PUBLIC DECLARATION REGARDING THE MANUFACTURE AND USE OF IN-HOUSE DEVICES BY CORK UNIVERSITY HOSPITAL

Name of Health institution: Cork University Hospital for Laboratory Medicine

Address: Cork University Hospital, Wilton, Cork

- The health institution declares that the devices described in the accompanying table are only manufactured and used in Cork University Hospital and do meet the applicable general safety and performance requirements (GSPR) of the medical devices regulation (EU 2017/745) or of the in vitro diagnostic medical devices regulation (EU 2017/746). A reasoned justification is provided in case applicable general safety and performance requirements are not fully met.

Name, function and signature of responsible person(s):

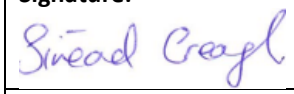
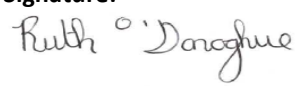
Name: Sinead Creagh	**Name: Ruth O'Donoghue**
Role: Laboratory Manager	**Role: Quality Officer**
Signature: 	**Signature:** 
Date: 19/07/2024	**Date: 19/07/2024**

Table of in-house device

Immunohistochemistry			
Device Identification (i.e. name, description)	**Device Type (IVD/MD)**	**Risk class[1] of the device**	**Intended purpose**
Name: **Bap-1 antibody** Description: RUO	IVD	C	Used on the automated Ventana Benchmark Ultra Immunostainer. Used as an aid in the diagnosis of Malignant Mesotheliomas on Formalin Fixed Paraffin Embedded (FFPE) Blocks. It can also be useful in skin lesions, in particular uveal melanomas. In uveal melanoma Bap-1 is used to evaluate metastatic risk for the patient.
Name: **Sars-CoV-2** Description: RUO	IVD	C	Used on the automated Ventana Benchmark Ultra Immunostainer. SARS COV-2 antibody is an antibody to aid in the identification of SARS COVID spike and spike proteins in diagnostic tissue. It is used as an aid in the diagnosis of Covid placentitis on Formalin Fixed Paraffin Embedded (FFPE) Blocks.
Name: **PRAME** Description: RUO	IVD	C	Used on the automated Ventana Benchmark Ultra Immunostainer. PRAME is a Melanoma marker which is used in the diagnosis of challenging melanocytic lesions particularly in discriminating severely dysplastic naevi from progression to Melamoma In Situ (MIS) on Formalin Fixed Paraffin Embedded (FFPE) Blocks.
Name: **IgG4** Description: RUO	IVD	C	Used on the automated Ventana Benchmark Ultra Immunostainer. IgG4 aids in the identification of plasma cells on Formalin Fixed Paraffin Embedded (FFPE) Blocks.

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Name: **Arginase** Description: RUO	IVD	C	Used on the automated Ventana Benchmark Ultra Immunostainer. Arginase is used as an aid in the diagnosis of Hepatocellular Carcinoma on Formalin Fixed Paraffin Embedded (FFPE) Blocks.
Name: **Fox L2** Description: RUO	IVD	C	Used on the automated Ventana Benchmark Ultra Immunostainer. FoxL2 is used as an aid in the diagnosis of Ovarian Sex Cord Tumours including Granulosa Cell Tumours (GCT) and Fibromas on Formalin Fixed Paraffin Embedded (FFPE) Blocks.
Name: **PDL-1 on cytology Blocks** Description: Lab Developed Test	IVD	C	Used on the automated Ventana Benchmark Ultra Immunostainer. PDL-1 is used to identify PD-L1 expression in non-small cell lung cancer (NSCLC) on Formalin Fixed Cytology Cell Blocks.
Name: **HPV mRNA ISH** Description: Lab Developed Test	IVD	C	Used on the automated Ventana Benchmark Ultra Immunostainer. These non CE-IVD probes are used to aid in the identification of HPV 16, HPV18 and HPV33 mutations in Head and Neck Squamous Cell Carcinoma and Gynae Squamous Cell Carcinoma on Formalin Fixed Paraffin Embedded (FFPE) Blocks.
Name: **MSH2** Description: Lab Developed Test	IVD	C	Used on the automated Ventana Benchmark Ultra Immunostainer. Used on non-colorectal and non gynae tissue for the identification of mismatch repair protein status.
Name: **MSH6** Description: Lab Developed Test	IVD	C	Used on the automated Ventana Benchmark Ultra Immunostainer. Used on non-colorectal and non gynae tissue for the identification of mismatch repair protein status.
Name: **PMS2** Description: Lab Developed Test	IVD	C	Used on the automated Ventana Benchmark Ultra Immunostainer. Used on non-colorectal and non gynae tissue for the identification of mismatch repair protein status.
Name: **MLH1** Description: Lab Developed Test	IVD	C	Used on the automated Ventana Benchmark Ultra Immunostainer. Used on non-colorectal and non gynae

