Declaration Regarding the Manufacture and Use of In-house Devices

Name of the Health Institution: SJH Centre for Laboratory Medicine & Molecular Pathology

Address: LabMed Building
St James's Hospital
1 James's Street
Dublin 8
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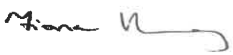
The devices described in this document are only manufactured and used in the health institution named above.

The devices meet the applicable general safety and performance requirements (GSPR) of the in vitro diagnostic medical devices Regulation (EU 2017/746).

Declaration Completed By:

Name:	Fiona Kearney	**Name:**	Christina Ryan
Role:	Laboratory Manager	**Role:**	Quality Manager
Signature:		**Signature:**	
Date:	26/05/2024	**Date:**	26/05/2024

BIOCHEMISTRY LABORATORY

Device indentification (e.g. name, description)	Device Type (IVD/MD)	Risk Class of the Device	Intended Purpose	Applicable GSPR Fully Met? Y/N	Information on & justification for applicable GSPR that are not fully met (using the numbering as in Annex 1 of the IVDR)
Porphyrin analysis by HPLC (Urine, Faeces, Plasma & Red Cells)	IVD	B	To diagnose & monitor Porphyria patients	Y	n/a
Erythrocyte Protoporphyrin Quantitation	IVD	B	To diagnose & monitor Porphyria patients	Y	n/a
Testing of Fluids for: 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	Y	n/a
Diasource Gastrin Assay	IVD	C	Gastrin analysis. The kit was previously CE marked and was reformulated in 2023 so it is RUO, they are in the process of obtaining CE marking	Y	n/a
Urea breath test IQC- Delta high and low by Westfalen	IVD	A	Only IQC available.	Y	n/a
Urinary Calcium	IVD	C	Test is used to monitor kidney function	Y	n/a
Urinary Urate	IVD	C	Test is used to monitor or diagnose gout; and to investigate a potential cause for kidney stones.	Y	n/a

BIOCHEMISTRY GENETICS LABORATORY

Device indentification (e.g. name, description)	Device Type (IVD/MD)	Risk Class of the Device	Intended Purpose	Applicable GSPR Fully Met? Y/N	Information on & justification for applicable GSPR that are not fully met (using the numbering as in Annex 1 of the IVDR)
Detection of pathogenic variants associated with Familial Hypercholesterolamia (FH) by Next-Generation sequencing using single molecule molecular inversion probes (smMIPs) smMIP panel	IVD	C	To detect clinically actionable variants in the LDLR gene, and specific variants in PCSK9 and APOB gene to genetically diagnose patients with Autosomal Dominant monogenic Familial hypercholesterolaemia.	Y	n/a
PCR amplification and Sanger sequencing of human genes associated with biochemical conditions	IVD	C	To detect a spectrum of clinically actionable variants to genetically diagnose patients with the following conditions and associated genes: Acute intermittent porphyria (AIP) HMBS Variegate porphyria (VP) PPOX Hereditary coproporphyria (HCP) CPOX Familial porphyria cutanea tarda (fPCT) UROD Erythropoietic protoporphyria (EPP) FECH X-linked protopoprhyria (XLP) ALAS2 ex 11 Congenital erythropoietic porphyria (CEP) UROS Hereditary Transthyretin mediated Amyloidosis TTR Gilbert's syndrome (Benign unconjugated hypberbilirubinaemia) UGT1A1	Y	n/a
SNP genotyping assays - Allelic discrimination	IVD	C	To detect specific known variants to genetically diagnose patients with the following conditions and associated genes: Dysbetalipoproteinaemia (Type III Hyperlipidaemia) APOE R176C Haemochromatosis HFE C282Y H63D	Y	n/a
Software: JSI Softare SeqNext module (RUO), JSI Software SeqPatient module (RUO), Alamut Visual Plus (RUO), 7500 Fast system SDS software (RUO)	IVD	C	To analyse and interpret Next generation sequencing data and sanger sequencing data and SNP genoyping data	Y	n/a

