**PUBLIC DECLARATION REGARDING THE MANUFACTURE AND USE OF IN-HOUSE DEVICES BY ST VINCENT'S HEALTHCARE GROUP (COMPRISING ST VINCENTS UNIVERSITY HOSPITAL, ST VINCENT'S PRIVATE HOSPITAL AND ST MICHAEL'S HOSPITAL)**

**Name of Health Institution:** Department of Pathology and Laboratory Medicine, St Vincent's Healthcare Group

**Address:** Elm Park, Dublin 4

- The health institution declares that the devices described in the accompanying table are only manufactured and used in St Vincent's University Hospital and do meet the applicable general safety and performance requirements (GSPR) of the medical services regulation (EU 2017/745) or 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: Roisin Wheatley | Name: Prof Aurelie Fabre |
|---|---|
| Role: Laboratory Manager | Role: Director of Pathology |
| Signature: Roisin Wh | Signature: |
| Date: 9/1/26. | Date: 09.1.2026 |

**Histology (Immunohistochemistry) St Vincent's University Hospital**

| Device Identification (i.e name, description) | Device Type (IVD/MD) | Risk Class[1] of the device type | Intended purpose | Justification for use |
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| Name: AMACR<br>Description: Lab Developed Test | IVD | C | DAKO ready to use antibody used on the automated Ventana Benchmark Ultra Immunostainer. Used as an aid in the diagnosis of prostate adenocarcinomas on formalin fixed paraffin embedded (FFPE) tissue. | This was the available antibody at optimisation. |
| Name: Bap-1<br>Description: RUO | IVD | C | Used on the automated Ventana Benchmark Ultra Immunostainer. Used in skin lesions, in particular uveal melanomas. In uveal melanoma BAP-1 is used to evaluate metastatic risk for the patient. | No alternative CE IVD marked antibody |
| Name: Basal cell cocktail/AMACR<br>Description: Lab Developed Test | IVD | C | Used on the automated Ventana Benchmark Ultra Immunostainer. Dual stain to aid in the diagnosis of prostate cancer. | To conserve tissue and used for easier visualisation of the antibodies on the same slide. |
| Name: BCL2<br>Description: Lab Developed Test | IVD | C | Used on the Dako Omnis platform as no alterative antibody for this platform. It is intended for use on the Dako Autostainer. This antibody labels cells expressing BCL2 oncoprotein. Used as an aid in the classification of follicular lymphomas and various diffuse lymphoproliferative diseases on formalin fixed paraffin embedded (FFPE) tissue. | No antibody available for the Omnis platform |
| Name: BCL10<br>Description: Lab Developed Test | IVD | C | Used on the automated Ventana Benchmark Ultra Immunostainer. Used as an aid Identification of Acinar Cell Carcinomas and Mixed-acinar Neuroendocrine Carcinomas on formalin fixed paraffin embedded (FFPE) tissue. | No alternative CE IVD marked antibody |
| Name: CD117<br>Description: Lab Developed Test | IVD | C | Leica Ready to use antibody used on the DAKO Omnis platform. Used as an aid in the diagnosis of Gastrointestinal Stromal Tumour (GIST) and for the identification of blast cells on formalin fixed paraffin embedded (FFPE) tissue. | No antibody available for use on the OMNIS. EQA satisfactory. |
| Name: DOG1<br>Description: Lab Developed Test | IVD | C | Leica ready to use antibody used on the DAKO Omnis platform. Used as an aid in the diagnosis of Gastrointestinal Stromal Tumour on formalin fixed paraffin embedded (FFPE) tissue. | No available antibody for use on the OMNIS platform. EQA results satisfactory. |
| Name: D240/AE1AE2<br>Description: Lab Developed Test | IVD | C | Used on the automated Ventana Benchmark Ultra Immunostainer. Dual stain to aid in the identification of | Used for easier visualisation of the antibodies on the same slide. |