			tissue for the identification of mismatch repair protein status.
Name: **BRAF** Description: Lab Developed Test	IVD	C	Used on the automated Ventana Benchmark Ultra Immunostainer. Braf antibody is used identify Braf V600E mutation in Melanomas.
Name: **TTF1/P40** Description: Lab Developed Test	IVD	C	Used on the automated Ventana Benchmark Ultra Immunostainer. Dual stain used to aid in the differentiation of adenocarcinoma and SCC of the lung.
Name: **Ki-67/Mel-A** Description: Lab Developed Test	IVD	C	Used on the automated Ventana Benchmark Ultra Immunostainer. Dual stain used to aid in the diagnosis of melanocytic lesions.
Name: **CD8** Description: Lab Developed Test	IVD	C	Leica Ready to use antibody used on the automated Ventana Benchmark Ultra Immunostainer. CD8 is used to identify T cells on Formalin Fixed Paraffin Embedded (FFPE) Blocks.
Name: **CD10** Description: Lab Developed Test	IVD	C	Leica Ready to use antibody used on the automated Ventana Benchmark Ultra Immunostainer. CD10 is used to identify B Cells on Formalin Fixed Paraffin Embedded (FFPE) Blocks.
Name: **CD68** Description: Lab Developed Test	IVD	C	Leica Ready to use antibody used on the automated Ventana Benchmark Ultra Immunostainer. CD68 is used to identify Macrophages on Formalin Fixed Paraffin Embedded (FFPE) Blocks.
Name: **Dog-1** Description: Lab Developed Test	IVD	C	Leica Ready to use antibody used on the automated Ventana Benchmark Ultra Immunostainer. Dog-1 is used to aid in the diagnosis of Gasto Intestinal Stromal Tumours (GIST) on Formalin Fixed Paraffin Embedded (FFPE) Blocks.
Name: **Napsin** Description: Lab Developed Test	IVD	C	Leica Ready to use antibody used on the automated Ventana Benchmark Ultra Immunostainer. Napsin is used to aid in the diagnosis of Lung Adenocarcinoma on Formalin Fixed Paraffin Embedded (FFPE) Blocks.
Name: **p501s** Description: Lab Developed Test	IVD	C	DAKO ready to use antibody used on the automated Ventana Benchmark Ultra Immunostainer. P501s is used to

			identify Prostate tissue on Formalin Fixed Paraffin Embedded (FFPE) Blocks.
Name: **Caldesmon** Description: Lab Developed Test	IVD	C	DAKO ready to use antibody used on the automated Ventana Benchmark Ultra Immunostainer. Caldesmon is used to identify smooth muscle cells on Formalin Fixed Paraffin Embedded (FFPE) Blocks.
Name: **Mum-1** Description: Lab Developed Test	IVD	C	DAKO ready to use antibody used on the automated Ventana Benchmark Ultra Immunostainer. Mum-1 is used to identify Plasma cells and some B cells on Formalin Fixed Paraffin Embedded (FFPE) Blocks.
Name: **Myogenin** Description: Lab Developed Test	IVD	C	DAKO ready to use antibody used on the automated Ventana Benchmark Ultra Immunostainer. Myogenin is used to aid in the diagnosis of Rhabdomyosarcoma on Formalin Fixed Paraffin Embedded (FFPE) Blocks.