BLOOD TRANSFUSION LABORATORY

Device indentification (e.g. name, description)	Device Type (IVD/MD)	Risk Class of the Device	Intended Purpose	Applicable GSPR Fully Met? Y/N	Information on & justification for applicable GSPR that are not fully met (using the numbering as in Annex 1 of the IVDR)
Antibody Investigation using Ortho Panel C Antibody Panel	IVD	D	Identification of antibodies in pre-transfusion testing using automated techniques on the Max Swift Analyser.	Y	n/a
Manual Indirect Antiglobulin Test using BioRad Gelcards and Reagent Red Cells	IVD	D	Pre-transfusion compatibility testing - antibody screening, antibody identifiction testing and compatibility testing.	Y	n/a

CANCER MOLECULAR DIAGNOSTICS (CMD) LABORATORY

Device indentification (e.g. name, description)	Device Type (IVD/MD)	Risk Class of the Device	Intended Purpose	Applicable GSPR Fully Met? Y/N	Information on & justification for applicable GSPR that are not fully met (using the numbering as in Annex 1 of the IVDR)
Detection of diagnostic mutations for myeloproliferative neoplasms (MPNs) - MPNPanel	IVD	C	Diagnostic aid for myeloproliferative neoplasms	Y	n/a
Detection of BRCA1/2 mutations	IVD	C	Predictive biomarker of response to PARPi therapy	Y	n/a
Detection of BRCA1/2 Large genomic rearrangements	IVD	C	Predictive biomarker of response to PARPi therapy	Y	n/a
Detection of treatment guiding mutations in Non Small Cell Lung Cancer, Melanoma, GIST and Colorectal Cancer	IVD	C	Predictove biomarker of response to targeted therapy in NSCLC, Melanoma, GIST and Colorectal Cancer	Y	n/a
Detection of clonal B and T cell rearrangements	IVD	B	Diagnostic aid for lymphoproliferative neoplasms	Y	n/a
Detection of BCL1::IGH and BCL2::IGH	IVD	C	Diagnostic aid for lymphoproliferative neoplasms	Y	n/a
Detection of MYD88 mutations	IVD	C	Diagnostic aid for lymphoproliferative neoplasms	Y	n/a
Detection of TP53 mutations in lymphoid malignancy	IVD	C	Diagnostic aid for lymphoproliferative neoplasms. Predictive biomarker of response to targeted therapy in CLL	Y	n/a
Somatic Hypermutation	IVD	C	Predictive and prognostic biomarker of treatment response in CLL	Y	n/a
Monitoring of donor chimerism	IVD	C	Monitoring on bone marrow transplant engraftment	Y	n/a
Tissue provenance testing	IVD	C	Confirmation of tissue provenance in paraffin blocks	Y	n/a
Myeloid Gene Panel	IVD	C	Prognostication and prediction of response to therapy in myeloid malignancy	Y	n/a

