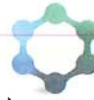
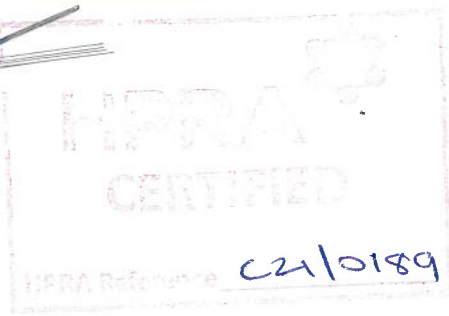


HPRA

An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority



Ref: VIETNAM
8892
غرفة التجارة العربية الأيرلندية
Arab-Irish Chamber of Commerce



20th January 2021

CERTIFICATE OF FREE SALE

To Whom It May Concern

The Health Products Regulatory Authority hereby certifies that:

- 1) The *in-vitro* diagnostic medical devices specified in the attached schedule are manufactured by Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland.
- 2) The *in-vitro* diagnostic medical devices specified in the attached schedule are CE marked in accordance with the European Communities (*In-vitro* Diagnostic Medical Device) Regulations, 2001 (which transposed the *In-vitro* Diagnostic Medical Devices Directive 98/79/EC into Irish law) and may be marketed and sold in Ireland.
- 3) Exportation of the *in-vitro* medical devices listed in the attached schedule is not prohibited.
- 4) The granting of this certificate is based on the information available to the Health Products Regulatory Authority on the date of issue of the certificate.

Issued To:

Abbott Ireland Diagnostics Division
Lisnamuck
Longford
Co. Longford
Ireland

Nhà sản xuất và
chủ sở hữu của
TTBYT

Expiry Date: 27th May 2025


Patrick Keating
Compliance Department
Health Products Regulatory Authority



CHỨNG NHẬN / HỢP PHÁP HÓA LÃNH SỰ
CONSULAR AUTHENTICATION

- 1. Quốc gia: **Việt Nam**
Country
- Giấy tờ, tài liệu này
This public document
- 2. do Ông (Bà): **Fiona Murphy** ký
has been signed by
- 3. với chức danh: **Cán bộ lãnh sự**
acting in the capacity of
- 4. và con dấu của Bộ Ngoại giao và Thương mại Ai-len
bears the stamp of
- được chứng nhận / hợp pháp hóa lãnh sự
Certified
- 5. tại **London** 6. Ngày **01/03/2021**
at the
- 7. Cơ quan cấp: Đại sứ quán Việt Nam tại VQ Anh và CH Ai-len
by
- 8. Số: **480**
N°



Ký tên và đóng dấu
Signature and seal/stamp
Bí thư thứ hai
Second Secretary
Nguyễn Quang Đông



Seen for the authentication of signature/seal
of **Patrick Keating**
Health Products Regulatory Authority

Signed

Position

Date **23/02/2021**

This only certifies the authenticity of the signature and the capacity of the person who has signed the public document, and, where applicable, the identity of the seal or stamp which the public document bears. The authentication does not certify the content of the document for which it is issued. To verify an Authentication issued by the Ministry of Foreign Affairs in Ireland, see authentications.dfa.ie