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| | | | vascular invasion, | |
| Name: E-cadherin<br>Description: Lab Developed Test | IVD | C | DAKO ready to use antibody used on the automated Ventana Benchmark Ultra Immunostainer. Used as an aid in the classification of ducal breast carcinoma on formalin fixed paraffin embedded (FFPE) tissue. | This was the available antibody at optimisation. EQA satisfactory. |
| Name: Insulin<br>Description: Lab Developed Test | IVD | C | Used on the DAKO Omnis to identify insulin and insulin-producing cells in normal and neoplastic formalin fixed paraffin embedded (FFPE) tissue. | No antibody available for the Omnis platform |
| Name: MLH1<br>Description: Lab Developed Test | IVD | C | Used on the DAKO OMNIS Immunostainer. Used on colorectal, non-colorectal and gyane tissue for the identification of mismatch repair protein status. | At time of validation no antibody available for the Omnis. EQA satisfactory. |
| Name: MSH2<br>Description: Lab Developed Test | IVD | C | Used on the DAKO OMNIS Immunostainer. Used on colorectal, non-colorectal and gyane tissue for the identification of mismatch repair protein status. | At time of validation no antibody available for the Omnis. EQA satisfactory. |
| Name: MSH6<br>Description: Lab Developed Test | | | Used on the DAKO OMNIS Immunostainer. Used on colorectal, non-colorectal and gyane tissue for the identification of mismatch repair protein status. | At time of validation no antibody available for the Omnis. EQA satisfactory. |
| Name: p63/AE1AE3<br>Description: Lab Developed Test | IVD | C | Used on the automated Ventana Benchmark Ultra Immunostainer. Dual stain to aid in the detect or to confirm the presence of micoinvasion or invasion | Used for easier visualisation of the antibodies on the same slide. |
| Name: Myosin/AE1AE3<br>Description: Lab Developed Test | IVD | C | Used on the automated Ventana Benchmark Ultra Immunostainer. Dual stain to aid in the detect or to confirm the presence of micoinvasion or invasion | Used for easier visualisation of the antibodies on the same slide. |
| Name: p63/CK5.6<br>Description: Lab Developed Test | IVD | C | Used on the automated Ventana Benchmark Ultra Immunostainer. Dual stain to aid in the diagnosis of SCC of the lung. | To conserve tissue for ancillary molecular testing. |
| Name: PD-L1 22C3 PharmDx<br>Description: Lab Developed Test | IVD | C | Used on the DAKO OMNIS Immunostainer. Used on cervical and urothelial cancer to determine PD-L1 expression. | Don't have the autostainer platform to perform this test. |
| Name: PD-L1 22C3 PharmDx on cytology blocks<br>Description: Lab Developed Test | IVD | C | Used on the DAKO OMNIS Immunostainer. Used on cervical and urothelial cancer to determine PD-L1 expression on cytology blocks. | Not validated by the manufacturer but testing on these samples is verified in house. |
| Name: PD-L1 (SP263) on cytology blocks<br>Description: Lab Developed Test | IVD | C | Used on the automated Ventana Benchmark Ultra Immunostainer. PD-L1 is used to identify PD-L1 expression in non-small lung cancer (NSCLC) on formalin fixed cytology cell blocks. | Not validated by the manufacturer but testing on these samples is verified in house. |
| Name: PMS2<br>Description: Lab Developed Test | IVD | C | Used on the DAKO OMNIS Immunostainer. Used on colorectal, non-colorectal and gyane tissue for the identification of mismatch repair protein status. | At time of validation no antibody available for the Omnis. EQA satisfactory. |