Device indentification (e.g. name, description)	Device Type (IVD/MD)	Risk Class of the Device	Intended Purpose	Applicable GSPR Fully Met? Y/N	Information on & justification for applicable GSPR that are not fully met (using the numbering as in Annex 1 of the IVDR)
Detection of BCR::ABL fusions (p190, p210, variants)	IVD	C	Detection and monitoring of BCR::ABL transcript levels in CML and ALL	Y	n/a
Detection of FLT3-ITD mutation	IVD	C	Prognostication and prediction of response to therapy in myeloid malignancy	Y	n/a
Detection of PML::RARA fusions	IVD	C	Diagnosis and monitoring of acure promyelocytic leukaemia	Y	n/a
Detection of EGFR mutations in cell free DNA	IVD	C	Prediction of response to targeted therapy in non small cell lung carcinoma	Y	n/a
Detection of NPM1 mutation	IVD	C	Prognostication in myeloid malignancy	Y	n/a
Total nucleic acid extraction from peripheral blood, bone marrow, plasma and FFPE tissue	IVD	C	Nucleic Acid Extraction for downstream molecular analysis	Y	n/a
Total nucleic acid extraction from FFPE tissue	IVD	C	Nucleic Acid Extraction for downstream molecular analysis	Y	n/a
RNA extraction from peripheral blood and bone marrow	IVD	C	Nucleic Acid Extraction for downstream molecular analysis	Y	n/a
DNA extraction from FFPE tissue	IVD	C	Nucleic Acid Extraction for downstream molecular analysis	Y	n/a
DNA extraction from fresh and fresh frozen tissue, cell pellets and lyophylised material	IVD	C	Nucleic Acid Extraction for downstream molecular analysis	Y	n/a
Analysis Software					
Genemapper 5.0 (Thermo Fisher)	Software	C	Analysis of data from capillary electrophoresis assays	Y	n/a
JSI SeqNext (JSI Medsystems)	Software	C	Analysis of data from Next Generation Sequencing assays	Y	n/a
LaserGene (DNA Star)	Software	C	Analysis of data from Next Generation Sequencing assays	Y	n/a

COAGULATION LABORATORY

Device indentification (e.g. name, description)	Device Type (IVD/MD)	Risk Class of the Device	Intended Purpose	Applicable GSPR Fully Met? Y/N	Information on & justification for applicable GSPR that are not fully met (using the numbering as in Annex 1 of the IVDR)
Reptilase Time	IVD	B	To differentiate between dysfibrinogenaemia and heparin contamination of coagulation samples	Y	n/a
Edoxaban Assay	IVD	C	To measure the concentration of edoxaban in a patient plasma	Y	n/a
Inhibitor Assays - FVIII inhibitor screen and assay - FIX inhibitor screen and assay	IVD	C	To detect the presence of and quantitate the titre of inhibitor in patients with inherited and acquired Haemophilia	Y	n/a
VWF Multimer analysis	IVD	B	For the separation of VWF protein into multimers of different molecular weight in order to assist in the subclassification of type 2 VWD	Y	n/a
Phenotypic assessment of platelet function in coagulation - Platelet Aggregation - Platelet Nucleotides	IVD	C	For the identification and classification of hereditary platelet disorders	Y	n/a
Fibrinogen antigen	IVD	B	For the investigation of patients with disorders of fibrinogen to subclassify as hypofibrinogenaemia or dysfibrinogenaemia	Y	n/a

CRYOBIOLOGY STEM CELL LABORATORY

Device indentification (e.g. name, description)	Device Type (IVD/MD)	Risk Class of the Device	Intended Purpose	Applicable GSPR Fully Met? Y/N	Information on & justification for applicable GSPR that are not fully met (using the numbering as in Annex 1 of the IVDR)
7-AAD Viability stain	IVD	B	The viability of all Haemopoietic Cell clinical products (HPCs) must be determined to establish the potency /functional quality of the product prior to product infusion or cryopreservation. 7-AAD is also used to determine the live cell count when preparing inoculation mix for in vitro functional colony forming assay CFU-GM/ BFU-E Progenitor Cultures	Y	n/a
RPMI Heparin Solution (sample collection media)	IVD	A	In House prepared media for preservation of sample material.	Y	n/a
Functional Colony Forming Unit (CFU-GM & BFU-E) Assay	IVD	B	In vitro CFU-GM & BFU-E colonies are grown using the MethoCult medium (Stem Cell Technologies) & the colonies are enumerated after 14 days to assess stem cell function of the samples tested (clinical product pre and post cryopreservation). Cells grown in culture correlate to stem cell function in vivo.	Y	n/a
BD Multitest CD3/CD8/CD45/CD4 Kit (Flow Cytometry)	IVD	B	Quantification of the T cell content of a bone marrow harvest, peripheral blood stem cell harvest or mononuclear cell apheresis collection. Following transplantation the T-cells can mediate a beneficial graft versus leukaemia effect, which eliminates residual disease. However, the T- cells can also cause the Graft versus host disease (GvHD) which has a high incidence of mortality and morbidity. T-cell quantification is now part of the quality control analysis of all allogenenic harvests (bone marrow, PBSC and DLI).	Y	n/a

