concentrations are given in both SI and conventional units, as appropriate.

The calibrator uncertainty estimates listed reflect typical values and may be used to calculate the total uncertainty of a test result. The total uncertainty depends on a variety of separate uncertainties, including those attributable to all absorbance readings; reagent, diluent and sample volumes; matrix effects; instrument drift; and intraindividual biological variation. As such, calibrator uncertainty is a small portion of a test result's total uncertainty. Total analytical uncertainty is driven by the assay system's analytical imprecision, including the assay and instrumentation. Additional sources include preanalytical and postanalytical uncertainties contributed by individual laboratories.

Analytical error is the difference between an observed sample value and the true value. In contrast, uncertainty is an estimate of the true value of a test result. According to metrological theory, the "true value" of a calibrator cannot be known, and only the range of values in which the true value lies can be estimated. Uncertainty is an estimate typically describing the 95 percent confidence limits for the true value of a specific calibrator. Uncertainty is not intended to describe a performance specification for a calibrator but is a statistical description of the likelihood the true value of the calibrator will be found in the cited range and within the stated confidence limits.

The Eurachem/CITAC Guide describes two methods for estimating uncertainty, commonly called the bottom-up and top-down approaches. The bottom-up method includes all possible sources of uncertainty identified and quantified in an uncertainty budget for a calibrator as it is manufactured. The uncertainties are statistically combined to produce the expanded total uncertainty. The top-down method estimates the uncertainty of measurement produced by an assay based on performance data. The calibrator uncertainties provided in this document are estimated primarily using the top-down approach.

This document will be updated with additional calibrator and uncertainty of measurement information as data become available.

References

1. ISO/BIPM Guide to the Expression of Uncertainty in Measurement (GUM), 2008. www.bipm.org/en/publications/guides/gum.html.
2. Ellison SLR, Williams A, eds. Eurachem/CITAC Guide: Quantifying Uncertainty in Analytical Measurement, 3rd edition, 2012. ISBN 978-0-948926-30-3. www.eurachem.org.

ASSAY NAME	ALINITY c / ARCHITECT c REAGENT LIST NUMBER	ALINITY c / ARCHITECT c CALIBRATOR LIST NUMBER – NAME	CONVENTIONAL UNITS (SI)	CALIBRATOR LEVEL	NOMINAL VALUE (SI)	UNCERTAINTY (SI) K = 2	REFERENCE MATERIAL (STANDARDIZATION)	REFERENCE METHOD
A-1-AGP Serum/Plasma	NA / 6L34	NA / 6K45 – Proteins Standard	mg/dL (g/L)	1 2 3 4 5	18 (0.18) 45 (0.45) 90 (0.90) 135 (1.35) 180 (1.80)	0.966 (0.010) 2.415 (0.024) 4.830 (0.048) 7.245 (0.072) 9.660 (0.097)	ERM-DA470/ IFCC	Immunoturbidi-metric
A1-AT Serum/Plasma	NA / 6K99	NA / 6K45 – Proteins Standard	mg/dL (g/L)	1 2 3 4 5	31 (0.31) 77.5 (0.78) 155 (1.55) 232.5 (2.33) 310 (3.10)	1.664 (0.017) 4.159 (0.042) 8.318 (0.083) 12.477 (0.125) 16.636 (0.166)	ERM-DA470/ IFCC	Immunoturbidi-metric
Albumin BCG Serum/Plasma	8P02 / 7D53	8P60 / 1E65 – Multiconstituent Calibrator	g/dL (g/L)	1 2	1.75 (17.5) 5.20 (52.0)	0.026 (0.258) 0.077 (0.767)	ERM-DA470	Visible spectrometry
Albumin BCP Serum/Plasma	8P03 / 7D54	8P60 / 1E65 – Multiconstituent Calibrator	g/dL (g/L)	1 2	1.75 (17.5) 5.20 (52.0)	0.030 (0.297) 0.088 (0.884)	ERM-DA470	Visible spectrometry
Amikacin Serum/Plasma	NA / 6L35	NA / 5P04 – TDM Multiconstituent Calibrator	µg/mL (µmol/L)	1 2 3 4 5 6	0.0 (0.00) 3.0 (5.20) 10.5 (17.89) 19.7 (33.62) 34.2 (58.4136) 48.7 (83.19)	† 0.091 (0.155) 0.312 (0.533) 0.586 (1.002) 1.018 (1.742) 1.450 (2.480)	USP grade Amikacin	Gravimetric
Ammonia Ultra Plasma	8P22 / 6K89	8P22 / 6K89 – Ammonia Ultra Calibrator	µg/dL (µmol/L)	1	500 (293.50)	10.000 (5.870)	Ultrapure Ammonium Sulphate	Gravimetric
Amphetamine/ Methamphetamine Urine	NA / 3L37	NA / 3L43 – DOA MC I Calibrators 1-4	ng/mL (µmol/L)	1 2 3 4	500 (3.35) 1000 (6.70) 1500 (10.05) 2000 (13.40)	33.333 (0.223) 66.667 (0.447) 100.000 (0.670) 133.33 (0.893)	≥99% pure Methampheta-mine stock standard	Volumetric
Apolipoprotein A1 Serum/Plasma	9P46 / 9D92	9P14 / 5P56 – Lipid Multiconstituent Calibrator	mg/dL (g/L)	1	145 (1.445)	3.166 (0.032)	WHO/IFCC/CDC Standard SP1-01	Radioimmunoassay
Apolipoprotein B Serum/Plasma	9P47 / 9D93	9P14 / 5P56 – Lipid Multiconstituent Calibrator	mg/dL (g/L)	1	117 (1.17)	3.401 (0.034)	WHO/IFCC/CDC Standard SP3-08	Immuno-nephelometry
ASO Serum	NA / 6K38	NA / 6K46 – ASO Standard	IU/mL (IU/mL)	1	300 (300.00)	20.000 (20.000)	WHO International Standard for ASO, NIBSC code: 97/662	Immunoturbidi-metric
B2-Microglobulin Serum/Plasma	NA / 6K39	NA / 6K47 – B2-Microglobulin Standard	mg/L (mg/L)	1	4.0 (4.00)	0.267 (0.267)	1st WHO International Standard for Beta-2 microgloblin, NIBSC code: B2M	Immunoturbidi-metric
Barbiturates Urine	NA / 3L38	NA / 3L43 – DOA MC I Calibrators 1-4	ng/mL (µmol/L)	1 2 3 4	100 (0.42) 200 (0.84) 500 (2.10) 1000 (4.20)	6.667 (0.028) 13.333 (0.056) 33.333 (0.140) 66.667 (0.280)	≥99% pure Secobarbital stock standard	Volumetric
Benzodiazepine Urine	NA / 3L39	NA / 3L43 – DOA MC I Calibrators 1-4	ng/mL (µmol/L)	1 2 3 4	100 (0.35) 200 (0.70) 500 (1.75) 1000 (3.50)	6.667 (0.023) 13.333 (0.047) 33.333 (0.117) 66.667 (0.233)	≥99% pure Oxazepam stock standard	Volumetric

†Uncertainty estimations are not calculated for 0-level calibrators.