345387

MEDICAL DEVICE SCHEDULE

Item number/ Product code	Description of device
01E0124	Immunoglobulin M
01E0224	Prealbumin
01E0424	Transferrin
01E0444	Transferrin
1P37-25	ARCHITECT Urine NGAL Reagent Kit
1P37-35	ARCHITECT Urine NGAL Reagent Kit
1P37-01	ARCHITECT Urine NGAL Calibrators
1P37-10	ARCHITECT Urine NGAL Control
1P74-25	ARCHITECT Folate Reagent Kit
1P74-35	ARCHITECT Folate Reagent Kit
1P74-40	ARCHITECT Folate RBC Lysis Diluent
1P74-50	ARCHITECT Folate Manual Diluent
1P74-01	ARCHITECT Folate Calibrators
1P74-10	ARCHITECT Folate Controls
2P40-25	ARCHITECT LH Reagent Kit
2P40-35	ARCHITECT LH Reagent Kit
2P40-01	ARCHITECT LH Calibrators
3P21-60	Folate Lysis Reagent
3P25-25	ARCHITECT STAT High Sensitive Troponin-I Reagent Kit
3P25-35	ARCHITECT STAT High Sensitive Troponin-I Reagent Kit
3P25-26	ARCHITECT STAT High Sensitive Troponin-I Reagent Kit
3P25-36	ARCHITECT STAT High Sensitive Troponin-I Reagent Kit
3P25-27	ARCHITECT STAT High Sensitive Troponin-I Reagent Kit
3P25-37	ARCHITECT STAT High Sensitive Troponin-I Reagent Kit
3P25-10	ARCHITECT STAT High Sensitive Troponin I Controls
3P25-01	ARCHITECT STAT High Sensitive Troponin I Calibrators
3P25-11	ARCHITECT STAT High Sensitive Troponin I Controls
3P25-02	ARCHITECT STAT High Sensitive Troponin I Calibrators
03P6824	Magnesium
03P6834	Magnesium
04S8920	Amylase2
04S9220	Cholesterol2
04S9230	Cholesterol2
04S9520	Creatinine2
04T1220	Urea Nitrogen2
04T1230	Urea Nitrogen2
04T1320	Uric Acid2
04T1330	Uric Acid2
04T3420	Albumin BCG2
04T3430	Albumin BCG2
04T8120	Total Protein2
04T8130	Total Protein2
04T8220	Albumin BCP2
04T8230	Albumin BCP2
04T8520	Amylase2
04T8820	Cholesterol2
04T8830	Cholesterol2
04U0920	Uric Acid2
04U0930	Uric Acid2

04U3020	Albumin BCG2
04U3030	Albumin BCG2
04U4420	Total Protein2
04U4430	Total Protein2
04U4520	Albumin BCP2
04U4530	Albumin BCP2
04V1501	Consolidated Chemistry Calibrator
04V6201	Consolidated Chemistry Calibrator
5P02-25	ARCHITECT 25-OH Vitamin D Reagent Kit
5P02-30	ARCHITECT 25-OH Vitamin D Reagent Kit
5P02-35	ARCHITECT 25-OH Vitamin D Reagent Kit
5P02-01	ARCHITECT 25-OH Vitamin D Calibrator Kit
5P02-10	ARCHITECT 25-OH Vitamin D Controls
7K59-20	ARCHITECT Ferritin Reagent Kit
7K59-25	ARCHITECT Ferritin Reagent Kit
7K59-30	ARCHITECT Ferritin Reagent Kit
7K59-35	ARCHITECT Ferritin Reagent Kit
7K59-01	ARCHITECT Ferritin Calibrators
7K59-10	ARCHITECT Ferritin Controls
7K61-25	ARCHITECT B12 Reagent Kit
7K61-35	ARCHITECT B12 Reagent Kit
7K61-01	ARCHITECT B12 Calibrators
7K61-10	ARCHITECT B12 Controls
7K62-20	ARCHITECT TSH Reagent Kit
7K62-25	ARCHITECT TSH Reagent Kit
7K62-30	ARCHITECT TSH Reagent Kit
7K62-35	ARCHITECT TSH Reagent Kit
7K62-01	ARCHITECT TSH Calibrators
7K62-10	ARCHITECT TSH Controls
7K63-20	ARCHITECT Free T3 Reagent Kit
7K63-25	ARCHITECT Free T3 Reagent Kit
7K63-30	ARCHITECT Free T3 Reagent Kit
7K63-35	ARCHITECT Free T3 Reagent Kit
7K63-01	ARCHITECT Free T3 Calibrators
7K63-10	ARCHITECT Free T3 Controls
7K63-27	ARCHITECT Free T3 Reagent Kit
7K63-32	ARCHITECT Free T3 Reagent Kit
7K63-37	ARCHITECT Free T3 Reagent Kit
7K63-02	ARCHITECT Free T3 Calibrators
7K63-12	ARCHITECT Free T3 Controls
7K64-20	ARCHITECT Total T3 Reagent Kit
7K64-25	ARCHITECT Total T3 Reagent Kit
7K64-30	ARCHITECT Total T3 Reagent Kit
7K64-35	ARCHITECT Total T3 Reagent Kit
7K64-01	ARCHITECT Total T3 Calibrators
7K64-50	ARCHITECT Total T3 Manual Diluent
7K64-27	ARCHITECT Total T3 Reagent Kit
7K64-32	ARCHITECT Total T3 Reagent Kit
7K64-37	ARCHITECT Total T3 Reagent Kit
7K64-02	ARCHITECT Total T3 Calibrators
7K65-20	ARCHITECT Free T4 Reagent Kit
7K65-25	ARCHITECT Free T4 Reagent Kit