HAEMATOLOGY LABORATORY

Device indentification (e.g. name, description)	Device Type (IVD/MD)	Risk Class of the Device	Intended Purpose	Applicable GSPR Fully Met? Y/N	Information on & justification for applicable GSPR that are not fully met (using the numbering as in Annex 1 of the IVDR)
Haematological Immunophenotyping - Acute Leukaemia Panel - B cell Acute Lymphoblastic Minimal Residual Disease detection (B ALL MRD) - Chronic Lymphoproliferative Panel - CSF Immunophenotying - Detection of Minimal Residual Disease (MRD) in B Chronic Lymphocytic Leukaemia (B-CLL) - Detection of Minimal Residual Disease (MRD) in Mantle Cell Lymphoma (MCL) - MDS Ogata and RED score by flow cytometry - T ALL MRD protocol - PNH (Paroxysmal Nocturnal Haemoglobinuria) analysis by flow cytometry - Eosin-5-Maleimide Staining of Erythrocytes - Platelet Immunophenotyping	IVD	C	The diagnosis and monitoring of haematological malignancies & disorders.	Y	n/a
Giemsa's Stain	IVD	B	The purpose is to stain blood and bone marrow cells for microscopical examination of morphology	Y	n/a
May-Grumwald Stain	IVD	B	The purpose is to stain blood and bone marrow cells for microscopical examination of morphology	Y	n/a
Rhodanile Blue stain	IVD	B	Used as a stain to demonstrate Heinz Bodies (denatured haemoglobin) in red blood cells	Y	n/a
Reticulocyte Stain (New Methylene Blue)	IVD	B	Used as a stain to demonstrate Haemoglobin H (tetramers of Beta globin) in red blood cells to confirm Alpha Thalassaemia states.	Y	n/a

HISTOPATHOLOGY INCLUDING CYTOLOGY LABORATORY

Device indentification (e.g. name, description)	Device Type (IVD/MD)	Risk Class of the Device	Intended Purpose	Applicable GSPR Fully Met? Y/N	Information on & justification for applicable GSPR that are not fully met (using the numbering as in Annex 1 of the IVDR)
Immunohistochemistry - Alpha-1-Antitrypsin, Caldesmon, - CD19, CD43, CD45, CD68, CD72, CD117, CD123, - CMV, Collagen IV, DOG-1, Factor 8 - GFAP, Glycophorin A, Glypican 3, - HBME-1, Herpes, HHV8, - IgA, IgG4, IgG, IgM - Keratin MNF, Ker 903, - MLH1, MUC-4, Myf-4, Myeloperoxidase - Neurofilament, Neuron Specific Enolase, OCT-4 - PLAP, PMS2, - SOX11, Syphilis, TIA-1, Tryptase, WT1	IVD	C	Use of antibodies for the pathological evaluation of tissues, to stratify the diagnosis of patient material, predict potential responses to therapy and provide prognostic information. Also used to confirm presence/absence of infectious agents in formalin fixed, parafin embedded tissues.	Y	n/a
Mohs H&E protocol	IVD	C	To diagnose BCC/SCC tumour in Mohs skin sections	Y	n/a
H&E Protocols (various) - Routine - Mega block - No oven start - Water start - Frozen sections	IVD	C	Processing of tissue sections to allow H&E staining. H and E staining helps identify different types of cells and tissues and provides important information about the pattern, shape, and structure of cells in a tissue sample. Frozen sections enable the pathologist to urgently report on specimen. In the majority of cases the patient is still in theatre, so time is critical and the procedure must be completed with minimal delay.	Y	n/a
Flourescence In Situ Hybridisation Assays using various probes -HER2 MYC (8q24) -MYC/IGH t(8;14) - BCL2 (18q21) - BCL2/IGH t(14;18) - BCL6 (3q37) - MALT1 (18q21) - CCND1/IGH t(11;14) - IGK/c-MYC - IGL/c-MYC - IRF4/DUSP22 - TP63/TBL1XR1 - 11q gain/loss - ALK (2p23) - ROS1 (6q22) - EWSR1 - MDM2/CEN12 - MAML2 - MYB	IVD	C	Molecular cytogenetic solid tumor technique that uses flourescent probes to identify a specific DNA sequence or an entire chromosome in a cell. FISH is used for the pathological evaluation of tissues, to stratify the diagnosis of patient material, predict potential responses to therapy and provide prognostic information.	Y	n/a