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ASSAY NAME	ALINITY c / ARCHITECT c REAGENT LIST NUMBER	ALINITY c / ARCHITECT c CALIBRATOR LIST NUMBER – NAME	CONVENTIONAL UNITS (SI)	CALIBRATOR LEVEL	NOMINAL VALUE (SI)	UNCERTAINTY (SI) K = 2	REFERENCE MATERIAL (STANDARDIZATION)	REFERENCE METHOD
Bile Acids* Serum	NA / 6K90	NA / 6K90 – Bile Acids Calibrator	µmol/L (mmol/L)	1	39 (0.04)	1.744 (0.002)	Internal standard obtained from cholic acid derivatives	Nitrotetrazolium blue/NADH
Total Bile Acids* Serum/Plasma	8P57 / 3R04	8P57 / 3R04 – Total Bile Acids Calibrator	µmol/L (mmol/L)	1	50 (0.05)	3.040 (0.003)	Internal standard obtained from cholic acid derivatives	Enzymatic Cycling Colorimetric/thio-NADH
Bilirubin, Direct Serum/Plasma	7P97 / 8G63	8P61 / 1E66 – Bilirubin Calibrator	mg/dL (µmol/L)	1 2	0.8 (13.68) 8.2 (140.22)	0.018 (0.306) 0.183 (3.135)	Human Samples	Doumas
Bilirubin, Total Serum/Plasma	NA / 6L45	NA / 1E66 – Bilirubin Calibrator	mg/dL (µmol/L)	1 2	1.4 (23.94) 17.0 (290.70)	0.031 (0.535) 0.380 (6.500)	NIST SRM 916	Doumas
Bilirubin, Total Serum/Plasma	7P96 / NA	8P61 / NA – Bilirubin Calibrator	mg/dL (µmol/L)	1 2	1.4 (23.94) 17.0 (290.70)	0.038 (0.642) 0.456 (7.800)	NIST SRM 916	Doumas
Calcium Serum/Plasma/Urine	7P57 / 3L79	8P60 / 1E65 – Multiconstituent Calibrator	mg/dL (mmol/L)	1 2	8.3 (2.08) 12.0 (3.00)	0.111 (0.028) 0.161 (0.040)	NIST SRM 956	ID-ICP-MS
Cannabinoids Urine	NA / 3L41	NA / 3L43 – DOA MC Neg Cal NA / 3L41 – Cannabinoids Calibrators 20, 50, 100, 200	ng/mL (µmol/L)	1 2 3 4 5	0 (0.00) 20 (0.06) 50 (0.15) 100 (0.29) 200 (0.58)	† 1.333 (0.004) 3.333 (0.010) 6.667 (0.019) 13.333 (0.039)	≥99% pure 11-nor-Δ9-THC-9-carboxylic acid stock standard	Volumetric
Carbamazepine Serum/Plasma	NA / 5P05	NA / 5P04 – TDM Multiconstituent Calibrator	µg/mL (µmol/L)	1 2 3 4 5 6	0.00 (0.00) 1.69 (7.15) 3.45 (14.59) 7.12 (30.12) 11.16 (47.21) 18.37 (77.71)	† 0.035 (0.149) 0.072 (0.305) 0.149 (0.629) 0.233 (0.985) 0.383 (1.622)	USP grade Carbamazepine	Gravimetric
Carbon Dioxide Serum/Plasma	7P72 / 3L80	8P72 / 1E64 – Carbon Dioxide Calibrator	mEq/L (mmol/L)	1 2	22 (22) 43 (43)	0.667 (0.667) 1.333 (1.333)	NIST 351	Gravimetric
Ceruloplasmin Serum/Plasma	NA / 6K91	NA / 6K31 – Plasmaproteins Calibrator	mg/dL (g/L)	1	95.0 (0.95)	4.478 (0.045)	ERM-DA470	Immunoturbidimetric
Chloride Serum/Plasma	7P53 / 2P32	8P69 / 1E46 – ICT Serum Calibrator	mmol/L (mmol/L)	Low High	80.0 (80.0) 120.0 (120.0)	1.000 (1.000) 1.000 (1.000)	NIST SRM 2202	Silver Titration
Chloride Urine	7P53 / 2P32	8P70 / 1E47 – ICT Urine Calibrator	mmol/L (mmol/L)	Low High	50 (50) 180 (180)	1.333 (1.333) 1.333 (1.333)	NIST SRM 918 NIST SRM 919	Silver Titration
Cholesterol Serum/Plasma	7P76 / 7D62	8P60 / 1E65 – Multiconstituent Calibrator	mg/dL (mmol/L)	1 2	98 (2.54) 384 (9.95)	1.315 (0.034) 5.152 (0.133)	SPRL Total Cholesterol Verification Set	Abell-Kendall procedure (CDC reference method)
Cholinesterase* Serum/Plasma	9P94 / 6K24	8P65 / 6K30 – Clin Chem Calibrator	U/L (µkat/L)	1	5350 (89.18)	131.048 (2.185)	ε Hexacyanoferrate (III)	DGKC Butyrylthiocholine 37°C
CK-MB* Serum/Plasma	NA / 6K25	NA / 6K25 – CK-MB Calibrator	U/L (µkat/L)	1	110 (1.83)	3.01 (0.050)	ε NADP	IFCC (immunoinhibition)
Cocaine Urine	NA / 3L40	NA / 3L43 – DOA MC I Calibrators 1-4	ng/mL (µmol/L)	1 2 3 4	150 (0.53) 300 (1.05) 500 (1.75) 1000 (3.50)	10.000 (0.035) 20.000 (0.070) 33.333 (0.117) 66.667 (0.233)	≥99% pure Benzoylecgonine stock standard	Volumetric

*Assay not available in the United States.
†Uncertainty estimations are not calculated for 0-level calibrators.

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ASSAY NAME	ALINITY c / ARCHITECT c REAGENT LIST NUMBER	ALINITY c / ARCHITECT c CALIBRATOR LIST NUMBER – NAME	CONVENTIONAL UNITS (SI)	CALIBRATOR LEVEL	NOMINAL VALUE (SI)	UNCERTAINTY (SI) K = 2	REFERENCE MATERIAL (STANDARDIZATION)	REFERENCE METHOD
Complement C3 Serum/Plasma	9P56 / 9D96	8P62 / 1E78 – Specific Proteins Multiconstituent Calibrator	mg/dL (g/L)	1 2 3 4 5	53 (0.53) 105 (1.05) 175 (1.75) 245 (2.45) 350 (3.50)	0.755 (0.008) 1.495 (0.015) 2.492 (0.025) 3.489 (0.035) 4.984 (0.050)	ERM-DA470/ IFCC	Gravimetric
Complement C4 Serum/Plasma	9P57 / 9D97	8P62 / 1E78 – Specific Proteins Multiconstituent Calibrator	mg/dL (g/L)	1 2 3 4 5	9 (0.09) 18 (0.18) 30 (0.30) 42 (0.42) 65 (0.65)	0.148 (0.001) 0.296 (0.003) 0.493 (0.005) 0.690 (0.007) 1.068 (0.011)	ERM-DA470/ IFCC	Gravimetric
Copper* Serum/Plasma	NA / 6K93	NA / 6K93 – Copper Calibrator	µg/dL (µmol/L)	1	100 (15.73)	2.000 (0.315)	NIST SRM 3114	Gravimetric
Creatinine Serum/Plasma	7P99 / 3L81	8P60 / 1E65 – Multiconstituent Calibrator	mg/dL (µmol/L)	1 2	0.89 (78.23) 5.00 (442.00)	0.024 (2.10) 0.134 (11.86)	NIST SRM 967	ID-LC/MS§
Creatinine Urine	7P99 / 3L81	8P60 / 1E65 – Multiconstituent Calibrator	mg/dL (mmol/L)	1 2	1.40 (0.12) 5.40 (0.48)	0.038 (0.003) 0.145 (0.013)	NIST SRM 914	Gravimetric
Creatinine – Enzymatic Serum/Plasma/Urine	8P01 / 8L24	8P65 / 6K30 – Clin Chem Calibrator	mg/dL (µmol/L)	1	4.00 (353.60)	0.059 (5.197)	NIST SRM 967	IDMS
CRP Vario, Standard Method Serum/Plasma	NA / 6K26	NA / 6K26 – CRP Calibrator Set	mg/dL (mg/L)	1 2 3 4 5 6	0.5 (5.00) 1.0 (10.00) 2.0 (20.00) 4.0 (40.00) 16.0 (160.00) 32.0 (320.00)	0.017 (0.167) 0.020 (0.200) 0.040 (0.400) 0.080 (0.800) 0.320 (3.200) 0.640 (6.400)	ERM-DA472/ IFCC	Immunoturbidi-metric
CRP Vario, High Sensitivity Method Serum/Plasma	7P56 / 6K26	7P56 / 6K26 – CRP Calibrator HS and CRP Calibrator Set	mg/dL (mg/L)	1 2 3 4 5 6	0.25 (2.50) 0.5 (5.00) 1.0 (10.00) 2.0 (20.00) 8.0 (80.00) 16.0 (160.00)	0.008 (0.080) 0.017 (0.167) 0.020 (0.200) 0.040 (0.400) 0.160 (1.600) 0.320 (3.200)	ERM-DA472/ IFCC	Immunoturbidi-metric
CRP Vario, Wide Range Method Serum/Plasma	7P56 / 6K26	7P56 / 6K26 – CRP Calibrator Set and CRP Calibrator WR	mg/dL (mg/L)	1 2 3 4 5 6	0.5 (5.00) 1.0 (10.00) 2.0 (20.00) 4.0 (40.00) 16.0 (160.00) 48.0 (480.00)	0.017 (0.167) 0.020 (0.200) 0.040 (0.400) 0.080 (0.800) 0.320 (3.200) 0.960 (9.600)	ERM-DA472/ IFCC	Immunoturbidi-metric
Cystatin C* Serum/Plasma	NA / 1P93	NA / 1P93 – Cystatin C Calibrator	mg/L (mg/L)	1	8 (8.00)	0.231 (0.231)	ERM-DA 471/ IFCC	Nephelometric
D-Dimer* Plasma	NA / 7K02	NA / 7K02 – D-Dimer Standard	ng/mL (ng/mL)	1	1600 (1600.00)	106.67 (106.67)	In-house standard assigned following the recommendations of the Scientific and Standardization Committee of the International Society on Thrombosis and Haemostasis (SSC of the ISTH)	Immunoturbidi-metric
Dibucaine CHE Liquid* Serum/Plasma	NA / 6K92	NA / 6K30 – Clin Chem Calibrator	U/L (µkat/L)	1	1000 (16.67)	32.66 (0.544)	ε Hexacyanofer-rate (III)	DGKC Butyrylthio-choline Inhibition 37°C
Dibucaine CHE* Serum/Plasma	NA / 4S21	NA/6K30 - Clin Chem Calibrator	U/L (ukat/L)	1	1000 (16.67)	2.8 (0.0467)	ε Hexacyanofer-rate (III)	DGKC Butyrylthio-choline Inhibition 37°C

*Assay not available in the United States.
§Use IDMS-traceable MDRD equation with factor 175 to estimate GFR.