7K65-30
7K65-01
7K65-10
7K65-22
7K65-27
7K65-32
7K65-35
7K65-02
7K65-24
7K65-29
7K65-34
7K65-39
7K66-20
7K66-25
7K66-27
7K66-30
7K66-32
7K66-35
7K66-37
7K66-01
7K66-02
7K66-10
7K66-12
7K72-20
7K72-25
7K72-35
7K72-01
7K72-10
7K72-50
7K73-20
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7K75-30
7K75-35
7K75-01
7K75-10
7K76-20
7K76-25
7K76-30
7K76-35
7K76-01
7K76-10
7K77-20
7K77-25
7K77-35
7K77-01
7K77-10
7K77-50

ARCHITECT Free T4 Reagent Kit
ARCHITECT Free T4 Calibrator
ARCHITECT Free T4 Controls
ARCHITECT Free T4 Reagent Kit
ARCHITECT Free T4 Reagent Kit
ARCHITECT Free T4 Reagent Kit
ARCHITECT Free T4 Reagent Kit
ARCHITECT Free T4 Calibrator
ARCHITECT Free T4 Reagent Kit
ARCHITECT Free T4 Reagent Kit
ARCHITECT Free T4 Reagent Kit
ARCHITECT Free T4 Reagent Kit
ARCHITECT Free T4 Reagent Kit
ARCHITECT Total T4 Reagent Kit
ARCHITECT Total T4 Reagent Kit
ARCHITECT Total T4 Reagent Kit
ARCHITECT Total T4 Reagent Kit
ARCHITECT Total T4 Reagent Kit
ARCHITECT Total T4 Reagent Kit
ARCHITECT Total T4 Calibrators
ARCHITECT Total T4 Calibrators
ARCHITECT Total T4 Controls
ARCHITECT Total T4 Controls
ARCHITECT Estradiol Reagent Kit
ARCHITECT Estradiol Reagent Kit
ARCHITECT Estradiol Reagent Kit
ARCHITECT Estradiol Calibrators
ARCHITECT Estradiol Controls
ARCHITECT Estradiol Manual Diluent
ARCHITECT Testosterone Reagent Kit
ARCHITECT Testosterone Reagent Kit
ARCHITECT Testosterone Calibrators
ARCHITECT Testosterone Control
ARCHITECT Testosterone Manual Diluent
ARCHITECT FSH Reagent Kit
ARCHITECT FSH Reagent Kit
ARCHITECT FSH Reagent Kit
ARCHITECT FSH Reagent Kit
ARCHITECT FSH Calibrators
ARCHITECT FSH Controls
ARCHITECT Prolactin Reagent Kit
ARCHITECT Prolactin Reagent Kit
ARCHITECT Prolactin Reagent Kit
ARCHITECT Prolactin Reagent Kit
ARCHITECT Prolactin Calibrators
ARCHITECT Prolactin Controls
ARCHITECT Progesterone Reagent Kit
ARCHITECT Progesterone Reagent Kit
ARCHITECT Progesterone Reagent Kit
ARCHITECT Progesterone Calibrators
ARCHITECT Progesterone Controls
ARCHITECT Progesterone Manual Diluent

