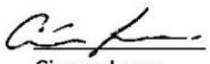
Declaration Regarding the Manufacture and Use of In-house Devices- Version 2.0			
Name of the Health Institution	Tallaght University Hospital [**HPRA Reference: CRN00H8RK**]		
Address	Belgard Road, Tallaght, Dublin 24, D24NR0A		
The devices described in this document are only manufactured and used in the health institution named above. They meet the applicable general safety and performance requirements (GSPR) of the in vitro diagnostic medical devices Regulation (EU 2017/746). A reasoned justification is provided where applicable general safety and performance requirements are not met.			
Declaration Completed By:			
Name:	Ciaran Love	**Name:**	Dr Ronan Desmond
Role:	Laboratory Manager	**Role:**	Laboratory Director
Signature:		**Signature:**	
Date:	13.05.2026	**Date:**	13.05.2026

Type	Discipline	Device indentification(e.g. name, description, UDI number)	Device Type(IVD/MD)	Risk Class of the Device	Manufacturer intended use as per CE mark (if applicable)	Intended use in Tallaght University Hospital	Information on, and justification for,application GSPR that are not fully met
Reagent	Blood Transfusion	NBS antibody panel (BioVue Cassettes)	IVD	Class C	Antibody investigation/ Identification	In house method - exclusion cells as part of antibody investigation	Used in BioVue technology (IFU states tube use only). In house method validation complete. IQC, EQA in place. Not used a primary panel, exclusion cells only.
Reagent	Blood Transfusion	Grifols D Weak Control Cells (Tube method)	IVD	Class D	Verification of RhD typing	In-house method - used for investigation of weak RhD reactions	IFU recommends use of Grifols tube test antisera. Testing in-house is performed using a third party antisera (same clones as recommended antisera - anti-D RUM1 And MS201). In-house method validation completed. IQC, EQA in place. All suspected weak D's are referred to the National Blood Centre for confirmation.

Equipment \Software	Blood Transfusion	Electronic Issue of Red Cells using WinPath Software	IVD	Class D	Laboratory Information System (WinPath) not CE marked by supplier.	Electronic Issue of Red Cells using WinPath Software	Not marked as an IVD by the supplier (Clinisys). LIMS validated, Electronic issue assessed and accredited by INAB. Manual checks and interpretations performed by medical scientist throughout each process. Automated blood grouping analyser will hold uninterpretable results.
Equipment	Blood Transfusion	Cold Room (custom build)	IVD	Class A	Fridge cooling unit	Blood stock fridge - storage of blood and blood products	Fridge/cold room is custom build (no overall CE mark, cooling unit is CE certified). Equipment validation complete. Temperature monitoring system, maintenance and calibration schedule in place. Assessed by INAB.
	Haematology	Haematology;Iron Stain	IVD	Class C		The purpose is to stain bone marrow cells for microscopical examination. Commercial control material unavailable; Positive control slides sourced from Histopathology (liver sections) Laboratory	Commercial control material unavailable.

						Consultants confirm correct staining pattern observed	
	Haematology	Haematology; RPMI Heparin Solution (Sample Collection Media)	IVD	Class C		In House prepared media for preservation of sample material (Bone marrow aspirates and CSF specimens for immunophenotyping analysis)	
	Haematology	Haematology; BD FACS Cants II used for Haematological Immunophenotyping Acute Leukaemia Panel Chronic Lymphoproliferative Panel CSF Immunophenotyping PNH (Paroxysmal Nocturnal Haemoglobinuria) analysis by flow cytometry	IVD	Class C		The diagnosis and monitoring of haematological malignancies & disorders.	Justification for use: BD FACS Canto II is CE Marked, IVDR was introduced after purchase of equipment. For antibody panels- IVDR compliant antibodies are used where commercially available but some antibodies are marked RUO, there are currently no IVDR compliant versions commercially available, and the antibodies are critical for diagnosis and monitoring of haematological malignancies & disorders.