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Digitoxin* Serum	NA / 6K40	NA / 6K48 – Digitoxin Standard	ng/mL (nmol/L)	1 2 3 4 5 6	0 (0.00) 5 (6.55) 10 (13.10) 20 (26.20) 40 (52.40) 80 (104.80)	† 0.667 (0.873) 1.333 (1.747) 2.000 (2.620) 4.000 (5.240) 8.000 (10.480)	USP Digitoxin Reference Standards	Gravimetric
Digoxin Serum/Plasma	8P37 / 1E06	NA / 1E06 – Digoxin Calibrator	ng/mL (nmol/L)	1 2 3 4 5 6	0.0 (0.00) 0.5 (0.64) 1.0 (1.28) 2.0 (2.56) 3.0 (3.84) 5.0 (6.40)	† 0.067 (0.085) 0.100 (0.128) 0.133 (0.171) 0.200 (0.256) 0.200 (0.256)	USP grade Digoxin	Gravimetric
		8P74 / 5P04 – TDM Multiconstituent Calibrator	ng/mL (nmol/L)	1 2 3 4 5 6	0.0 (0.00) 0.5 (0.63) 0.9 (1.19) 1.9 (2.41) 2.9 (3.69) 4.7 (6.00)	† 0.012 (0.015) 0.022 (0.028) 0.028 (0.036) 0.043 (0.055) 0.070 (0.089)	USP grade Digoxin	Gravimetric
Ecstasy Urine	NA / 3L42	NA / 3L42 – Ecstasy Calibrators 250, 500, 750, 1000	ng/mL (µmol/L)	1 2 3 4	250 (1.30) 500 (2.60) 750 (3.90) 1000 (5.20)	16.667 (0.087) 33.333 (0.173) 50.000 (0.260) 66.667 (0.347)	≥99% pure 3,4-Methylene-dioxymetham-phetamine stock standard	Volumetric
Ethanol Serum/Plasma/Urine	8P41 / 3L36	8P41 / 3L36 – Ethanol Calibrator	mg/dL (mmol/L)	1 2	0 (0.00) 100 (21.70)	† 6.667 (1.447)	>99% pure Ethanol Standard	Volumetric
Ferritin Serum/Plasma	NA / 6K41	NA / 6K49 – Ferritin Standard	ng/mL (µg/L)	1 2 3 4	25 (25.00) 100 (100.00) 200 (200.00) 500 (500.00)	2.500 (2.500) 10.000 (10.000) 20.000 (20.000) 50.000 (50.000)	3rd WHO International Standard for Ferritin (recombinant), NIBSC code: 94/572	Immunoturbidi-metric
Fructosamine* Serum/Plasma	NA / 6K94	NA / 6K94 – Fructosamine Calibrator	µmol/L (µmol/L)	1	350 (350.00)	7.144 (7.144)	Glycated poly-L-lysine/14C-glucose	Gravimetric
Gentamicin Serum/Plasma	8P55 / 1E11	8P74 / 5P04 – TDM Multiconstituent Calibrator	µg/mL (µmol/L)	1 2 3 4 5 6	0.0 (0.00) 0.4 (0.88) 1.4 (2.84) 2.8 (5.77) 5.1 (10.55) 8.4 (17.62)	† 0.009 (0.018) 0.028 (0.059) 0.082 (0.172) 0.151 (0.315) 0.251 (0.525)	USP grade Gentamicin	Gravimetric
Glucose Serum/Plasma/ Urine/CSF	7P55 / 3L82	8P60 / 1E65 – Multiconstituent Calibrator	mg/dL (mmol/L)	1 2	100 (5.55) 447.5 (24.84)	2.683 (0.149) 12.008 (0.666)	NIST SRM 965	ID-GC/MS
Haptoglobin Serum/Plasma	9P59 / 9D91	8P62 / 1E78 – Specific Proteins Multiconstituent Calibrator	mg/dL (g/L)	1 2 3 4 5	41 (0.41) 83 (0.83) 138 (1.38) 193 (1.93) 275 (2.75)	0.898 (0.009) 1.818 (0.018) 3.023 (0.030) 4.228 (0.042) 6.025 (0.060)	ERM-DA470/ IFCC	Gravimetric
HbA1c Whole Blood/ Hemolysate	8P43 / 4P52	8P43 / 4P52 – HbA1c Calibrators	%NGSP (µmol/L-IFCC)	1 2	5.2 (33.32) 11.6 (103.28)	0.62% (0.350) 0.63% (0.798)	IFCC Monitoring Program Reference Sample	NGSP (HPLC) and IFCC (capillary electrophoresis)
HBDH Liquid* Serum/Plasma	1R01 / 6K23	8P65 / 6K30 – Clin Chem Calibrator	U/L (µkat/L)	1	250 (4.17)	6.124 (0.102)	ε NADH	DGKC 37°C

*Assay not available in the United States.
†Uncertainty estimations are not calculated for 0-level calibrators.

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HDL, Ultra Serum/Plasma	7P75 / 3K33	9P14 / 5P56 – Lipid Multiconstituent Calibrator	mg/dL (mmol/L)	1	60 (1.55)	1.073 (0.028)	Human Samples	CDC Abell-Kendall Reference Method; Cholesterol Reference Method Laboratory Network
Immunoglobulin A Serum/Plasma	9P61 / 9D98	8P62 / 1E78 – Specific Proteins Multiconstituent Calibrator	mg/dL (g/L)	1 2 3 4 5	105 (1.05) 210 (2.10) 350 (3.50) 490 (4.90) 700 (7.00)	1.572 (0.016) 3.144 (0.031) 5.240 (0.052) 7.336 (0.073) 10.480 (0.105)	ERM-DA470/ IFCC	Gravimetric
Immunoglobulin E Serum/Plasma	NA / 6K42	NA / 6K50 – IgE Standard	IU/mL (IU/mL)	1 2 3 4 5	50 (50.00) 100 (100.00) 200 (200.00) 500 (500.00) 1000 (1000.00)	3.333 (3.333) 6.667 (6.667) 13.333 (13.333) 33.333 (33.333) 67.667 (67.667)	2nd WHO International Reference Preparation for Human Serum Immunoglobulin E, NIBSC code: 75/502	Immunonephelo-metric
Immunoglobulin G Serum/Plasma	9P62 / 9D99	8P62 / 1E78 – Specific Proteins Multiconstituent Calibrator	mg/dL (g/L)	1 2 3 4 5	608 (6.08) 1215 (12.15) 2025 (20.25) 2835 (28.35) 4250 (42.50)	7.548 (0.075) 15.084 (0.151) 25.140 (0.251) 35.197 (0.352) 52.764 (0.528)	ERM-DA470/ IFCC	Gravimetric
Immunoglobulin M Serum/Plasma	9P63 / 1E01	8P62 / 1E78 – Specific Proteins Multiconstituent Calibrator	mg/dL (g/L)	1 2 3 4 5	50 (0.50) 99 (0.99) 165 (1.65) 231 (2.31) 330 (3.30)	0.803 (0.008) 1.591 (0.016) 2.651 (0.027) 3.711 (0.037) 5.302 (0.053)	ERM-DA470/ IFCC	Gravimetric
Iron Serum/Plasma	8P39 / 6K95	4U75 / 1E65 – Multiconstituent Calibrator	µg/dL (µmol/L)	1	100 (17.90)	2.236 (0.400)	NIST SRM 3126	Gravimetric
Kappa Light Chains* Serum/Plasma	NA / 6K96	NA / 6K31 – Plasmaproteins Calibrator	mg/dL (g/L)	1	635 (6.35)	12.221 (0.122)	ERM-DA470/ IFCC	Immunoturbidi-metric
Lactic Acid Plasma	NA / 9D89	8P60 / 1E65 – Multiconstituent Calibrator	mg/dL (mmol/L)	1	42.5 (4.72)	1.20 (0.13)	Reagent Grade Lactic Acid	Titration
	8P21 / 9P18			1 2	10.00 (1.11) 42.50 (4.72)	0.18 (0.02) 0.76 (0.08)		
Lambda Light Chains* Serum/Plasma	NA / 4P80	NA / 6K31 – Plasmaproteins Calibrator	mg/dL (g/L)	1	382 (3.82)	7.352 (0.074)	ERM-DA470/ IFCC	Immunoturbidi-metric
LDL, Direct Serum/Plasma	7P71 / 1E31	9P14 / 5P56 – Lipid Multiconstituent Calibrator	mg/dL (mmol/L)	1	127.5 (3.30)	2.281 (0.059)	Human Samples	CDC Abell-Kendall Reference Method; Cholesterol Reference Method Laboratory Network
Lipase Serum/Plasma	NA / 7D80	NA / 3E16 – Lipase Calibrator	U/L (U/L)	1	240.5 (240.5)	4.033 (4.033)	Purified Human Pancreatic Lipase (>900 U/L activity)	Gravimetric
Lithium Serum/Plasma	8P53 / 8L25	8P65 / 6K30 – Clin Chem Calibrator	mmol/L (mmol/L)	1	1.500 (1.500)	0.031 (0.031)	NIST SRM 956	Colorimetric

