ABBOTT

Declaration of Conformity

Certificate Identification: 6K01

Legal Manufacturer's Name: Abbott Laboratories
Diagnostics Division
Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
6K01-20	56676	Acid Wash	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.

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: November 5, 2014

Date Issued: 11-5-2014

Supersedes: December 11, 2006

Digitally signed by Ceaicovschi Tudor
Date: 2022.11.10 09:34:46 EET
Reason: MoldSign Signature
Location: Moldova

Signature: Mark Littlefield

Full Name: Mark Littlefield

Position: Associate Director, Regulatory Affairs

Date of Approval: November 5, 2014

Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038

Effective (Date or Lot Number): November 17, 2014

ABBOTT

Declaration of Conformity

Certificate Identification: 9D31
Legal Manufacturer's Name: Abbott Laboratories Diagnostics Division
Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
9D31-20	58236	Alkaline Wash	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.

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: 5-28-2015
Date Issued: 5-28-2015
Supersedes: March 28, 2013

Signature: Mark Littlefield
Full Name: Mark Littlefield
Position: Associate Director, Regulatory Affairs
Date of Approval: 5-28-2015
Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038
Effective (Date or Lot Number): 5-28-2015

ABBOTT

Declaration of Conformity

Certificate Identification: 1J72
Legal Manufacturer's Name: Abbott Laboratories Diagnostics Division
Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
1J72-20	59058	Detergent A	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.

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: 5-28-2015
Date Issued: 5-28-2015
Supersedes: March 28, 2013

Signature: Mark Littlefield
Full Name: Mark Littlefield
Position: Associate Director, Regulatory Affairs
Date of Approval: 5-28-2015
Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038
Effective (Date or Lot Number): 5-28-2015

ABBOTT

Declaration of Conformity

Certificate Identification: 2J94
Legal Manufacturer's Name: Abbott Laboratories
Diagnostics Division
Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
2J94-21	59058	Detergent B	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.

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: December 4, 2014
Date Issued: December 4, 2014
Supersedes: New

Signature: Mark Littlefield
Full Name: Mark Littlefield
Position: Associate Director, Regulatory Affairs
Date of Approval: December 4, 2014
Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038
Effective (Date or Lot Number): December 4, 2014

ABBOTT

Declaration of Conformity

Certificate Identification: 9D29
Legal Manufacturer's Name: Abbott Laboratories Diagnostics Division
Abbott Park, Illinois 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
9D29-20	56676	Water Bath Additive	Self-declared
9D29-21	56676	Water Bath Additive	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.

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: 6-11-2015
Date Issued: 6-11-2015
Supersedes: March 28,2013

Signature: Mark Littlefield
Full Name: Mark Littlefield
Position: Associate Director, Regulatory Affairs
Date of Approval: 6-11-2015
Place Issued: Abbott Laboratories
1921 Hurd Drive
Irving, TX 75038
Effective (Date or Lot Number): 6-11-2015

Abbott

Declaration of Conformity

Certificate Identification:	ARCH Sys Acc LC	IRIS V3
Legal Manufacturer's Name:	Abbott Laboratories	
Legal Manufacturer's Address:	Diagnostics Division Abbott Park, IL 60064 USA	

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
4D18-03	NA	ARCHITECT Septum	Self-declared
4D19-01	NA	ARCHITECT Replacement Caps	Self-declared
7C14-01	NA	ARCHITECT Sample Cups	Self-declared
7C15-02	NA	ARCHITECT Reaction Vessels	Self-declared
7C15-03	NA	ARCHITECT Reaction Vessels	Self-declared

Authorized European Representative (name and address)	Abbott GmbH & Co. KG Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (name and address)	Abbott Laboratories Diagnostics Division Abbott Park, IL 60064 USA
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.