Molecular

Device Identification (i.e. name, description)	Device Type (IVD/MD)	Risk class[1] of the device	Intended purpose
Name: **Oncomine Precision Assay (OPA) on the Ion Torrent Genexus CEIVD** Description: Assay RUO	IVD	C	The Oncomine Precision assay (OPA) is a panel run on the Ion Torrent™ Genexus™ Platform (CEIVD) it includes relevant targets for precision medicine; this 50 gene panel covers oncogenes, fusion genes, genes susceptible to copy number variation and tumour suppressors from formalin-fixed paraffin-embedded (FFPE) tissue or liquid biopsy specimens.
Name: **Genexus Purification Instrument (GPI)** Description: Assay RUO, Instrument RUO	IVD	C	The Ion Torrent™ Genexus™ Purification Instrument (GPI) automates the extraction of nucleic acids from various sample types, including: formalin-fixed, paraffin-embedded (FFPE) lysate, and plasma. The system has been validated for use with the Ion Torrent™ Genexus™ Integrated Sequencer System, it can be used in Stand Alone mode or as part of a Sample-to-Result workflow.
Name: **Oncomine** Reporter Description : Software	IVD	C	Utilising a source file generated from the Genexus assay (OPA) the Oncomine™ Reporter (OR) software matches genetic variant information with relevant data from a curated set of published evidence from public sources. The software is used to prepare a report that presents a sample-specific view of data with each variant matched with relevant data, including labels, guidelines, and potentially clinical trials.
Name: **IDH1/2** Description: Assay RUO	IVD	C	The Idylla™ IDH1-2 Mutation Assay Kit performed on the Biocartis Idylla™ System, is a fully automated in vitro

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			diagnostic assay for the qualitative detection of five IDH1 mutations in codon R132 (R132C/H/G/S/L), four IDH2 mutations in codon R140 (R140Q/L/G/W) and six IDH2 mutations in codon R172 (R172K/M/G/S/W).
Name: **NRAS/BRAF** Description: Assay IVD, used outside the IFU (Melanoma).	IVD	C	The Idylla™ NRAS-BRAF Mutation Assay performed on the Biocartis Idylla™ System is an assay for the qualitative detection of mutations in, codons 12, 13, 59, 61, 117, 146 of the NRAS gene and codon 600 of the BRAF gene. It is used in the differential diagnosis of melanoma.
Name: **Gene Fusion RUO (NTRK)** Description: Assay RUO	IVD	C	The Biocartis Idylla™ GeneFusion Panel is a fully automated in vitro diagnostic test intended for the qualitative detection of specific gene fusions of, ALK, ROS1, RET, MET exon 14 skipping and NTRK 1/2/3. The Idylla™ GeneFusion Panel is intended for use with formalin-fixed, paraffin embedded (FFPE) tumour tissue sections.

Neuropathology

Device Identification (i.e. name, description)	Device Type (IVD/MD)	Risk class[1] of the device	Intended purpose
Name: **Alpha-Synuclein** Description: RUO Leica NCL-L-ASYN	IVD	C	Antibody used to detect alpha-synuclein in the context of neuropathological diagnosis of dementia.
Name: **AT8 Tau** Description: RUO Imogenetics Bro3	IVD	C	Antibody used in the detection of pathological phosphorylated tau in Neurodegenerative disease.
Name: **Beta Amyloid Precursor Protein** Description: RUO Merck MAB348	IVD	C	Antibody used to demonstrate axonal pathology in the context of trauma and hypoxia.
Name: **Brachyury** Description: RUO Abcam ab20680	IVD	C	Antibody to Brachyury, a transcription factor expressed in chordomas
Name: **C5b-9** Description: RUO Thermo D1A0110102	IVD	C	Antibody used to demonstrate activation of complement mediated injury to muscle.
Name: **H3K27M** Description: RUO RevMab 31-1175-00	IVD	C	Antibody used in identification of H3K27M mutant midline tumours of the brain.
Name: **H3K27ME3** Description: RUO RevMab 31-1062-00	IVD	C	Antibody used to assess the presence of trimethylation of histone H3 gene.
Name: **INI1** Description: RUO BD 612110	IVD	C	INI1 (SMARCB1) may be lost (mutated) in a number of rhabdoind and non-rhabdoid CNS tumours, as well as in some peripheral nerve sheath tumours and sarcomas. Demonstration of loss of staining is useful in classifying some tumours.
Name: **MAP 2** Description: RUO Merck AB5622	IVD	C	Antibody to MAP2 protein, a neuronal cytoskeletal protein which may be lost in cerebrovascular and other diseases.