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Lp(a) Serum/Plasma	NA / 7K00	NA / 7K00 – Lp(a) Standard	mg/dL (mg/dL)	1 2 3 4 5	6 (6.00) 12 (12.00) 27 (27.00) 57 (57.00) 95 (95.00)	0.509 (0.509) 1.018 (1.018) 2.291 (2.291) 4.837 (4.837) 8.061 (8.061)	Internal Reference Material for Lipoprotein(a)	ELISA
		NA / 5P83 – Lp(a) Calibrators	mg/dL (mg/dL)	1 2 3 4 5	8.5 (8.5) 18.0 (18.0) 35.0 (35.0) 67.5 (67.5) 91.0 (91.0)	0.186 (0.186) 0.394 (0.394) 0.767 (0.767) 1.479 (1.479) 1.994 (1.994)	Internal Reference Material for Lipoprotein(a)	ELISA
Magnesium Serum/Plasma/Urine	NA / 7D70	NA / 1E69 – Iron/Magnesium Calibrator	mEq/L (mmol/L)	1 2	0.85 (0.43) 3.40 (1.70)	0.016 (0.008) 0.065 (0.032)	NIST SRM 956	ID-ICP-MS
Magnesium* Serum/Plasma/Urine	8P19 / 3P68	8P60 / 1E65 – Multiconstituent Calibrator	mg/dL (mmol/L)	1 2	1.20 (0.49) 4.70 (1.93)	0.032 (0.013) 0.126 (0.052)	NIST SRM 956	ID-ICP/MS
Methadone Urine	NA / 3L35	NA / 3L43 – DOA MC I Calibrators 1-4	ng/mL (µmol/L)	1 2 3 4	150 (0.48) 300 (0.96) 500 (1.60) 1000 (3.20)	10.000 (0.032) 20.000 (0.064) 33.333 (0.107) 66.667 (0.213)	≥99% pure Methadone stock standard	Volumetric
Microalbumin Urine	8P04 / 2K98	8P04 / 2K98 – Microalbumin Calibrator	µg/mL (mg/L)	1 2 3 4 5	5 (5.00) 25 (25.00) 100 (100.00) 300 (300.00) 500 (500.00)	0.333 (0.333) 1.000 (1.000) 3.333 (3.333) 8.000 (8.000) 10.000 (10.000)	ERM-DA470/ IFCC	Immunoturbidi-metric
Myoglobin* Serum/Plasma	NA / 6L32	NA / 6L33 – Myoglobin Standard	ng/mL (ng/mL)	1 2 3 4 5	0.0 (0.00) 62.5 (62.50) 125 (125.00) 250 (250.00) 500 (500.00)	† 4.167 (4.167) 8.333 (8.333) 16.667 (16.667) 33.333 (33.333)	In-house standard	Immunoturbidi-metric
Opiates Urine For Opi2Q and Opi6SQ applications	NA / 3L34	NA / 3L34 – Opiate Calibrators 150, 300, 500, 1000	ng/mL (µmol/L)	1 2 3 4	150 (0.53) 300 (1.05) 500 (1.75) 1000 (3.50)	10.000 (0.035) 20.000 (0.070) 33.333 (0.117) 66.667 (0.233)	≥99% pure Morphine stock standard	Volumetric
Opiates Urine For Opi3Q and Opi1SQ applications	NA / 3L34	NA / 3L43 – DOA MC I Calibrators 1-4	ng/mL (µmol/L)	1 2 3 4	1000 (3.50) 2000 (7.00) 4000 (14.00) 6000 (21.00)	66.667 (0.233) 133.333 (0.467) 266.667 (0.933) 400.00 (1.400)	≥99% pure Morphine stock standard	Volumetric
Pancreatic Amylase* Serum/Plasma	1R04 / 6K22	8P65 / 6K30 – Clin Chem Calibrator	U/L (µkat/L)	1	170 (2.83)	4.164 (0.069)	ε p-Nitrophenol	IFCC Liquid EPS 37°C
Phencyclidine Urine	NA / 6L96	NA / 3L43 – DOA MC I Calibrators 1-4	ng/mL (µmol/L)	1 2 3 4	12.5 (0.05) 25 (0.10) 50 (0.21) 100 (0.41)	1.000 (0.004) 1.667 (0.007) 3.333 (0.014) 6.667 (0.027)	≥99% pure Phencyclidine stock standard	Volumetric
Phenobarbital Serum/Plasma	NA / 5P07	NA / 5P04 – TDM Multiconstituent Calibrator	µg/mL (µmol/L)	1 2 3 4 5 6	0.00 (0.00) 4.75 (20.47) 10.01 (43.14) 19.54 (84.22) 39.65 (170.89) 77.50 (334.03)	† 0.099 (0.427) 0.209 (0.900) 0.408 (1.758) 0.827 (3.567) 1.617 (6.971)	USP grade Phenobarbital	Gravimetric