Device indentification (e.g. name, description)	Device Type (IVD/MD)	Risk Class of the Device	Intended Purpose	Applicable GSPR Fully Met? Y/N	Information on & justification for applicable GSPR that are not fully met (using the numbering as in Annex 1 of the IVDR)
May Grunwald Giemsa Stain	IVD	C	To visulise extracellular material such as mucin, connective tissue ground substance and intracellular granules, to aid in the diagnosis of Diagnostic Cytopathology Specimens.	Y	n/a
Hanks Balance Salt Solution	IVD	A	Used to wash cells	Y	n/a
Dithiothreitol	IVD	A	Used to wash cells removing excess mucus in respiratory specimens	Y	n/a
RPM1	IVD	A	Used as a transport medium /wash for the diagnosis and classification of lymphomas using solid tissue and FNAs	Y	n/a
Tissue Processing Protocols (various) - Biopsy tissues - Surgical tissues - Megablock tissues - Fatty tissues		B	To process tissues involving treatment with a series of reagents to fix, dehydrate and clear the tissues before impregnation in a support material to allow for subsequent histological examination	Y	n/a
Manual Special Histochemical Stains (various) - Sirius red and Congo red /Crystal Violet - Gram Twort stain - Martius Scarlet Blue - Haematoxylin Van Gieson - Von Kossa - Masson Fontana/Melanin - Mucicarmine - Wade Fite-Carbol Fuchin - Shikata Orecein - Elastic Fibres-Millers Elastic - Toludine Blue	IVD	B/C	Manual special histochemical stains used for the identification and visualisation of specific structures, material and/or microorganisms which cannot be identified using the H&E stain	Y	n/a

HAEMOSTASIS MOLECULAR DIAGNOSTICS (HMD) LABORATORY

Device identification (e.g. name, description)	Device Type (IVD/MD)	Risk Class of the Device	Intended Purpose	Applicable GSPR Fully Met? Y/N	Information on & justification for applicable GSPR that are not fully met (using the numbering as in Annex 1 of the IVDR)
PCR amplification and Sanger sequencing of human genes associated with inherited bleeding and allied disorders	IVD	C	To detect variants in genes associated with inherited bleeding and allied disorders: FVIII deficiency: F8 FIX deficiency: F9 Fibrinogenemias: FGA, FGB, FGG Von Willebrands Disease (VWD): VWF Antithrombin deficiency: SERPINC1 MYH9-related disorders (MMYH9-RD): MYH9	Y	n/a
Fragment analysis of the F8 and F9 genes	IVD	C	To detect intronic variants within the F8 gene and copy number variations within the F8 and F9 genes causing FVIII and FIX deficiencies.	Y	n/a
Software: JSI Sequence Pilot SeqPatient module / Alamut Visual / Applied Biosystems GeneMapper	IVD	C	To analyse and interpret sequencing and fragment analysis data for identifying variants within genes associated with inherited bleeding and allied disorders	Y	n/a