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

Signature:		Signature:	
Full Name:	_Lauren Sieber_	Full Name:	_Deborah Hinkley_
Position:	Product Quality Assurance Manager	Position:	Regulatory Affairs Director
Date of Approval:	5/28/2015	Date of Approval:	5/29/2015
Date Issued:	06/02/2015	Place Issued:	Abbott Laboratories Diagnostics Division Abbott Park, IL 60064 USA
Supersedes:	June 13, 2013	Effective (Date or Lot Number):	06/06/2015

Abbott

Declaration of Conformity

Certificate Identification:	08D15 LC IRIS V7.0
Legal Manufacturer's Name:	Abbott Laboratories Diagnostics Division
Legal Manufacturer's Address:	Abbott Park, IL 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
8D15-25	54125	ARCHITECT Cortisol Reagent Kit	**Self-declared**
8D15-35	54125	ARCHITECT Cortisol Reagent Kit	**Self-declared**
8D15-02	54126	ARCHITECT Cortisol Calibrators	**Self-declared**

Authorized European Representative (Name and Address)	Abbott GmbH Max-Planck-Ring-2 65205 Wiesbaden, Germany
Storage Site of Technical Documentation (Name and Address)	Fisher Diagnostics a division of Fisher Scientific Company LLC a part of Thermo Fisher Scientific Inc. 8365 Valley Pike, Middletown, VA 22645-1905
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.

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

Signature: 

Full Name: Elizabeth Wernquist

Position: Director QA, LC Site

Date of Approval: 27 OCT 2021

Date Issued: 8 November 2021

Supersedes: 1 July 2021

Signature: 

Full Name: Jacek Gorzowski

Position: Associate Director Regulatory Affairs

Date of Approval: 8 November 2021

Place Issued: Abbott Laboratories Diagnostics Division
Abbott Park, IL 60064 U.S.A.

Effective (Date or Lot Number): 8 November 2021

Abbott

Declaration of Conformity

Certificate Identification: DOC-8K27-SD-DLK-TPM

Legal Manufacturer's Name: Abbott GmbH

Legal Manufacturer's Address: Max-Planck-Ring 2, 65205 Wiesbaden, Germany

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
8K27-21	54139	ARCHITECT DHEA-S Reagent Kit (4x100 Tests)	**Self-declared**
8K27-27	54139	ARCHITECT DHEA-S Reagent Kit (1x100 Tests)	**Self-declared**
8K27-11	54141	ARCHITECT DHEA-S Controls	**Self-declared**
8K27-02	54140	ARCHITECT DHEA-S Calibrators	**Self-declared**

Authorized European Representative (name and address)	N/A
Storage of technical documentation (name and address)	BIOKIT, S.A., Av. Can Montcau 7, 08186 Lliçà d'Amunt, Barcelona-Spain
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.

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

Signature: C. Becker

Full Name: **Claudia Becker**

Position: **Director Quality Assurance**

Date of Approval: 31 May 2021

Signature: Susanne Ulrich

Full Name: **Susanne Ulrich**

Position: **Assoc. Director Regulatory Affairs**

Date of Approval: 26 May 2021

Date Issued: 31 May 2021

Place Issued: 65205 Wiesbaden, Germany

Supersedes: 20-March-2019

Effective (Date or Lot Number): 31 May 2021

Biokit
A Werfen Company

CE DECLARATION OF CONFORMITY

Manufacturer:		
Hersteller *Fabricante* *Fabricant* *Produttore*	*Fabricante* *Producent* *Tillverkare* *Κατασκευαστής*	**BIOKIT, S.A.** **Av. Can Montcau, 7.** **08186 Lliçà d'Amunt** **Barcelona – Spain**

Biokit hereby declares that the product(s) listed below conform to the European Union directive and standards identified in this declaration.

Biokit erklärt, dass die aufgeführten Produkt(e) mit den Bestimmungen der angegebenen EU-Richtlinien und mit den aufgeführten normativen Dokumenten in Übereinstimmung sind.