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Phenytoin Serum/Plasma	8P54 / 5P08	8P74 / 5P04 – TDM Multiconstituent Calibrator	µg/mL (µmol/L)	1 2 3 4 5 6	0.00 (0.00) 2.45 (9.70) 4.83 (19.13) 9.71 (38.45) 19.88 (78.72) 39.07 (154.72)	† 0.058 (0.231) 0.115 (0.456) 0.232 (0.917) 0.474 (1.878) 0.932 (3.690)	USP grade Phenytoin	Gravimetric
Phosphorus Serum/Plasma/Urine	8P40 / 7D71	8P60 / 1E65 – Multiconstituent Calibrator	mg/dL (mmol/L)	1 2	3.90 (1.26) 7.85 (2.54)	0.080 (0.026) 0.161 (0.052)	NIST SRM 2186-I	Gravimetric
Potassium Serum/Plasma	7P53 / 2P32	8P69 / 1E46 – ICT Serum Calibrator	mmol/L (mmol/L)	Low High	3.40 (3.40) 8.0 (8.0)	0.033 (0.033) 0.050 (0.050)	NIST SRM	Flame Photometry
Potassium Urine	7P53 / 2P32	8P70 / 1E47 – ICT Urine Calibrator	mmol/L (mmol/L)	Low High	9.0 (9.0) 90 (90)	0.133 (0.133) 1.333 (1.333)	NIST SRM 918 NIST SRM 919	Flame Photometry
Prealbumin Serum	9P86 / 1E02	4S01 / 6E57 – Prealbumin Calibrator	mg/dL (g/L)	1 2 3 4 5	5.0 (0.05) 15.0 (0.15) 30.0 (0.30) 45.0 (0.45) 60.0 (0.60)	0.100 (0.001) 0.301 (0.003) 0.602 (0.006) 0.904 (0.009) 1.205 (0.012)	ERM-DA470/ IFCC	Immunoturbidi-metric
Propoxyphene Urine	NA / 6L97	NA / 3L43 – DOA MC I Calibrators 1-4	ng/mL (µmol/L)	1 2 3 4	150 (0.44) 300 (0.88) 500 (1.47) 1000 (2.95)	10.000 (0.029) 20.000 (0.059) 33.333 (0.098) 66.667 (0.196)	≥99% pure Propoxyphene stock standard	Volumetric
Protein, Total Serum/Plasma	7P52 / 7D73	8P60 / 1E65 – Multiconstituent Calibrator	g/dL (g/L)	1 2	3.95 (39.50) 7.00 (70.00)	0.053 (0.530) 0.094 (0.939)	NIST SRM 927	Biuret
Quinidine Serum/Plasma	NA / 6L31	NA / 5P04 – TDM Multiconstituent Calibrator	µg/mL (µmol/L)	1 2 3 4 5 6	0.0 (0.00) 0.5 (1.51) 0.9 (2.71) 1.9 (5.73) 3.5 (10.84) 7.4 (22.70)	† 0.015 (0.045) 0.026 (0.081) 0.055 (0.171) 0.105 (0.323) 0.220 (0.677)	USP grade Quinidine	Gravimetric
RF* Serum	NA / 6K44	NA / 6K52 – RF Standard	IU/mL (IU/mL)	1	200 (200.00)	13.333 (13.333)	WHO Rheumatoid Arthritis Serum, NIBSC, 2010, W 1066	Immunoturbidi-metric
Rheumatoid Factor Serum	NA / 8G66	NA / 8G67 – Rheumatoid Factor Calibrator	IU/mL (IU/mL)	1 2 3 4 5	10 (10.00) 20 (20.00) 40 (40.00) 120 (120.00) 200 (200.00)	0.533 (0.533) 1.067 (1.067) 1.867 (1.867) 2.400 (2.400) 4.000 (4.000)	WHO International Standard Prepara-tion of Rheumatoid Arthritis Serum, NIBSC code: 64/2	Immunoturbidi-metric
Salicylate Serum/Plasma	8P59 / 3K01	8P59 / 3K01 – Salicylate Calibrator	mg/dL (mmol/L)	1	20.7 (1.50)	0.207 (0.015)	USP grade Salicylate	Manual Trinder Absorbance
Serum Benzodiazepines Serum/Plasma	NA / 6L30	NA / 6L36 – Tox Calibrators 1-3	ng/mL (µmol/L)	1 2 3	25 (0.09) 50 (0.18) 100 (0.35)	1.667 (0.006) 3.333 (0.012) 6.667 (0.023)	≥99% pure Diazepam in-house standard	Volumetric
Sodium Serum/Plasma	7P53 / 2P32	8P69 / 1E46 – ICT Serum Calibrator	mmol/L (mmol/L)	Low High	120.0 (120.0) 160.0 (160.0)	1.000 (1.000) 1.000 (1.000)	NIST SRM	Flame Photometry
Sodium Urine	7P53 / 2P32	8P70 / 1E47 – ICT Urine Calibrator	mmol/L (mmol/L)	Low High	50 (50) 180 (180)	1.333 (1.333) 1.333 (1.333)	NIST SRM 918 NIST SRM 919	Flame Photometry

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Theophylline Serum/Plasma	NA / 5P06	NA / 5P04 – TDM Multiconstituent Calibrator	µg/mL (µmol/L)	1 2 3 4 5 6	0.00 (0.00) 2.58 (14.32) 5.14 (28.53) 10.21 (56.67) 20.65 (114.61) 39.28 (218.00)	† 0.062 (0.342) 0.123 (0.680) 0.244 (1.352) 0.493 (2.734) 0.937 (5.200)	USP grade Theophylline	Gravimetric
Tobramycin Serum/Plasma	NA / 7F93	NA / 7F93 – Tobramycin Calibrator	µg/mL (µmol/L)	1 2 3 4 5 6	0.0 (0.00) 0.5 (1.07) 1.5 (3.21) 3.0 (6.42) 6.0 (12.84) 10.0 (21.40)	† 0.017 (0.036) 0.050 (0.107) 0.100 (0.214) 0.200 (0.428) 0.333 (0.713)	USP grade Tobramycin	Gravimetric
Transferrin Serum/Plasma	8P38 / 1E04	8P62 / 1E78 – Specific Proteins Multiconstituent Calibrator	mg/dL (g/L)	1 2 3 4 5	86 (0.86) 171 (1.71) 285 (2.85) 399 (3.99) 530 (5.30)	1.570 (0.016) 3.122 (0.031) 5.203 (0.052) 7.285 (0.073) 9.676 (0.097)	ERM-DA470/ IFCC	Gravimetric
Tricyclic Antidepressants Serum/Plasma	NA / 6L28	NA / 6L36 – Tox Calibrators 1-3	ng/mL (nmol/L)	1 2 3	150 (570.00) 300 (1140.00) 500 (1900.00)	10.000 (38.000) 20.000 (76.000) 33.333 (126.667)	≥99% pure Nortriptyline in-house standard	Volumetric
Triglyceride Serum/Plasma	7P77 / 7D74	8P60 / 1E65 – Multiconstituent Calibrator	mg/dL (mmol/L)	1 2	93 (1.05) 470 (5.31)	2.080 (0.023) 10.510 (0.119)	ACS Grade Glycerol	Gas Chromatography
UIBC Serum/Plasma	NA / 4P79	NA / 4P79 - UIBC Calibrator	µg/dL (µmol/L)	1	500 (89.50)	10.000 (1.790)	NIST SRM 3126	Gravimetric
UIBC Serum/Plasma	8P44 / 4R29	8P44 / 4R29 – UIBC Calibrator	µg/dL (µmol/L)	1	500 (89.50)	0.13 (0.023)	NIST SRM 3126	Gravimetric
Urea Nitrogen‖ Serum/Plasma/Urine	8P16 / 7D75	8P60 / 1E65 – Multiconstituent Calibrator	mg/dL (mmol/L)	1 2	18 (6.43) 56 (19.99)	0.362 (0.129) 1.127 (0.402)	NIST SRM 912	Differential Scanning Calorimetry
Uric Acid Serum/Plasma/Urine	8P56 / 3P39	8P60 / 1E65 – Multiconstituent Calibrator	mg/dL (mmol/L)	1 2	4.05 (0.24) 9.00 (0.53)	0.105 (0.006) 0.233 (0.014)	NIST SRM 913	Gravimetric
Urine/CSF Protein Urine/CSF	7P59 / 7D79	8P71 / 1E71 – Urine/CSF Protein Calibrator	mg/dL (mg/L)	1 2 3 4 5	10 (100) 20 (200) 40 (400) 80 (800) 200 (2000)	1.333 (13.333) 1.333 (13.333) 1.333 (13.333) 2.667 (26.667) 6.667 (66.667)	NIST SRM 927	Biuret
Valproic Acid Serum/Plasma	NA / 1E13	NA / 5P04 – TDM Multiconstituent Calibrator	µg/mL (µmol/L)	1 2 3 4 5 6	0.0 (0.00) 12.2 (84.27) 25.3 (175.05) 50.5 (349.90) 100.9 (699.38) 135.7 (940.68)	† 0.181 (1.256) 0.377 (2.610) 0.753 (5.216) 1.504 (10.426) 2.023 (14.023)	USP grade Valproic Acid	Gravimetric
Vancomycin Serum/Plasma	8P52 / 6E44	8P74 / 5P04 – TDM Multiconstituent Calibrator	µg/mL (µmol/L)	1 2 3 4 5 6	0.0 (0.00) 5.0 (3.44) 10.0 (6.87) 25.2 (17.35) 48.4 (33.41) 107.4 (74.10)	† 0.148 (0.102) 0.297 (0.205) 0.750 (0.517) 1.444 (0.996) 3.202 (2.209)	USP grade Vancomycin	Gravimetric

*Assay not available in the United States.

†Uncertainty estimations are not calculated for 0-level calibrators.

‖7D75 Urea Nitrogen assay reports concentrations of urea nitrogen (mg/dl) in conventional units and concentrations of urea (mmol/L) in SI units.