IMMUNOLOGY LABORATORY

Device indentification (e.g. name, description)	Device Type (IVD/MD)	Risk Class of the Device	Intended Purpose	Applicable GSPR Fully Met? Y/N	Information on & justification for applicable GSPR that are not fully met (using the numbering as in Annex 1 of the IVDR)
Skin biopsy (Direct Immunofluorescence using Microscopy)	IVD	B	Use in the diagnosis of bullous skin disorders	Y	n/a
Cytokine Profile	IVD	B	Measurement of cytokine levels for various inflammatory conditions	Y	n/a
R&D Quantikine CD25-IL2 Rα ELISA kit	IVD	B	Use in the diagnosis of Hemophagocytic lymphohistiocytosis	Y	n/a
In-house controls for the following CE marked assays - Phospholipase A2 receptor In house control - Anti Glomerular basement membrane In house control - Urine CD163 In house control - Glutamic acid decarboylase In house control - Complement function - C 1 inhibitor function - Pneumococcal antibody - Tetanus antibody - Haemophilus influenza b - dsDNA titre - Skin antibodies titre - Smooth muscle antibody titre	IVD	B	Independent IQC for the assay	Y	n/a
CRISP Control Cells (RUO commerical control) - Used in the HLA B27 assay	IVD	B	Independent IQC for the assay	Y	n/a
Extended Lymphocyte surface markers by Flow Cytometry	IVD	B	Use in the diagnosis of Primary Immunodeficiencies	Y	n/a
Oxidative burst by Flow Cytometry	IVD	B	Use in the diganosis of Chronic Granulomatous disease	Y	n/a
Measurement of Leuocyote Adhesion Molecules	IVD	B	Measurement of the expression of adhesion molecules on neutrophils	Y	n/a
Assessment of T-cell proliferation	IVD	B	Analysis of in vitro lymphocyte proliferation as a screening tool for cellular immunodeficiency	Y	n/a
Identification of the presence of a Precipiting IgM using Dithiothreitol (RUO reagent) and Immunofixation	IVD	B	Breakdown IgM aggregates so the monoclonal protein present can be identified.	Y	n/a

IRISH MYCOBACTERIUM REFERENCE LABORATORY (IMRL)

Device identification (e.g. name, description)	Device Type (IVD/MD)	Risk Class of the Device	Intended Purpose	Applicable GSPR Fully Met? Y/N	Information on & justification for applicable GSPR that are not fully met (using the numbering as in Annex 1 of the IVDR)
Investigation of specimens for Mycobacterium Species on the MGIT culture system	IVD	C	To investigate specimens for the presence of Mycobacterium species.	Yes	n/a
Processing Positive Cultures	IVD	C	To test all cultures that flag positive on the MGIT system for the presence of mycobacteria, using ZN & GRAM staining and culture techniques.	Yes	n/a
Susceptibility Testing of Mycobacterium species	IVD	C	To perform phenotypic drug susceptibility testing of positive M tuberculosis complex isolates against WHO defined Group A, B and C anti-TB drugs that may be used as part of the TB treatment regimen.	Yes	n/a
Staining Techniques - Auramine O Fluorescence Staining	IVD	C	To screen smears prepared from specimens before the decontamination process.	Yes	n/a
Xpert MTB/RIF Ultra and MTB/XDR Assays	IVD	C	Xpert MTB/RIF Ultra assay: 1) the detection of M tuberculosis complex DNA in sputum samples or concentrated sediments prepared from sputum samples, 2) the detection of Rifampin resistance associated mutations. XDR-TB assay: 1) the detection of M tuberculosis complex DNA in sputum samples or concentrated sediments prepared from sputum samples, 2) the detection of isoniazid, fluoroquinolone, amikacin, kanamycin, capreomycin and ethionamide resistance associated mutations.	Yes	n/a
Sequencing of the hsp65 gene for the identification of Non-tuberculosis Mycobacteria in the IMRL	IVD	C	Identification of non-tuberculosis mycrobacteria species for the diagnosis of patients from cultured isolates by sequencing the hsp65 gene for the diagnosis of patients	Yes	n/a
Sanger Sequencing of the 16S-23S ITS region rRNA for identification of Non-tuberculous Mycobacteria at the IMRL	IVD	C	Identification of non-tuberculosis mycrobacteria species for the diagnosis of patients from cultured isolates by sequencing the 16S-23S ITS region rRNA for the diagnosis of patients	Yes	n/a
Confirmation of Pyrazinamide Resistant Mycobacterium tuberculosis using sequencing methods in the IMRL	IVD	C	Identification of a mutations/variants conferring resistance within the *pnca* gene of *m.tuberculosis*	Yes	n/a
Confirmation of rifampicin resistance in Mycobacterium tuberculosis Complex (MTBC) isolates using DNA sequencing of the rpoB gene at the IMRL	IVD	C	Identification of a mutations/variants conferring resistance within the *rpoB* gene of *m.tuberculosis*	Yes	n/a
Whole genome sequencing analysis of mycobacterium species using an illumina Sequencing-by-synthesis platform and IMRL bioinformatic analysis pipeline	IVD	C	Identification of a mutations/variants conferring resistance, lineage calling and relatedness analysis of Mycobacterium tuberculosis Complex for the diagnosis of patients	Yes	n/a