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| Name: RB1<br>Description: RUO | IVD | C | Used on the automated Ventana Benchmark Ultra Immunostainer. Rb1 is used to distinguish poorly differentiated neuroendocrine carcinomas (NEC) from well differentiated neuroendocrine tumours (NET) in formalin fixed paraffin embedded (FFPE) tissue. | No CE IVD alternative |
| Name: SBH-B<br>Description: RUO | IVD | C | Used on the Ultra platform. Used to identify SDH deficient tumours. | No CE IVD alternative |
| Name: Somatostatin Receptor 2<br>Description: RUO | IVD | C | Used on the Ultra platform for the for the diagnosis, prognosis and potential therapeutic targets for NETs | No CE IVD alternative at the time of optimisation |
| Name: Tdt<br>Description: RUO | IVD | C | Used on the Dako Omnis Platform for the classification of malignant lymphomas. | No antibody available for the Omnis platform |
| Name: TTF1/Napsin<br>Description: Lab Developed Test | IVD | C | Used on the automated Ventana Benchmark Ultra Immunostainer. Dual stain to aid in the diagnosis of adenocarcinoma of the lung. | To conserve tissue for ancillary molecular testing. |
| Name: WT1<br>Description: Lab Developed Test | IVD | C | Used on the Dako Omnis platform. Used for the identification of mesothelioma and ovarian serous carcinomas. | No antibody available for the Omnis platform |

[1] Annex VIII Classification Rules

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.

| **Molecular Histology (Solid Tumour Analysis) St Vincent's University Hospital** | | | | |
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| **Device Identification (i.e name, description)** | **Device Type (IVD/MD)** | **Risk Class[1] of the device type** | **Intended purpose** | **Justification for use** |
| Name: **Thermofisher Oncomine Focus Assay**<br>Description: RUO assay used for detection of variants from DNA/RNA of solid tumour cancers. | IVD (inhouse) | C | Oncomine Focus Assay (OFA) is a workflow used to detect variants in input DNA and RNA. OFA reagents are used in combination with Ion Torrent Chef to produce library pools, these are templated on Ion Torrent Chef and sequenced on Ion Torrent S5 Sequencer producing fastq files.<br>OFA includes 52 genes and is designed to be used with DNA/RNA from formalin-fixed paraffin-embedded (FFPE) tissue specimens. The output is used to detect predictive biomarkers of response to therapy in lung cancer, melanoma, GIST, colorectal cancer and other solid tumour cancers. | No CE IVD alternative.<br>In-house validation performed. |
| Name: **Ion Torrent Chef instrument**<br>Description: RUO Instrument used for automation in OFA workflow | IVD (inhouse) | C | The Ion Torrent Chef is a robot providing automated library and template preparation using pre-packaged reagent kits. | No CE IVD alternative.<br>In-house validation performed. |
| Name: **Roche LC480**<br>Description: RUO Instrument used for quantification of library pools | IVD (inhouse) | C | Library pools from Ion torrent Chef are at varying concentrations. The Roche LC480 is used to determine the concentration to allow equimolar dilution for sequencing. | The cobas z 480 analyzer includes dedicated software for IVD use. Used in RUO mode for quantification.In-house validation performed. |
| Name: **Ion GeneStudio S5 Sequencer**<br>Description: RUO Instrument used to sequence | IVD (inhouse) | C | The Ion GeneStudio S5 is a sequencer that produces fastq sequencing files from templated library pools created by Ion Torrent Chef. | No CE IVD alternative.<br>In-house validation performed. |
| Name: **Ion Reporter**<br>Description: RUO software used for preliminary data analysis of OFA workflow. | Software | C | Performs automated sequence analysis and variant calling from data generated by Ion Genestudio S5. | No CE IVD alternative.<br>In-house validation performed. |
| Name: **JSI SeqNext (JSI Medsystems)**<br>Description: RUO Software used for primary data analysis in OFA workflow | Software | C | Performs automated analysis of fastq files from Ion Genestudio S5. User-curated VCF files are produced containing clinically relevant results. | No CE IVD alternative.<br>In-house validation performed. |
| Name: **MOLTRACK (in-house)**<br>Description: In-house Software used for sample tracking through OFA workflow. | Software | C | In-house sample tracker used for data entry to produce intermediate files. Parses Ion Reporter and JSI SeqNext VCF files into human-readable format. Generates the final report transcribed to the hospital LIS. | No CE IVD alternative.<br>In-house validation performed. |