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Clinical Chemistry Traceability for the Enzyme Assays Using Calibration Factors

ASSAY NAME	ALINITY c / ARCHITECT c REAGENT LIST NUMBER	ASSAY SHORT NAME	METHODOLOGY	REFERENCE METHOD	TRACEABILITY
Acid Phosphatase Serum	NA / 9D87	ACP	Alpha-naphthylphosphate	Original Procedure, Hillman G. (1971)[1]	Molar extinction factor
Alanine Aminotransferase Serum/Plasma	7P98 / 7D56	ALT	NADH without pyridoxal phosphate	NADH molar extinction factor	Molar extinction factor
Alanine Aminotransferase Activated Serum/Plasma	8P18 / 8L92	A-ALT	NADH with pyridoxal phosphate	IFCC Reference Procedure (2002)[2]	IFCC
Alkaline Phosphatase Serum/Plasma	8P20 / 7D55	AlkP	para-Nitrophenyl-phosphate	IFCC Reference Procedure (2011)[3]	IFCC
				p-nitrophenol molar extinction factor	Molar extinction factor
Amylase Serum/Plasma	7P58 / 7D58	Amy	2-chloro-4-nitrophenyl-α-D-maltotrioside	IFCC Reference Procedure (2006)[4]	IFCC
				2-chloro-4-nitrophenol molar extinction factor	Molar extinction factor
Aspartate Aminotransferase Serum/Plasma	8P17 / 7D81	AST	NADH without pyridoxal phosphate	NADH molar extinction factor	Molar extinction factor
Aspartate Aminotransferase Activated Serum/Plasma	8P23 / 8L91	A-AST	NADH with pyridoxal phosphate	IFCC Reference Procedure (2002)[5]	IFCC
Creatine Kinase Serum/Plasma	8P42 / 7D63	CK	NADPH	IFCC Reference Procedure (2002)[6]	IFCC
Gamma-glutamyl Transferase Serum/Plasma	7P73 / 7D65	GGT	L-Gamma-glutamyl-3-carboxy-4-nitroanilide	IFCC Reference Procedure (2002)[7]	IFCC
				3-carboxy-4-nitroalanine molar extinction factor	Molar extinction factor
Lactate Dehydrogenase Serum/Plasma	7P74 / 2P56	LDH	Lactate to Pyruvate	IFCC Reference Procedure (2002)[8]	IFCC

1. Hillman G. Continuous. Photometric Measurement of Prostate Acid Phosphatase Activity. *Z Klin Chem. Klin Biochem.* 1971; 9:273-4.
2. Schumann G, Bonora R, Ceriotti F, et al. IFCC primary reference procedures for the measurement of catalytic activity concentrations of enzymes at 37 degrees C. International Federation of Clinical Chemistry and Laboratory Medicine. Part 4. Reference procedure for the measurement of catalytic concentration of alanine aminotransferase. *Clin Chem Lab Med.* 2002; 40(7):718-24.
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8. Schumann G, Bonora R, Ceriotti F, et al. IFCC primary reference procedures for the measurement of catalytic activity concentrations of enzymes at 37 degrees C. International Federation of Clinical Chemistry and Laboratory Medicine. Part 3. Reference procedure for the measurement of catalytic concentration of lactate dehydrogenase. *Clin Chem Lab Med.* 2002; 40(6):643-8.

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Active B12 (Holotranscobalamin) Serum	NA / 3P24	NA / 3P24	pmol/L	A B C D E F	0.0 8.0 16.0 32.0 64.0 128.0	† 0.081 0.162 0.27 0.67 1.46	Internal Reference Standard (Recombinant human holotranscobalamin [rHTC])‡
AFP Serum/Plasma/ Amniotic Fluid	7P90 / 3P36	7P90 / 3P36	ng/mL	A B C D E F	0 15 45 300 1500 2000	† 0.06 0.18 1.23 8.54 10.96	WHO 1st International Standard 72/225
Anti-CCP Serum/Plasma	9P27 / 1P65	9P27 / 1P65	U/mL	A B C D E F	0.0 5.0 25.0 50.0 100.0 200.0	† 0.04 0.17 0.71 1.42 2.57	Internal Reference Standard (Positive Human Plasma)‡
Anti-HBs* Serum/Plasma	NA / 7C18-20, 25, 30	NA / 7C18	mIU/mL	1 2	0 100	† 1.10	WHO 1st International Standard W1042
Anti-HBs* Serum/Plasma	NA / 7C18-27, 28, 34, 37, 38	NA / 7C18	mIU/mL	A B C D E F	0 10 50 100 500 1000	† 0.04 0.11 0.22 1.42 2.83	WHO 2nd International Standard 07/164
Anti-HBs* Serum/Plasma	7P89 / 7C18-29, 33, 39, 41, 42	7P89 / 7C18	mIU/mL	A B C D E F	0 10 50 100 500 1000	† 0.07 0.13 0.26 1.30 2.61	WHO 2nd International Standard 07/164
Anti-Tg Serum/Plasma	9P34 / 2K46	9P34 / 2K46	IU/mL	A B C D E F	0.0 5.0 62.5 125.0 500.0 1000.0	† 0.06 0.56 0.81 4.74 11.30	WHO 1st International Standard 65/093
Anti-TPO Serum/Plasma	9P35 / 2K47	9P35 / 2K47	IU/mL	A B C D E F	0.0 5.0 20.0 62.5 250.0 1000.0	† 0.08 0.18 0.46 2.18 8.74	International Reference Preparation MRC 66/387‡
AUSAB# Serum/Plasma	NA / 1L82	NA / 1L82	mIU/mL	A B C D E F	0 10 50 100 500 1000	† 0.08 0.33 0.64 3.29 7.44	WHO 1st International Standard W1042
AUSAB# Serum/Plasma	NA / 1L82	NA / 1L82	mIU/mL	A B C D E F	0 10 50 100 500 1000	† 0.40 1.48 3.10 15.40 33.80	WHO 2nd International Standard 07/164

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B12 Serum/Plasma	7P67 / 7K61	7P67 / 7K61	pg/mL	A B C D E F	0 110 250 500 1000 2000	† 0.71 1.61 2.06 4.11 8.22	USP Cyanocobalamin Reference Standard
BhCG Total Serum/Plasma	7P51 / 7K78	7P51 / 7K78	mIU/mL	A B C D E F	0 10 250 1000 7500 15000	† 0.10 2.56 4.63 32.15 64.30	WHO 4th International Standard 75/589
BNP Plasma	8P24 / 8K28	8P24 / 8K28	pg/mL	A B C D E F	0 75 375 750 2500 5000	† 0.76 2.62 8.23 14.67 51.87	Internal Reference Standard (Synthetic BNP-32 [human])‡
BNP-JP Plasma	8P25 / 2P14	8P25 / 2P14	pg/mL	A B C D E F	0.0 44.0 218.0 435.0 1451.0 2902.0	† 0.424 2.079 2.97 6.65 11.36	Internal Reference Standard (Synthetic BNP-32 [human])‡
CA 125 II Serum/Plasma	8P51 / 2K44	8P49 / 2K45	U/mL	A B C D E F	0 20 75 225 500 1000	† 0.13 0.50 1.56 3.75 7.50	Internal Reference Standard (OC125 Defined Antigen)‡
CA 15-3 Serum/Plasma	8P51 / 2K44	8P51 / 2K44	U/mL	A B C D E F	0 20 80 160 400 800	† 0.13 0.54 1.09 3.64 8.52	Internal Reference Standard (DF3 Defined Antigen)‡
CA 19-9$_{XR}$ Serum/Plasma	8P32 / 2K91	8P32 / 2K91	U/mL	A B C D E F	0 30 100 250 600 1200	† 0.51 0.89 2.05 7.78 20.04	Internal Reference Standard (1116-NS-19-9 Defined Antigen)‡
iCarbamazepine Serum/Plasma	NA / 1P36	NA / 1P36	µg/mL	A B C D E F	0.00 2.00 4.00 8.00 12.00 20.00	† 0.011 0.017 0.03 0.06 0.10	USP Carbamazepine Reference Standard (5H-Dibenz[b,f]azepine-5-carboxamide)
CEA Serum/Plasma	7P62 / 7K68	7P62 / 7K68	ng/mL	1 2	0 10	† 0.08	WHO 1st International Standard 73/601
Stat CK-MB Serum/Plasma	NA / 2K42	NA / 2K42	ng/mL	A B C D E F	0.0 3.8 12.0 60.0 135.0 300.0	† 0.03 0.09 0.55 1.24 2.75	Internal Reference Standard (Recombinant CK-MB)‡

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¶Assay available only in Japan.