7K78-20	ARCHITECT β -HCG Reagent Kit
7K78-25	ARCHITECT β -HCG Reagent Kit
7K78-30	ARCHITECT β -HCG Reagent Kit
7K78-35	ARCHITECT β -HCG Reagent Kit
7K78-01	ARCHITECT β -HCG Calibrators
7K78-10	ARCHITECT β -HCG Controls
07P4820	Alinity i TSH Reagent Kit
07P4830	Alinity i TSH Reagent Kit
07P4801	Alinity,i TSH Calibrators
07P4810	Alinity i TSH Controls
07P4920	Alinity i FSH Reagent Kit
07P4930	Alinity i FSH Reagent Kit
07P4901	Alinity i FSH Calibrators
07P4910	Alinity i FSH Controls
07P5020	Alinity i Estradiol Reagent Kit
07P5030	Alinity i Estradiol Reagent Kit
07P5001	Alinity i Estradiol Calibrators
07P5010	Alinity i Estradiol Control
07P5040	Alinity i Estradiol Manual Diluent
07P5120	Alinity i Total β -hCG Reagent Kit
07P5130	Alinity i Total β -hCG Reagent Kit
07P5101	Alinity i Total β -hCG Calibrators
07P5110	Alinity i Total β -hCG Controls
07P6520	Alinity i Ferritin Reagent Kit
07P6530	Alinity i Ferritin Reagent Kit
07P6501	Alinity i Ferritin Calibrators
07P6510	Alinity i Ferritin Controls
07P6620	Alinity i Prolactin Reagent Kit
07P6630	Alinity i Prolactin Reagent Kit
07P6601	Alinity i Prolactin Calibrators
07P6610	Alinity i Prolactin Controls
07P6722	Alinity i B12 Regent Kit
07P6732	Alinity i B12 Reagent Kit
07P6701	Alinity i B12 Calibrators
07P6710	Alinity i B12 Controls
07P6920	Alinity i Free T3 Reagent Kit
07P6930	Alinity i Free T3 Reagent Kit
07P6901	Alinity i Free T3 Calibrators
07P6910	Alinity i Free T3 Controls
07P7020	Alinity i Free T4 Reagent Kit
07P7030	Alinity i Free T4 Reagent Kit
07P7001	Alinity i Free T4 Calibrators
07P7010	Alinity i Free T4 Controls
07P9120	Alinity i LH Reagent kit
07P9130	Alinity i LH Reagent Kit
07P9101	Alinity i LH Calibrators
07P9420	Alinity i Total T3 Regent Kit
07P9430	Alinity i Total T3 Reagent Kit
07P9401	Alinity i Total T3 Calibrators
07P9440	Alinity i Total T3 Manual Diluent
07P9520	Alinity i Total T4 Reagent Kit
07P9530	Alinity i Total T4 Reagent Kit

07P9501
07P9510
08G6624
08L9124
08L9144
08P1322
08P1324
08P1332
08P1334
08P1327
08P1337
08P1301
08P1310
08P1422
08P1432
08P1440
08P1460
08P1401
08P1410
08P1542
08P1925
08P1934
08P2324
08P3620
08P3630
08P3601
08P3610
08P3640
08P3824
08P4522
08P4532
08P4501
08P4510
09D9124
09D9224
09D9324
09D9624
09D9724
09D9824
09D9924
09P2920
09P2901
09P2910
09P4624
09P4724
09P5624
09P5724
09P5924
09P6124
09P6224
09P6324
09P8624

Alinity i Total T4 Calibrators
Alinity i Total T4 Controls
Rheumatoid Factor
Activated Aspartate Aminotransferase
Activated Aspartate Aminotransferase
Alinity i STAT High Sensitive Troponin-I Reagent Kit
Alinity i STAT High Sensitive Troponin-I Reagent Kit
Alinity i STAT High Sensitive Troponin-I Reagent Kit
Alinity i STAT High Sensitive Troponin-I Reagent Kit
Alinity i STAT High Sensitive Troponin-I Reagent Kit
Alinity i STAT High Sensitive Troponin-I Reagent Kit
Alinity i STAT High Sensitive Troponin I Calibrators
Alinity i STAT High Sensitive Troponin I Controls
Alinity i Folate Reagent Kit
Alinity i Folate Reagent Kit
Alinity i Folate RBC Lysis Diluent
Alinity i Folate Manual Diluent
Alinity i Folate Calibrators
Alinity i Folate Controls
Alinity i Folate Lysis Reagent
Magnesium
Magnesium
Activated Aspartate Aminotransferase
Alinity i Progesterone Reagent Kit
Alinity i Progesterone Reagent kit
Alinity i Progesterone Calibrators
Alinity i Progesterone Controls
Alinity i Progesterone Manual Diluent
Transferrin
Alinity i 25-OH Vitamin D Reagent Kit
Alinity i 25 OH Vitamin D Reagent Kit
Alinity i 25 OH Vitamin D Calibrators
Alinity i 25 OH Vitamin D Controls
Haptoglobin
Apolipoprotein A1
Apolipoprotein B
Complement C3
Complement C4
Immunoglobulin A
Immunoglobulin G
Alinity i Urine NGAL Reagent kit
Alinity i Urine NGAL Calibrators
Alinity i Urine NGAL Controls
Apolipoprotein A1
Apolipoprotein B
Complement C3
Complement C4
Haptoglobin
Immunoglobulin A
Immunoglobulin G
Immunoglobulin M
Prealbumin