Biokit declara por la presente que los producto(s) abajo mencionados, están conformes con las directivas y normas Europeas identificadas en esta declaración.

Biokit déclare par la présente, que le(s) produit(s) sous-mentionné(s), est (sont) conforme(s) aux directives et normes Européennes identifiées dans cette déclaration.

Biokit dichiara con la presente che il(i) prodotto(i) sottomenzionato(i) è(sono) conformi alla direttiva e agli standard specificati in questa dichiarazione.

Biokit declara pelo presente que o(s) produto(s) abaixo mencionado(s) está/estão conforme a Directiva e normas da Comissão Europeia especificadas nesta declaração.

Biokit erklærer herved, at det (de) nedenfor anførte produkt(er) er i overensstemmelse med de EU-direktiver og standarder, der er anført i denne erklæring.

Biokit bekräftar härmed att produkt(er) listade nedan, vara förenlig(a) med Europeiska Union-ens direktiv och standarder identifierade i denna deklaration.

Η Biokit με το παρόν δηλώνει ότι τα προϊόντα που αναφέρονται κατωτέρω συμμορφούνται με την οδηγία της Ευρωπαϊκής Ενωσης και τα πρότυπα που προσδιορίζονται στην παρούσα δήλωση.

EU Directive:
EU-Richtlinie Directiva UE Directive Européenne Direttiva Europea Directiva UE EU-direktiv EU Direktiv Οδηγία ΕΕ

IVD - 98/79/EC (27/10/1998) – Annex III

Standard(s):
Normen und Richtlinien Estándar(es) Norme(s) Norma(e) Padrão/Padrões Standard(er) Standard(er) Πρότυπα

ISO 13485

Name: José Luis Zarroca
CEO
Biokit, S.A.

Lliçà d'Amunt, 23rd November 2020
R01

Biokit
A Werfen Company

Product(s) *Produkt(e)* *Producto(s)* *Produit(s* *Prodotto(i)*	*Produto(s)* *Produkt(er)* *Produkt(er)* *Προϊόντα*	*GMDN code*
P/N		
6K38-02	Quantia ASO	59055
6K39-02	Quantia ß2-Microglobulin	53927
6K40-02	Quantia Digitoxin	59084
6K41-02	Quantia Ferritin	53718
6K42-02	Quantia IgE	61274
6K44-02	Quantia RF	55111
6K45-03	Quantia PROTEINS Standard	30505
6K46-03	Quantia ASO Standard	51744
6K47-03	Quantia ß2-Microglobulin Standard	38215
6K48-02	Quantia Digitoxin Standard	55330
6K49-03	Quantia Ferritin Standard	41927
6K50-03	Quantia IgE Standard	53777
6K52-03	Quantia RF Standard	42230
6K53-02	Quantia PROTEINS Control	30506
6K57-02	Quantia Digitoxin Control	38533
6K54-02	Quantia ASO RF Control I	30506
6K55-02	Quantia ASO RF Control II	30506
6K56-02	Quantia Ferritin/Myoglobin/IgE Control	30506
6K99-02	Quantia A1-Antitrypsin	53602
6L32-43	Quantia Myoglobin	59042
6L33-05	Quantia Myoglobin Standard	41733
6L34-43	Quantia A-1-AGP	53606
7K00-03	Quantia Lp(a)	53438
5P83-02	Lp(a) Calibrators	41417
5P84-11	Lp(a) Control	41418
7K02-02	Quantia D-Dimer	47346
7K02-21	Quantia D-Dimer Control	47347
7K02-11	Quantia D-Dimer Standard	47348

Biokit, S.A.
Barcelona, Spain
Av. Can Montcau 7
08186 Lliçà d'Amunt
Tel. +34 93 860 9000
www.biokit.com

ABBOTT

Declaration of Conformity

Certificate Identification: 01P74
Legal Manufacturer's Name: Abbott Ireland Diagnostics Division
Legal Manufacturer's Address: Lisnamuck, Longford, Co. Longford, Ireland.