| **Clinical Chemistry St Vincent's University Hospital** | | | | |
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| **Device Identification (i.e name, description)** | **Device Type (IVD/MD)** | **Risk Class[1] of the device type** | **Intended purpose** | **Justification for use** |
| Roche Alkaline Phosphatase (ACN 683) | IVD | C | In vitro test for the quantitative determination of alkaline phosphatase in human serum and plasma on cobas c and COBAS systems. | Not for dilutions above 6000U/L Dilutions performed above the extended technical limit. Diluted value of Clinical benefit |
| Roche Alanine Aminotransaminase (ACN 685) | IVD | C | In vitro test for the quantitative determination of alanine aminotransferase (ALT) in human serum and plasma on COBAS systems. | Not for dilutions above 7000U/L Dilutions performed above the extended technical limit. Diluted value of Clinical benefit |
| Roche Aspartate Aminotransminase (ACN 687) | IVD | C | In vitro test for the quantitative determination of aspartate aminotransferase (AST) in human serum and plasma on cobas c and COBAS systems. | Not for dilutions above 7000U/L Dilutions performed above the extended technical limit. Diluted value of Clinical benefit |
| Roche Amylase (ACN 570) | IVD | C | In vitro test for the quantitative determination of α-amylase in human serum, plasma and urine on cobas c and COBAS systems. | Not for dilutions above 7500U/L Dilutions performed above the extended technical limit. Diluted value of Clinical benefit |
| Roche Creatine Kinase (ACN 550) | IVD | C | In vitro test for the quantitative determination of creatine kinase (CK) in human serum and plasma on COBAS 8000 systems. | Not for dilutions above 22000U/L Dilutions performed above the extended technical limit. Diluted value of Clinical benefit |
| Roche Lactate Dehydrogenase (ACN 080) | IVD | C | In vitro test for the quantitative determination of lactate dehydrogenase in human serum and plasma on cobas c and COBAS 8000 systems. | Not for dilutions above 2500U/L Dilutions performed above the extended technical limit. Diluted value of Clinical benefit |
| Roche Triglyceride (ACN 781) | IVD | C | In vitro test for the quantitative determination of triglycerides in human serum and plasma on cobas c and COBAS 8000 systems | Not for dilutions above 50mmol/L Dilutions performed above the extended technical limit. Diluted value of Clinical benefit |
| Roche Alphafetoprotein (ACN 134) | IVD | C | Immunoassay for the in vitro quantitative determination of CA Alphafetoprotein in human serum and plasma on COBAS 8000 | Not for dilutions above 50000kU/L Dilutions performed above the extended technical limit. Diluted value of Clinical benefit |
| Roche CA125 (ACN 053) | IVD | C | Immunoassay for the in vitro quantitative | Not for dilutions above 25,000 kIU/L |

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| | | | determination of CA125 in human serum and plasma on COBAS 8000 | Dilutions performed above the extended technical limit.<br>Diluted value of Clinical benefit |
| Roche CA19-9 (ACN 054) | IVD | C | Immunoassay for the in vitro quantitative determination of CA 19-9 in human serum and plasma on COBAS 8000 | Not for dilutions above 10,000 kIU/L<br>Dilutions performed above the extended technical limit.<br>Diluted value of Clinical benefit |
| Roche CA15-3 (ACN 052) | IVD | C | Immunoassay for the in vitro quantitative determination of CA15-3 in human serum and plasma on COBAS 8000 | Not for dilutions above 3,000 kIU/L<br>Dilutions performed above the extended technical limit.<br>Diluted value of Clinical benefit |
| Roche Human Chorionic Gonadotropin (ACN 148) | IVD | C | Immunoassay for the in vitro quantitative determination of CA Beta HCG in human serum and plasma on COBAS 8000 | Not for dilutions above 1,000,000 IU/L<br>Dilutions performed above the extended technical limit.<br>Diluted value of Clinical benefit |
| Roche Ferritin (ACN 067) | IVD | C | Immunoassay for the in vitro quantitative determination of ferritin in human serum and plasma on COBAS 8000 | Not for dilutions above 100000 µg/L<br>Dilutions performed above the extended technical limit.<br>Diluted value of Clinical benefit |
| **Testing of Fluids for:**<br>Amylase, Albumin, Cholesterol, Creatinine, Glucose, LDH, Total Protein, Triglyceride, Urea on the Cobas 8000 | IVD | C | Measurement of parameters in fluids gives clinicians valuable information when compared to the values obtained in the serum/plasma and can be diagnostic of some disease states | |
| Urinary Total Protein | IVD | C | Roche total protein. Not for dilutions above 6g/L<br>Dilutions performed above the extended technical limit | Test is used to monitor renal function |