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Name: **MHC1** Description: RUO Abcam Ab22432	IVD	C	Antibody used in diagnosis of immune inflammatory myopathies.
Name: **MHC2** Description:RUO Abcam Ab7856	IVD	C	Antibody used in conjunction with MHC1 in the diagnosis of inflammatory myopathies
Name: **Myelin Basic Protein** Description: RUO Merck MAB386	IVD	C	Antibody used to mark myelin in the diagnosis of neurological disorders associated with deficiencies of myelin assembly and structure.
Name: **Measles** Description: RUO Santa Cruz SC101356	IVD	C	Antibody to measles virus associated with measles encephalitis
Name: **MxA** Description: RUO Merck MABF938	IVD	C	Antibody to MxA protein - sarcoplasmic expression of which has been demonstrated in dermatomyositis.
Name: **Myosin Fast** Description: RUO Leica NCL-MHCf	IVD	C	Antibody used for fibre typing – marks type 2 fibres
Name: **Myosin Slow** Description: RUO Leica NCL-MHCs	IVD	C	Antibody used for fibre typing – marks type 1 fibres
Name: **Myosin Neonatal** Description: RUO Leica NCL-MHCn	IVD	C	Antibody demonstrates neonatal type heavy chain myosin.
Name: **Nestin** Description: RUO Abcam Ab6320	IVD	C	Antibody to nestin, an intermediate filament protein expressed in stem cells of developing nervous system, used In diagnosis of primitive tumours
Name: **NEU-N** Description: RUO Merck MAB377	IVD	C	Antibody to Neu-N nuclear protein, used in the assessment of neuronal status
Name: **Olig 2** Description: RUO Proteintech 13999-1-AP	IVD	C	Olig2 protein is a marker of oligodendrocyte progenitor cells and is expressed (variably) in gliomas, where it serves as a useful lineage marker.

Name: **P62** Description: RUO Santa Cruz SC25575	IVD	C	Antibody to p62 is used for demonstration of specific inclusion bodies in IBM and abnormal protein depositions in dementia brains.
Name: **SSTR(Somatostatin)** Description: RUO Abcam Ab134152	IVD	C	Antibody to somatostatin used to identify meningioma's
Name: **SV40** Description: RUO Merck CZL1	IVD	C	Antibody to SV40 used to detect JC polyomavirus in brain tissue.
Name: **Tau-RD3** Description: RUO Merck 05-803	IVD	C	Antibody to RD3 protein expressed in Alzheimer's and tauopathies. Used as part of a panel including RD4 and AT8tau allowing distinction of subgroups.
Name: **Tau-RD4** Description: RUO Merck 05-804	IVD	C	Antibody to RD4 protein expressed in Alzheimer's and tauopathies. Used as part of a panel including RD3 and AT8tau allowing distinction of subgroups.
Name: **Anti phosphoTDP43** Description: RUO Cosmo-Bio-TIP-PTD-M01	IVD	C	Antibody to phosphorylated TDP protein inclusions associated with many neurodegenerative disorders.
Name: **Toxoplasma Gondii** Description: RUO Abcam ab138698	IVD	C	Antibody to Toxoplasma sporozan.
Name: **Caveolin 3** Description: RUO BD610421	IVD	C	Antibody which marks caveolin 3 protein in muscle membrane. Used as part of a panel in diagnosis of muscular dystrophies
Name: **Collagen 6** Description: RUO Merck MAB3303	IVD	C	Antibody which marks collagen 6 protein in muscle membrane. Used as part of a panel in diagnosis of muscular dystrophies
Name: **Lamin** Description: RUO Merck 05-714	IVD	C	Antibody which marks nuclear lamin. Deficiency of this protein occurs in various muscular dystrophies
Name: **Anti-hCG alpha antibody** Description:RUO Abcam 11232	IVD	C	Antibody labels alpha subunit component of TSH, FSH, LH and GH hormones aiding in classification of pituitary adenomas.

Name: **PIT 1** Description: RUO Sigma HPA041646	IVD	C	PIT1 antibody aids classification of pituitary tumours as somatotropes or lactotropes or thyrotropes.
Name: **SF1** Description: RUO Biosciences 434200	IVD	C	Anti-SF1 aids classification of pituitary tumours as gonadotrophs.
Name: **T-PIT** Description: RUO Atlas AMAb91409	IVD	C	Anti T-Pit antibody aids classification of pituitary tumours as cortotrophs.
Name: **NF(2F11)** Description: Roche Cell Marque 760-2661	IVD	C	CE/IVD marked antibody to neurofilament protein. Manufacturer validated for use on Ventana not Bond.
Name: **KI-67** Description: Roche 05278384001	IVD	C	CE/IVD marked antibody to Mib-1 is a proliferation marker. Manufacturer validated for use on Ventana not Bond.