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CMV IgG* Serum/Plasma	7P42 / 6C15	7P42 / 6C15	AU/mL	A B C D E F	0 10.0 50.0 75.0 125.0 250.0	† 0.03 0.13 0.20 0.33 0.75	Internal Reference Standard (Human Anti-CMV IgG)‡
Cortisol Serum/Plasma/Urine	8P33 / 8D15	8P33 / 8D15	µg/dL	A B C D E F	0.0 3.0 5.4 10.7 25.2 59.8	† 0.03 0.07 0.10 0.23 0.45	Internal Reference Standard (Cortisol USP Standard)‡
C-Peptide Serum/Plasma/Urine	NA / 3L53	NA / 3L53	ng/mL	A B C D E F	0.00 0.05 0.24 1.20 6.00 30.00	† 0.0004 0.002 0.01 0.03 0.14	WHO International Standard 84/510
Cyclosporine Whole Blood	NA / 1L75	NA / 1L75	ng/mL	A B C D E F	0 40 150 400 800 1500	† 1.08 3.12 7.23 13.37 28.86	USP Cyclosporine Reference Standard
CYFRA 21-1* Serum/Plasma	NA / 2P55	NA / 2P55	ng/mL	A B C D E F	0.0 2.5 10.0 25.0 50.0 100.0	† 0.021 0.067 0.170 0.300 0.610	Maintained Reference Preparation (Cytokeratin 8/19 Antigen)
DHEA-S Serum/Plasma	NA / 8K27	NA / 8K27	µg/dL	A B C D E F	0 5 12 60 300 1500	† 0.02 0.04 0.07 0.34 1.88	Internal Reference Standard (Purified Synthetic DHEA-S), Sigma D5297; Dehydroisoandrosterone 3-sulfate sodium salt dihydrate‡
i Digoxin Serum/Plasma	NA / 1P32	NA / 1P32	ng/mL	A B C D E F	0.0 0.5 1.0 2.0 3.0 4.0	† 0.005 0.01 0.01 0.02 0.03	USP Digoxin Reference Standard
Estradiol Serum/Plasma	7P50 / 7K72	7P50 / 7K72	pg/mL	A B C D E F	0 50 100 250 500 1000	† 0.74 1.47 1.30 2.30 4.60	Internal Reference Standard (ß-Estradiol)‡
Ferritin Serum/Plasma	7P65 / 7K59	7P65 / 7K59	ng/mL	1 2	10 1000	0.13 12.75	WHO Ferritin 1st International Standard 80/602
Folate II* Serum/Plasma/ Red Blood Cells	8P14 / 1P74	8P14 / 1P74	ng/mL	A B C D E F	0.0 1.5 3.0 5.0 10.0 20.0	† 0.01 0.02 0.03 0.05 0.09	WHO Serum Folate International Standard 03/178

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Folate[#] Serum/Plasma	NA / 1P74	NA / 1P74	ng/mL	A B C D E F	0.0 1.5 3.0 5.0 10.0 20.0	† 0.01 0.02 0.03 0.05 0.09	WHO Serum Folate International Standard 03/178
Free PSA[*] Serum	7P93 / 7K71	7P93 / 7K71	ng/mL	1 2	0 10	† 0.09	WHO 1st International Standard 96/670
Free PSA[#] Serum	NA / 6C07	NA / 6C07	ng/mL	1 2	0 10	† 0.09	WHO 1st International Standard 96/670
Free T3 Serum/Plasma	NA / 7K63	NA / 7K63	pg/mL	1 2	1.4 30.0	0.01 0.26	Internal Reference Standard (L-Triiodothyronine sodium salt and L-Thyroxine sodium pentahydrate)[‡]
Free T3 Serum/Plasma	7P69 / 7K63	7P69 / 7K63	pg/mL	A B C D E F	0.0 1.4 3.5 7.0 17.2 30.0	† 0.0538 0.0644 0.2100 0.5435 2.9520	Internal Reference Standard (L-Triiodothyronine sodium salt and L-Thyroxine sodium pentahydrate)[‡]
Free T4 Serum/Plasma	7P70 / 7K65	7P70 / 7K65	ng/dL	A B C D E F	0.0 0.5 1.0 2.0 3.5 6.0	† 0.005 0.005 0.009 0.038 0.128	Internal Reference Standard (L-Thyroxine Sodium Pentahydrate)[‡]
FSH Serum/Plasma	7P49 / 7K75	7P49 / 7K75	mIU/mL	1 2	0 100	† 0.84	WHO 1st International Standard 92/510
Galectin-3[*] Serum/Plasma	NA / 5P03	NA / 5P03	ng/mL	A B C D E F	0.0 5.7 11.4 22.8 68.4 114.0	† 0.08 0.11 0.24 1.08 1.67	Maintained Reference Preparation (Recombinant Human Galectin-3)
iGentamicin Serum/Plasma	NA / 1P31	NA / 1P31	µg/mL	A B C D E F	0.00 0.30 1.50 5.00 8.00 10.00	† 0.001 0.003 0.014 0.031 0.042	USP Gentamicin Reference Standard (Gentamicin sulfate salt)
HbA1c Whole Blood	NA / 4P72	NA / 4P72	nmol/L	A B C D E F	4.0 5.5 7.5 9.0 12.0 14.5	0.029 0.040 0.051 0.07 0.09 0.11	Internal Reference Standard (IFCC Reference Standard)[‡]
HBeAg Quantitative[*] Serum/Plasma	7P64 / 6C32	9P10 / 7P24	PEI U/mL	A B C D E F	0.00 0.70 1.50 10.00 150.00 700.00	† 0.03 0.06 0.42 6.51 32.20	Reference Standard HBe-Referenzantigen 82
HBsAg[*] Serum/Plasma	NA / 6C36	NA / 3M61	IU/mL	1 2	0.5 250	0.01 4.43	WHO International Standard 80/549

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HBsAg* Serum/Plasma	8P08 / 6C36	8P08 / 3M61	IU/mL	A B C D E F	0.0 0.5 5.0 28.0 100.0 250.0	† 0.00 0.01 0.06 0.28 0.60	WHO International Standard 80/549
HCV Ag* Serum/Plasma	NA / 6L47	NA / 6L47	fmol/L	A B C D E F	0.00 10.00 80.00 600.00 4500.00 20000.00	† 0.18 1.32 9.15 62.03 275.67	Internal Reference Standard (Cal B-D: Recombinant HCV Core Ag, Cal E-F: Lactose Recombinant HCV Core Ag)‡
HE4 Serum	8P50 / 2P54	8P50 / 2P54	pmol/L	A B C D E F	0 30 100 250 750 1500	† 0.27 0.88 2.18 6.47 13.82	Internal Reference Standard (Recombinant Ig-HE4 fusion protein consisting of a Human Fc antibody fragment and Human Epididymis protein [HE4])‡
Homocysteine Serum/Plasma	NA / 1L71	NA / 1L71	µmol/L	A B C D E F	0.0 2.5 5.0 10.0 20.0 50.0	† 0.03 0.06 0.08 0.16 0.33	Internal Reference Standard (S-adenosyl-L-homocystein in phosphate buffer)‡
Stat* High Sensitive Troponin-I Serum/Plasma	8P13 / 3P25	8P13 / 3P25	pg/mL	A B C D E F	0 20 100 500 10000 50000	† 2.8 14.1 70.7 1414.2 7071.1	Internal Reference Standard (Recombinant Human Cardiac Troponin IC Complex); Calibrator B is traceable to NIST SRM 2921 at 20 pg/mL‡
Insulin Serum/Plasma	4T75 / 8K41	4T75 / 8K41	µU/mL	A B C D E F	0 3 10 30 100 300	† 0.03 0.09 0.17 0.48 1.44	WHO 1st International Standard 66/304
Intact PTH Serum/Plasma	8P31 / 8K25	8P31 / 8K25	pg/mL	A B C D E F	0.0 4.8 24.0 120.0 600.0 3000.0	† 0.02 0.10 0.27 1.21 6.07	WHO 1st International Standard 79/500
LH Serum/Plasma	7P91 / 2P40	7P91 / 2P40	mIU/mL	A B C D E F	0.0 1.0 3.5 15.0 50.0 250.0	† 0.01 0.02 0.08 0.30 1.56	WHO 2nd International Standard 80/552
Methotrexate* Serum/Plasma	NA / 2P49	NA / 2P49	µmol/L	A B C D E F	0.000 0.040 0.100 0.250 0.700 1.500	† 0.000 0.001 0.002 0.005 0.014	Methotrexate Reference Standard (USP)