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
1P74-25 1P74-35	60982	ARCHITECT Folate Reagent Kit	**Self-declared**
1P74-40	54455	ARCHITECT Folate RBC Lysis Diluent	**Self-declared**
1P74-50	58208	ARCHITECT Folate Manual Diluent	**Self-declared**
1P74-01	41931	ARCHITECT Folate Calibrators	**Self-declared**
1P74-10	41932	ARCHITECT Folate Controls	**Self-declared**
3P21-60	54455	Folate Lysis Reagent	**Self-declared**

Authorized European Representative (name and address)	N/A
Storage site of technical documentation (name and address)	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland.
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.
This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature:	Siobhan Wright	Signature:	Lorraine Whitney
Full Name:	**Siobhan Wright**	Full Name:	**Lorraine Whitney**
Position:	**Director Quality Assurance/ Site Quality Head**	Position:	**Senior Manager Regulatory Affairs**
Date of Approval:	24-APR-19	Date of Approval:	19 APR 2019
Date Issued:	24-APR-19	Place Issued	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland.
Supersedes	09-Jan-2015	Effective (Lot number or date)	24-APR-19

Abbott

Declaration of Conformity

Certificate Identification: DoC-5P20-SD DELK TPM
Legal Manufacturer's Name: Abbott GmbH
Legal Manufacturer's Address: Max-Planck-Ring 2, 65205 Wiesbaden, Germany

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
5P20-25	54375	ARCHITECT Thyroglobulin Reagent Kit (1 x 100 Tests)	**Self-declared**
5P20-35	54375	ARCHITECT Thyroglobulin Reagent Kit (1 x 500 Tests)	**Self-declared**
5P20-01	41712	ARCHITECT Thyroglobulin Calibrators	**Self-declared**
5P20-10	41711	ARCHITECT Thyroglobulin Controls	**Self-declared**

Authorized European Representative (name and address)	N/A
Storage site of technical documentation (name and address)	Fujirebio Diagnostics, Inc., 201 Great Valley Parkway, Malvern, Pennsylvania 19355, USA.
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.

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

Signature: J. A

Full Name: **Dr. Jörg Amborn**

Position: **Director Quality Assurance**

Date of Approval: 2020-08-12

Signature: Susanne Ulrich

Full Name: **Susanne Ulrich**

Position: **Senior Manager Regulatory Affairs**

Date of Approval: 30/Jul/2020

Date Issued: 12/Aug/2020

Place Issued: 65205 Wiesbaden, Germany

Supersedes: 14-Dec-2018

Effective (Date or Lot Number): 12/Aug/2020

ABBOTT

Declaration of Conformity

Certificate Identification: 07K61
Legal Manufacturer's Name: Abbott Ireland Diagnostics Division
Legal Manufacturer's Address: Lisnamuck, Longford, Co. Longford, Ireland.

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
7K61-25 7K61-35	60779	ARCHITECT B12 Reagent Kit	**Self-declared**
7K61-01	41337	ARCHITECT B12 Calibrators	**Self-declared**
7K61-10	41338	ARCHITECT B12 Controls	**Self-declared**

Authorized European Representative (name and address)	N/A
Storage of technical documentation (name and address)	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland.
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 and transposed Irish Regulation S.I. No 304 of 2001 and to the EC Directive 98/79/EC as it is transposed into the laws of the member states.
This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: Siobhan Wright
Full Name: **Siobhan Wright**
Position: **Director Quality Assurance/Site Quality Head**
Date of Approval: 24-APR-19
Date Issued: 24-APR-19
Supersedes: 12 OCT 2018

Signature: Lorraine Whitney
Full Name: **Lorraine Whitney**
Position: **Senior Manager Regulatory Affairs/**
Date of Approval: 19 APR 2019
Place Issued: Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland
Effective (Date or Lot Number): 24-APR-19