	Microbiology	Microbiology; Testing respiratory samples for MTB and MTB Rif resistance using GeneXpert and Xpert MTB/RIF Ultra	IVD/CE Marked	Class D	To detect M.tuberculosis complex and Rifampicin resistance	Used as manufacture intended. Occasionally used to test unvalidated specimens. Non CE marked controls used	Unvalidated specimens are not reported. Adjunct IQC only (manufacturers IVDR controls in use also), not used for primary diagnostic decisions. CE mark process is in progress with Zeptometrix
	Microbiology	Microbiology; Investigation of specimens for Mycobacterium Species on the MGIT culture system	IVD/CE Marked	Class D	To investigate sputum and BAL specimens for the presence of Mycobacterium species.	To investigate specimens for the presence of Mycobacterium species. Non validated samples types also tested.	No validated method for testing of specimen types other than sputa nad BAL's. IVDR status unknown. Company has been contacted.
	Microbiology	Microbiology; Testing CSF samples for the N. meningitis using Biofire Film Array and ME Panel	IVD/CE Marked	Class C	To detect N. meningitis, CMV and other pathogens	Used as manufacture intended. Non CE marked controls used.	Adjunct IQC only (manufacturers IVDR controls in use also), not used for primary diagnostic decisions. CE mark process is in progress with Zeptometrix
	Microbiology	Broths used for enrichment or dilution of Microorganisms. Liquid Media: Nutrient broths, Tryptic Soya Broth (TSB), Saline 0.9%, Nutrient agar slopes.	Not CE marked	Class A	Enrichment and dilution broths/agar used to support the growth of Microorganisms	Enrichment and dilution broths/agar used to support the growth of Microorganisms	No CE marked options available.

	Microbiology	Protect Microorganism Preservation system	Not CE marked	Class A	To store/freeze bacterial isolates and strains	To store/freeze bacterial isolates and strains- no change from manufacturer's instructions.	No CE marked options available.
Reagent	Clinical Chemistry	Roche Creatine Kinase (application number 8057 on c702)	IVD/CE Marked	Class C	In vitro test for the quantitative determination of creatine kinase (CK) in human serum and plasma on the COBAS 8000 systems (c702 module).	As per Manufacturer intended use as per CE mark (if applicable) and occasionally to analyse samples above the measuring range quoted by manufacturer.	Not for dilutions above 22,000 U/L. Dilutions performed above the extended technical limit. Diluted value of Clinical benefit.
Reagent	Clinical Chemistry	Roche Alpha1-fetoprotein (AFP, application number 10209 on e801)	IVD/CE Marked	Class C	Immunoassay for the in vitro quantitativedetermination of CA Alpha1 fetoprotein inhuman serum and plasma on COBAS 8000 (e801 module).	As per Manufacturer intended use as per CE mark (if applicable) and occasionally to analyse samples above the measuring range quoted by manufacturer.	Not for dilutions above 50,000 IU/mL.Dilutions performed above the extended technical limit.Diluted value of Clinical benefit.

Reagent	Clinical Chemistry	Roche CA 125 (application number 10018 on e801)	IVD/CE Marked	Class C	Immunoassay for the in vitro quantitative determination of CA 125 in human serum and plasma on COBAS 8000 (e801 module).	As per Manufacturer intended use as per CE mark (if applicable) and occasionally to analyse samples above the measuring range quoted by manufacturer.	Not for dilutions above 25,000 U/mL. Dilutions performed above the extended technical limit. Diluted value of Clinical benefit.
Reagent	Clinical Chemistry	Roche CA 19-9 (application number 10019 on e801)	IVD/CE Marked	Class C	Immunoassay for the in vitro quantitative determination of CA 19-9 in human serum and plasma on COBAS 8000 (e801 module).	As per Manufacturer intended use as per CE mark (if applicable) and occasionally to analyse samples above the measuring range quoted by manufacturer.	Not for dilutions above 10,000 U/mL. Dilutions performed above the extended technical limit. Diluted value of Clinical benefit.
Reagent	Clinical Chemistry	Roche CA15-3 (application number 10002 on e801)	IVD/CE Marked	Class C	Immunoassay for the in vitro quantitative determination of CA15-3 in human serum and plasma on COBAS 8000 (e801 module).	As per Manufacturer intended use as per CE mark (if applicable) and occasionally to analyse samples above the measuring range quoted by manufacturer.	Not for dilutions above 3,000 U/mL. Dilutions performed above the extended technical limit. Diluted value of Clinical benefit.