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***Stat* Myoglobin** Serum/Plasma	NA / 2K43	NA / 2K43	ng/mL	A B C D E F	0.0 30.0 100.0 300.0 600.0 1200.0	† 0.33 0.99 3.18 5.69 11.38	Internal Reference Standard (Purified human cardiac myoglobin)‡
Urine NGAL* Urine	NA / 1P37	NA / 1P37	ng/mL	A B C D E F	0.0 10.0 100.0 500.0 1000.0 1500.0	† 0.04 0.28 1.51 2.45 3.68	Internal Reference Standard (Recombinant human NGAL)‡
PCT (BRAHMS)* Serum/Plasma	NA / 6P22	NA / 6P22	ng/mL	A B C D E F	0.00 0.10 0.50 12.10 20.50 100.00	† 0.0014 0.0063 0.1912 0.3157 3.7200	Internal Reference Standard (recombinant human PCT)‡
Pepsinogen I* Serum/Plasma	NA / 8D07	NA / 8D07	ng/mL	1 2	0 70	† 1.92	Internal Reference Standard (Pepsinogen I Antigen)‡
Pepsinogen II* Serum/Plasma	NA / 9D65	NA / 9D65	ng/mL	1 2	0 5	† 0.13	Internal Reference Standard (Pepsinogen II Antigen)‡
i Phenytoin Serum/Plasma	NA / 1P34	NA / 1P34	µg/mL	A B C D E F	0.0 2.5 5.0 10.0 20.0 40.0	† 0.02 0.03 0.07 0.14 0.36	USP Phenytoin Reference Standard
i Phenobarbital Serum/Plasma	NA / 1P33	NA / 1P33	µg/mL	A B C D E F	0.0 5.0 10.0 20.0 40.0 80.0	† 0.04 0.08 0.16 0.31 1.31	USP Phenobarbital Reference Standard
PIVKA-II* Serum/Plasma	NA / 2P48	NA / 2P48	mAU/mL	A B C D E F	0 40 100 300 5000 30000	† 0.8000 1.5600 4.3800 124.0000 1062.0000	Internal Reference Standard (purified human prothrombin)‡
Progesterone Serum/Plasma	8P36 / 7K77	8P36 / 7K77	ng/mL	1 2	0.7 40.0	0.01 0.26	USP Progesterone Reference Standard
ProGRP* Serum/Plasma	NA / 1P45	NA / 1P45	pg/mL	A B C D E F	0.0 20.0 80.0 320.0 1250.0 5000.0	† 0.18 0.78 2.86 11.18 33.54	Internal Reference Standard (Synthetic ProGRP)‡
Prolactin Serum/Plasma	7P66 / 7K76	7P66 / 7K76	ng/mL	1 2	5 30	0.05 0.23	WHO 3rd International Standard 84/500
Rubella IgG* Serum/Plasma	8P46 / 6C17	8P46 / 6C17	IU/mL	A B C D E F	0 5 15 75 250 500	† 0.09 0.26 1.21 6.30 13.54	WHO 1st International Standard RUBI-1-94

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SCC* Serum/Plasma	NA / 8D18	NA / 8D18	ng/mL	A B C D E F	0 1 5 20 40 70	† 0.01 0.05 0.21 0.42 0.67	Internal Reference Standard (SCC Stock Antigen)‡
SHBG Serum/Plasma	NA / 8K26	NA / 8K26	nmol/L	A B C D E F	0.0 2.0 6.0 25.0 125.0 250.0	† 0.01 0.03 0.07 0.81 0.93	WHO 2nd International Standard 08/266
Sirolimus Whole Blood	NA / 1L76	NA / 1L76	ng/mL	A B C D E F	0 3 6 12 20 30	† 0.05 0.07 0.14 0.20 0.30	Internal Reference Standard (Sirolimus powder, purity ≥ 92% as anhydrous powder)‡
Tacrolimus Whole Blood	NA / 1L77	NA / 1L77	ng/mL	A B C D E F	0 3 6 12 20 30	† 0.04 0.06 0.13 0.23 0.34	Internal Reference Standard (Tacrolimus powder, purity ≥ 98.0% as anhydrous powder)‡
2nd Generation Testosterone Serum/Plasma	7P68 / 2P13	7P68 / 2P13	nmol/L	A B C D E F	0.0 0.1 0.2 1.6 12.5 30.0	† 0.001 0.002 0.01 0.08 0.19	USP Testosterone Reference Standard
i Theophylline Serum/Plasma	NA / 1P29	NA / 1P29	µg/mL	A B C D E F	0.0 2.5 5.0 10.0 20.0 40.0	† 0.03 0.06 0.13 0.23 0.47	USP Theophylline Reference Standard
Total PSA* Serum	7P92 / 7K70	7P92 / 7K70	ng/mL	1 2	0 15	† 0.17	WHO 1st International Standard (90:10) 96/670
Total PSA# Serum	NA / 6C06	NA / 6C06	ng/mL	1 2	0 15	† 0.17	WHO 1st International Standard (90:10) 96/670
Total T3 Serum/Plasma	NA / 7K64	NA / 7K64	ng/mL	1 2	0.5 8.0	0.006 0.058	USP L-Triiodothyronine Reference Standard
Total T3 Serum/Plasma	7P94 / 7K64	7P94 / 7K64	ng/mL	A B C D E F	0.20 0.50 0.75 1.50 3.50 6.00	0.0375 0.0134 0.0185 0.0396 0.1057 0.4488	Triiodo-L-Thyronine (T3) Solution (CRM) (3 3' 5–Triiodo–L–thyronine (T3))
Total T4 Serum/Plasma	NA / 7K66	NA / 7K66	µg/dL	1 2	0.0 18.0	† 0.213	USP L-Thyroxine Reference Standard
Total T4 Serum/Plasma	7P95 / 7K66	NA / 7K66	µg/dL	A B C D E F	0 3 6 12 18 24	† 0.027 0.049 0.143 0.215 0.287	USP L-Thyroxine Reference Standard

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***Stat* Troponin-I** Serum/Plasma	NA / 2K41	NA / 2K41	ng/mL	A B C D E F	0.00 0.25 0.50 1.50 10.00 50.00	† 0.003 0.005 0.012 0.067 0.397	Internal Reference Standard (Recombinant Troponin IC Complex)‡
Toxo IgG* Serum/Plasma	7P45 / 6C19	7P45 / 6C19	IU/mL	A B C D E F	0.0 5.0 25.0 50.0 100.0 200.0	† 0.01 0.05 0.11 0.33 0.66	WHO 1st International Standard 01/600
TSH Serum/Plasma	7P48 / 7K62	7P48 / 7K62	µIU/mL	1 2	0.0 40.0	† 0.288	WHO International Standard 80/558
T-Uptake Serum/Plasma	8P12 / 2K48	8P12 / 2K48	T-Uptake Units	A B C D E F	0.00 0.40 0.67 1.09 1.42 1.89	† 0.004 0.004 0.005 0.01 0.01	Internal Reference Standard (normal human serum, T4 binding capacity)‡
i Valproic Acid Serum/Plasma	NA / 1P35	NA / 1P35	µg/mL	A B C D E F	0.00 9.00 18.00 36.00 75.00 150.00	† 0.08 0.16 0.26 0.68 1.22	USP Valproic Acid Reference Standard
i Vancomycin Serum/Plasma	NA / 1P30	NA / 1P30	µg/mL	A B C D E F	0.0 5.0 10.0 25.0 50.0 100.0	† 0.05 0.09 0.24 0.51 1.21	USP Vancomycin Hydrochloride Reference Standard
25-OH Vitamin D Serum/Plasma	NA / 3L52	NA / 3L52	ng/mL	A B C D E F	0.0 4.0 10.0 30.0 75.0 160.0	† 0.038 0.094 0.252 0.444 0.984	Internal Reference Standard (25-OH Vitamin D3), Sigma 17938; 25-Hydroxyvitamin D3 monohydrate‡
25-OH Vitamin D Serum/Plasma	8P45 / 5P02	8P45 / 5P02	ng/mL	A B C D E F	0.0 4.0 10.0 30.0 75.0 160.0	† 0.22 0.42 1.24 3.02 8.03	NIST Standard Reference Material (SRM) 2972

ACS – American Chemical Society
ERM – European Reference Material
GFR – Glomerular Filtration Rate
ID-ICP-MS – Isotope Dilution Inductively Coupled Plasma Mass Spectrometry
ID-GC/MS – Isotope Dilution-Gas Chromatography Mass Spectrometry
ID-LC/MS – Isotope Dilution-Liquid Chromatography Mass Spectrometry
MDRD – Modification of Diet in Renal Disease
NIST – National Institute of Standards and Technology
SRM – Standard Reference Material

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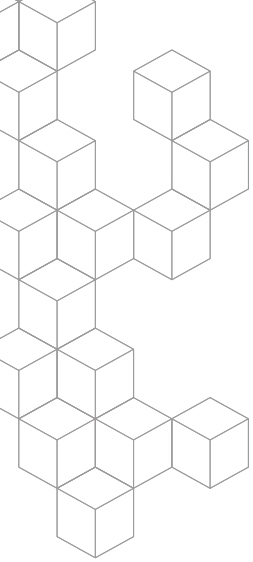

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