| **Clinical Chemistry St Vincent's Private Hospital** | | | | |
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| **Device Identification (i.e name, description)** | **Device Type (IVD/MD)** | **Risk Class[1] of the device type** | **Intended purpose** | **Justification for use** |
| Roche Alkaline Phosphatase (ACN 683) | IVD | C | In vitro test for the quantitative determination of alkaline phosphatase in human serum and plasma on cobas c and COBAS INTEGRA systems. | Not for dilutions above 6000U/L<br>Dilutions performed above the extended technical limit.<br>Diluted value of Clinical benefit |

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| Roche Alanine Aminotransaminase (ACN 685) | IVD | C | In vitro test for the quantitative determination of alanine aminotransferase (ALT) in human serum and plasma on cobas c and COBAS INTEGRA systems. | Not for dilutions above 7000U/L Dilutions performed above the extended technical limit. Diluted value of Clinical benefit |
| Roche Aspartate Aminotransminase (ACN 687) | IVD | C | In vitro test for the quantitative determination of aspartate aminotransferase (AST) in human serum and plasma on cobas c and COBAS INTEGRA systems. | Not for dilutions above 7000U/L Dilutions performed above the extended technical limit. Diluted value of Clinical benefit |
| Roche Amylase (ACN 570) | IVD | C | In vitro test for the quantitative determination of α-amylase in human serum, plasma and urine on cobas c and COBAS INTEGRA systems. | Not for dilutions above 7500U/L Dilutions performed above the extended technical limit. Diluted value of Clinical benefit |
| Roche Creatine Kinase (ACN 550) | IVD | C | In vitro test for the quantitative determination of creatine kinase (CK) in human serum and plasma on cobas c and COBAS INTEGRA systems. | Not for dilutions above 22000U/L Dilutions performed above the extended technical limit. Diluted value of Clinical benefit |
| Roche Lactate Dehydrogenase (ACN 080) | IVD | C | In vitro test for the quantitative determination of lactate dehydrogenase in human serum and plasma on cobas c and COBAS INTEGRA systems. | Not for dilutions above 2500U/L Dilutions performed above the extended technical limit. Diluted value of Clinical benefit |
| Roche Triglyceride (ACN 781) | IVD | C | In vitro test for the quantitative determination of triglycerides in human serum and plasma on cobas c and COBAS INTEGRA systems | Not for dilutions above 50mmol/L Dilutions performed above the extended technical limit. Diluted value of Clinical benefit |
| Roche Alphafetoprotein (ACN 134) | IVD | C | Immunoassay for the in vitro quantitative determination of CA Alphafetoprotein in human serum and plasma | Not for dilutions above 50000kU/L Dilutions performed above the extended technical limit. Diluted value of Clinical benefit |
| Roche CA125 (ACN 053) | IVD | C | Immunoassay for the in vitro quantitative determination of CA125 in human serum and plasma | Not for dilutions above 25,000 kIU/L Dilutions performed above the extended technical limit. Diluted value of Clinical benefit |
| Roche CA19-9 (ACN 054) | IVD | C | Immunoassay for the in vitro quantitative determination of CA 19-9 in human serum and plasma | Not for dilutions above 10,000 kIU/L Dilutions performed above the extended technical limit. Diluted value of Clinical benefit |
| Roche CA15-3 (ACN 052) | IVD | C | Immunoassay for the in vitro quantitative determination of CA15-3 in | Not for dilutions above 3,000 kIU/L Dilutions performed above the extended technical |