Reagent	Clinical Chemistry	Roche Human Chorionic Gonadotropin (hCG) (application number 10072 on e801)	IVD/CE Marked	Class C	Immunoassay for the in vitro quantitative determination of HCG producing tumour cells in human serum and plasma on COBAS 8000 (e801 module).	As per Manufacturer intended use as per CE mark (if applicable) and occasionally to analyse samples above the measuring range quoted by manufacturer.	Not for dilutions above 1,000,000 mIU/mL. Dilutions performed above the extended technical limit. Diluted value of Clinical benefit.
Reagent	Clinical Chemistry	Roche Carcinoembryonic antigen (CEA application number 10003 on e801)	IVD/CE Marked	Class C	Immunoassay for the in vitro quantitative determination of carcinoembryonic antigen (CEA) in human serum and plasma.	As per Manufacturer intended use as per CE mark (if applicable) and occasionally to analyse samples above the measuring range quoted by manufacturer.	Not for dilutions above 50,000 ng/mL. Dilutions performed above the extended technical limit. Diluted value of Clinical benefit.
Reagent	Clinical Chemistry	Fluid analysis on Roche c702: Albumin, Amylase, Creatinine, Glucose, LDH, Total Protein, Triglycerides, Urea	IVD/CE Marked	Class C	Sample type Fluid not validated	Unvalidated sample type (fluid) used for analysis of some tests.	Parameters measured in fluid samples can give clinicians additional information when compared to the values obtained in serum or plasma which can be used to diagnose some diseases. These tests are essential for patient care. There is currently no CE alternative available.

Reagent	Clinical Chemistry	CEA Fluid analysis (Roche e801)	IVD/CE Marked	Class C	Sample type Fluid not validated	Unvalidated sample type (fluid) used for analysis.	Parameters measured in fluid samples can give clinicians additional information when compared to the values obtained in serum or plasma which can be used to diagnose some diseases. This test is essential for patient care. There is currently no CE alternative available.
Reagent	Clinical Chemistry	Cryoglobulins	IVD/CE Marked	Class C	Sample type: Serum tube Used in the diagnosis and monitoring of patients with suspected Cryoglobulinaemia	Non CE marked cryoglobulin tubes used.	This test is essential for patient care. There is currently no CE alternative available.
Reagent	Clinical Chemistry	Aluminium (plasma) Varian	IVD/CE Marked	Class C	Measurement of Aluminium using graphite furnace Atomic Absorption Spectrometry.	In-house developed method	This test is essential for patient care. In house developed method using commercially supplied standards.
Reagent	Clinical Chemistry	Copper (plasma) Nexion 2000	IVD/CE Marked	Class C	Measurement of plasma copper on the NexION 2000 using Inductively Coupled Plasma Mass Spectrometry (ICPMS).	In-house developed method	This test is essential for patient care. In house developed method using commercially supplied standards.
Reagent	Clinical Chemistry	Zinc (plasma) ICPMS Nexion 2000	IVD/CE Marked	Class C	Measurement of plasma zinc on the NexION 2000 using Inductively Coupled Plasma Mass Spectrometry (ICPMS).	In-house developed method	This test is essential for patient care. In house developed method using commercially supplied standards.

Reagent	Clinical Chemistry	Copper (urine) Varian AA	IVD/CE Marked	Class C	Measurement of urine Copper using graphite furnace Atomic Absorption Spectrometry.	In-house developed method	This test is essential for patient care. In house developed method using commercially supplied standards.
Equipment	Clinical Chemistry	pH fluid (Radiometer ABL90)	IVD\CE marked	Class C	Sample type Fluid not validated for use on Radiometer ABL90	Unvalidated sample type used for analysis of pH in fluid.	Parameters measured in fluid samples can give clinicians additional information when compared to the values obtained in serum or plasma which can be used to diagnose some diseases. This test is essential for patient care. There is currently no CE alternative available.
	Cellular Pathology	Caldesmon	IVD/CE Marked	Class C	Immunohistochemical staining of Caldesmon protein involved in the classification of tumors with smooth muscle cell differentiation.	As stated in Manufacturer intended use as per CE mark for immunohistochemistry. However, it is recommended on a different staining platform (EnVision FLEX autostainer platform)	This test is essential for patient care. In house developed method using a Ventana Ultra staining module..

