



13<sup>th</sup> August 2020

## 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 diagnostic 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  
TTBYT**

**Expiry Date:** 13<sup>th</sup> August 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 **14/ 09/ 2020**  
at the
7. Cơ quan cấp: **Đại sứ quán Việt Nam tại VQ Anh và CH Ai-len**  
by
8. Số: **3333**  
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 DO

Date 07/09/2020



## MEDICAL DEVICE SCHEDULE

Item Number/Product Code	Description of Device
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
04T1220	Urea Nitrogen2
04T1230	Urea Nitrogen2
04T3420	Albumin BCG2
04T3430	Albumin BCG2
04U4420	Total Protein2
04U4430	Total Protein2
04V1501	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

## MEDICAL DEVICE SCHEDULE

Item Number/Product Code	Description of Device
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	ARCHITECT Free T4 Reagent Kit
7K65-01	ARCHITECT Free T4 Calibrator
7K65-10	ARCHITECT Free T4 Controls
7K65-22	ARCHITECT Free T4 Reagent Kit
7K65-27	ARCHITECT Free T4 Reagent Kit
7K65-32	ARCHITECT Free T4 Reagent Kit
7K65-35	ARCHITECT Free T4 Reagent Kit
7K65-02	ARCHITECT Free T4 Calibrator
7K65-24	ARCHITECT Free T4 Reagent Kit
7K65-29	ARCHITECT Free T4 Reagent Kit

## MEDICAL DEVICE SCHEDULE

Item Number/Product Code	Description of Device
7K65-34	ARCHITECT Free T4 Reagent Kit
7K65-39	ARCHITECT Free T4 Reagent Kit
7K66-20	ARCHITECT Total T4 Reagent Kit
7K66-25	ARCHITECT Total T4 Reagent Kit
7K66-27	ARCHITECT Total T4 Reagent Kit
7K66-30	ARCHITECT Total T4 Reagent Kit
7K66-32	ARCHITECT Total T4 Reagent Kit
7K66-35	ARCHITECT Total T4 Reagent Kit
7K66-37	ARCHITECT Total T4 Reagent Kit
7K66-01	ARCHITECT Total T4 Calibrators
7K66-02	ARCHITECT Total T4 Calibrators
7K66-10	ARCHITECT Total T4 Controls
7K66-12	ARCHITECT Total T4 Controls
7K72-20	ARCHITECT Estradiol Reagent Kit
7K72-25	ARCHITECT Estradiol Reagent Kit
7K72-35	ARCHITECT Estradiol Reagent Kit
7K72-01	ARCHITECT Estradiol Calibrators
7K72-10	ARCHITECT Estradiol Controls
7K72-50	ARCHITECT Estradiol Manual Diluent
7K73-20	ARCHITECT Testosterone Reagent Kit
7K73-25	ARCHITECT Testosterone Reagent Kit
7K73-01	ARCHITECT Testosterone Calibrators
7K73-10	ARCHITECT Testosterone Control
7K73-50	ARCHITECT Testosterone Manual Diluent
7K75-20	ARCHITECT FSH Reagent Kit
7K75-25	ARCHITECT FSH Reagent Kit
7K75-30	ARCHITECT FSH Reagent Kit
7K75-35	ARCHITECT FSH Reagent Kit
7K75-01	ARCHITECT FSH Calibrators
7K75-10	ARCHITECT FSH Controls
7K76-20	ARCHITECT Prolactin Reagent Kit
7K76-25	ARCHITECT Prolactin Reagent Kit
7K76-30	ARCHITECT Prolactin Reagent Kit
7K76-35	ARCHITECT Prolactin Reagent Kit
7K76-01	ARCHITECT Prolactin Calibrators
7K76-10	ARCHITECT Prolactin Controls
7K77-20	ARCHITECT Progesterone Reagent Kit
7K77-25	ARCHITECT Progesterone Reagent Kit
7K77-35	ARCHITECT Progesterone Reagent Kit
7K77-01	ARCHITECT Progesterone Calibrators
7K77-10	ARCHITECT Progesterone Controls
7K77-50	ARCHITECT Progesterone Manual Diluent
7K78-20	ARCHITECT $\beta$ -HCG Reagent Kit
7K78-25	ARCHITECT $\beta$ -HCG Reagent Kit
7K78-30	ARCHITECT $\beta$ -HCG Reagent Kit
7K78-35	ARCHITECT $\beta$ -HCG Reagent Kit

## MEDICAL DEVICE SCHEDULE

Item Number/Product Code	Description of Device
7K78-01	ARCHITECT $\beta$ -HCG Calibrators
7K78-10	ARCHITECT $\beta$ -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 $\beta$ -hCG Reagent Kit
07P5130	Alinity i Total $\beta$ -hCG Reagent Kit
07P5101	Alinity i Total $\beta$ -hCG Calibrators
07P5110	Alinity i Total $\beta$ -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

## MEDICAL DEVICE SCHEDULE

<b>Item Number/Product Code</b>	<b>Description of Device</b>
07P9520	Alinity i Total T4 Reagent Kit
07P9530	Alinity i Total T4 Reagent Kit
07P9501	Alinity i Total T4 Calibrators
07P9510	Alinity i Total T4 Controls
08P1322	Alinity i STAT High Sensitive Troponin-I Reagent Kit
08P1324	Alinity i STAT High Sensitive Troponin-I Reagent Kit
08P1332	Alinity i STAT High Sensitive Troponin-I Reagent Kit
08P1334	Alinity i STAT High Sensitive Troponin-I Reagent Kit
08P1301	Alinity i STAT High Sensitive Troponin I Calibrators
08P1310	Alinity i STAT High Sensitive Troponin I Controls
08P1422	Alinity i Folate Reagent Kit
08P1432	Alinity i Folate Reagent Kit
08P1440	Alinity i Folate RBC Lysis Diluent
08P1460	Alinity i Folate Manual Diluent
08P1401	Alinity i Folate Calibrators
08P1410	Alinity i Folate Controls
08P1542	Alinity i Folate Lysis Reagent
08P1925	Magnesium
08P1934	Magnesium
08P3620	Alinity i Progesterone Reagent Kit
08P3630	Alinity i Progesterone Reagent kit
08P3601	Alinity i Progesterone Calibrators
08P3610	Alinity i Progesterone Controls
08P3640	Alinity i Progesterone Manual Diluent
08P3824	Transferrin
08P4522	Alinity i 25-OH Vitamin D Reagent Kit
08P4532	Alinity i 25 OH Vitamin D Reagent Kit
08P4501	Alinity i 25 OH Vitamin D Calibrators
08P4510	Alinity i 25 OH Vitamin D Controls
09P2920	Alinity i Urine NGAL Reagent kit
09P2901	Alinity i Urine NGAL Calibrators
09P2910	Alinity i Urine NGAL Controls