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| | | | human serum and plasma | limit.<br>Diluted value of Clinical benefit |
| Roche Human Chorionic Gonadotropin (ACN 148) | IVD | C | Immunoassay for the in vitro quantitative determination of CA Beta HCG in human serum and plasma | Not for dilutions above 1,000,000 IU/L<br>Dilutions performed above the extended technical limit.<br>Diluted value of Clinical benefit |
| Roche Ferritin (ACN 067) | IVD | C | Immunoassay for the in vitro quantitative determination of ferritin in human serum and plasma. | Not for dilutions above 100000 µg/L<br>Dilutions performed above the extended technical limit.<br>Diluted value of Clinical benefit |

| **Haematology St Vincent's University Hospital** | | | | |
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| **Device Identification (i.e name, description)** | **Device Type (IVD/MD)** | **Risk Class[1] of the device type** | **Intended purpose** | **Justification for use** |
| Immunophenotyping – Flow Cytometry<br>Description: RUO Beckman Coulter | IVD | C | The diagnosis and monitoring of haematological malignancies & disorders. | Laboratory has full compliance with EN ISO 15189 standards for Immunophenotyping testing. The lab is currently in the process of working towards implementing the requirement listed in IVDR Regulation (EU) 2017/746 Article. 5.5 |

| **Blood Bank St Vincent's University Hospital** | | | | |
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| **Device Identification (i.e name, description)** | **Device Type (IVD/MD)** | **Risk Class[1] of the device type** | **Intended purpose** | **Justification for use** |
| Manual Indirect Antiglobulin Test using Biorad Gelcards and Reagent red cells | IVD | D | Pre-transfusion compatibility testing- antibody screening & antibody identification testing. | No alternative available |

| **Tissue Establishment St Vincent's University Hospital** | | | | |
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| **Device Identification (i.e name, description)** | **Device Type (IVD/MD)** | **Risk Class[1] of the device type** | **Intended purpose** | **Justification for use** |
| CryoMacs Freezing Bags | IVD | A | These are the bags in which Processed Stem Cells are cryopreserved and stored. | The manufacturer's instructions state that the recommended capacity of these bags is 55ml-100ml. The bags have been validated in house to store 55-110mls in accordance with manufacturer's recommendations. |
| Biomerieux SA and FA Plus Blood Culture Bottles | IVD | C | Sterility testing of harvested peripheral blood stem cells. | Manufacturer's instructions state that blood culture bottles should be inoculated with up to 10ml of blood. Only 1% of Stem Cell Collection is inoculated (minimum 1ml) in order to conserve stem cells for reinfusion. Blood culture incubation time is extended. |
| Wak Chemi Cryosure Dimethyl Sulfoxide (DMSO) | IVD | C | DMSO is an additive used during the processing of Stem Cells. It is an intracellular cryoprotective agent which penetrates the cell membrane. It reduces the osmotic charge of the cells during freezing and thawing and antagonizes the osmotic shock. Furthermore it protects cells from dehydration and shrinking during freezing and prevents the formation of ice crystals. | Volume of DMSO that can be safely reinfused is calculated by consultant haematologist based on patient weight and documented on transplant form. |

| **Microbiology St Vincent's University Hospital** | | | | |
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| **Device Identification (i.e name, description)** | **Device Type (IVD/MD)** | **Risk Class[1] of the device type** | **Intended purpose** | **Justification for use** |
| Xpert MTb Rif Ultra assay | IVD | C | The detection of M.tuberculosis complex DNA in sputum samples or concentrated sediment prepared from sputum samples and<br>the detection of rifampicin resistance associated mutations | No available alternative for use in specimens other than sputum samples or concentrated sediment prepared from sputum samples. |