	Cellular Pathology	CMV (RUO)	RUO	Class C	Immunohistochemical staining for detection of Human cytomegalovirus (Human herpesvirus 5). Research use only.	As stated in manufacturer IFU but for patient diagnostics (not research)	This test is essential for patient care. In house developed method using commercially supplied standards. There is currently no CE alternative available.
	Cellular Pathology	MLH1	IVD/CE Marked	Class C	Human MutL Protein Homolog 1 (MLH1) for detecting MLH1 protein in tumors of the gastrointestinal tract.	As stated in Manufacturer intended use as per CE mark for immunohistochemistry. However, it is recommended on a different staining platform (EnVision FLEX autostainer platform)	This test is essential for patient care. In house developed method using a Ventana Ultra staining module.
	Cellular Pathology	OR	IVD/CE Marked	Class C	Immunohistochemical staining for detection of Oestrogen receptor	As stated in Manufacturer intended use as per CE mark for immunohistochemistry. However, it is recommended with a different staining kit (iView or Ultraview DAB kit)	This test is essential for patient care. In house developed method using OptiView DAB kit. Test is used for site specification and not for prognostic purposes

	Cellular Pathology	PMS2	IVD/CE Marked	Class C	Immunohistochemical staining for detection of PMS1 homolog 2, that encodes a protein essential for DNA mismatch repair (MMR)	As stated in Manufacturer intended use as per CE mark for immunohistochemistry. However, it is recommended on a different staining platform (EnVision FLEX autostainer platform)	This test is essential for patient care. In house developed method using a Ventana Ultra staining module..
	Cellular Pathology	TdT	IVD/CE Marked	Class C	Immunohistochemical staining for detection of Terminal deoxynucleotidyl transferase, a diagnostic marker for identifying pre-B and pre-T acute lymphoblastic leukemia/lymphoblastic lymphoma (ALL/LBL	As stated in Manufacturer intended use as per CE mark for immunohistochemistry. However, it is recommended on a different staining platform (EnVision FLEX autostainer platform)	This test is essential for patient care. In house developed method using a Ventana Ultra staining module..
	Cellular Pathology	IHC Double stains: CD31/CH, CD31/KR, DES/KR, D2-40/KR, D2-40/MEL, MIB/MEL, PAX8/CAIX, P63/NAPSIN, P63/AMACR,	IVD/CE Marked	Class C	Individual antibodies and kits are CE marked	To visualise two antibodies on the same slide, conserving tissue, and enabling easier identification of metastases	No other suitable option available

		S100/KR, TF/CK5,6, K/LLCP					
	Cellular Pathology	Frozen H&E stain	IVD/CE Marked	Class C	H&E staining	Rapid diagnosis of frozen tissue samples for intraoperative frozen section or DIF	No other suitable option available, method is validated and EQA is in place
	Cellular Pathology	Histochemical stains: Miller Elastic PAS/DPAS Shikata Orcein	IVD/CE Marked	Class C	Manual special histochemical stains used for the identification and visualisation of specific structures and/or material which cannot be identified using the H&E stain	Manual special histochemical stains used for the identification and visualisation of specific structures and/or material which cannot be identified using the H&E stain	Manual stains, method modified, methods are validated and EQA is in place
	Cellular Pathology	Hanks balanced salt solution	RUO	Class C	N/A	Preparation of non-gynae fluid samples for cytopathology	No CE marked Hanks solution available
	Cellular Pathology	Nigrosin stain	N/A	Class C	N/A	Background colour for sperm vitality stain	No CE marked alternative available