RUO antibodies – All of these antibodies are specialised assays used together with microscopic assessment and do not function as a single test but rather functions as part of a panel of tests used to make a diagnosis.

Haematology Laboratory

Device Identification (i.e. name, description)	Device Type (IVD/MD)	Risk class[1] of the device	Intended purpose
Name: **Sickle Cell Screen (Reagent)**	IVD	B	None CE marked kit, used in detection of sickle cell disease.
Name: **Sickle Cell Screen (IQC)**	IVD	B	None CE marked kit, IQC for sickle cell kit used in detection of sickle cell disease.
Name: **Factor XIII**	IVD	B	Lab developed test for the screening for the presence/ absence of Factor XIII in patients.
Name: **Inhibitor Screen**	IVD	C	Pooled samples used to determine the presence of clotting inhibitor in patients.
Name: **Iron Stain (Potassium Ferrocyanide)**	IVD	B	Potassium Ferrocyanide not CE marked, one stain used to stain iron in bone marrow slides.
Name: **Immunophenotyping – Flow Cytometry** Description: RUO BD Biosciences	IVD	C	Antibody panels used in the detection and classification of haematological malignancies.

RUO antibodies – All of these antibodies are specialised antibodies used together with CE marked antibodies and do not function as a single test but rather functions as part of a panel of antibody cocktail used to make a diagnosis.

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Blood Transfusion

Device Identification (i.e. name, description)	Device Type (IVD/MD)	Risk class[1] of the device	Intended purpose
Name: **Panocell - Antibody ID panel.**	IVD	D	Used for the identification of antibodies.
Name: **IgG Sensitized Cells**	IVD	D	Used to confirm the validity of negative IAT tests in tubes and as a positive DAT daily QC.

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Microbiology Laboratory

Device Identification (i.e. name, description)	Device Type (IVD/MD)	Risk class[1] of the device	Intended purpose
Name: **Xpert MTB Rif Ultra Assay**	IVD	C	Xpert MTB Rif Ultra Assay: 1. The detection of M.tuberculosis complex DNA in sputum samples or concentrated sediment prepared from sputum samples, 2. The detection of rifampicin resistance associated mutations
Name: **Whole Genome Sequencing (Covid)**	IVD	B	Oxford Nanopore Surveillance of SARS CoV2 virus
Name: ***Bronchoalveolar lavage (BAL) sample type tested using either Xpert Xpress SARS Co-V-2/Flu/RSV Assays (combined /individual tests)(Sars COV only kit nasopharyngeal swabs only)***	IVD	D	To detect SARS-CoV2 RNA/Flu/RSV in clinical BAL samples
Name: ***Bronchoalveolar lavage (BAL) sample type tested using ePlex RP2 assay for the detection of Respiratory Pathogens on ePlex testing system (nasopharyngeal swabs only)**	IVD	D	To detect respiratory viruses in clinical BAL samples
Name: ***Bronchoalveolar lavage (BAL) sample type tested using Cobas SARS CoV2 or SARSCoV2/Flu combined assay on Cobas testing platform *(nasopharyngeal, and combined nasopharyngeal/throat)**	IVD	D	To detect SARS-CoV2 RNN/Flu in clinical BAL samples
Name: **Eye swab sample collected in Cobas PCR media for Chlamydia testing on the Cobas CT/NG combined assay on the Cobas testing platform.**	IVD	C	To detect Chlamyda DNA in clinical eye samples

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Biochemistry Laboratory

Device Identification (i.e. name, description)	Device Type (IVD/MD)	Risk class[1] of the device	Intended purpose
Testing of fluids for: amylase, albumin, cholesterol, creatinine, glucose, LDH, total protein, triglyceride, urea and lactate on the AU5832.	IVD	C	Measurement of these parameters in fluid is useful in conjunction with measurement of parameters in serum and urine. This may be diagnostic in some disease states.

CSF Lactate, CSF TP, CSF Albumin, CSF Glucose are CE marked

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