Device identification (e.g. name, description)	Device Type (IVD/MD)	Risk Class of the Device	Intended Purpose	Applicable GSPR Fully Met? Y/N	Information on & justification for applicable GSPR that are not fully met (using the numbering as in Annex 1 of the IVDR)
ANALYSIS SOFTWARE					
TBeXist software used with the BD Bactec MGIT instrument	IVD	C	To extend susceptibility testing to all MTC isolates against different concentrations of primary drugs so that a MIC can be generated.	Yes	n/a
DNAStar Lasergene Seqman Pro 17 Software module	IVD	C	Analysis of data from capillary electrophoresis assays.	Yes	n/a
NCBI BLAST software tool online	IVD	C	Analysis of data from capillary electrophoresis assays.	Yes	n/a
TBProfiler Software	IVD	C	Analysis of data from Illumina sequencers.	Yes	n/a
MTBSeq bioinformatic pipeline	IVD	C			
SeqSphere software pipeline	IVD	C			
Kraken analysis tool	IVD	C			
RAxML program	IVD	C			
SNIP Distance matrix	IVD	C			

MICROBIOLOGY LABORATORY

Device indentification (e.g. name, description)	Device Type (IVD/MD)	Risk Class of the Device	Intended Purpose	Applicable GSPR Fully Met? Y/N	Information on & justification for applicable GSPR that are not fully met (using the numbering as in Annex 1 of the IVDR)
ePlex blood culture identification system	IVD	C	MMQCI ePlex BCID-GN Control M326, ePlex BCID-GP Control M323 and ePlex BCID-FP Control M320 are used for Batch Acceptance and ITPC for the ePlex BCID-GN, ePlex BCID-GP and ePlex BCID-FP panels which are CE/IVD qualitative nucleic acid multiplex in vitro diagnostic tests intended for use on the cobas eplex instrument for simultaneous qualitative detection and identification of multiple potentially pathogenic gram-negative, gram positive bacterial organismsand fungi and select determinants associated with antimicrobial resistance in positive blood culture	Y	n/a
Protect Microorganism Preservation system	IVD	A (Class 1s-FDA)	Used to store microorganisms at low temperature, long term storage of stock and QC microorganismes	Y	n/a
Broths used for enrichment or dilution of Microoganisms. Liquid Media: Nutrient broths, , Tryptic Soya Broth (TSB) , TSB + Gycerol, Fraser Broth, Brain heart infusion Broth, Phophate Buffered Saline (PBS), Saline 0.9% and PDA agar, PDA Slopes, Nutrient agar slopes.	IVD	A	Enrichment and dilution broths/agar used to support the growth of Microorganismes:	Y	n/a
Aptima™ Neisseria gonorrhoeae Assay	IVD	C	As a secondary confirmatory assay if required on bacterial isolates received in the GC reference lab from external labs. Used for the in vitro qualitative detection of ribosomal RNA (rRNA) from Neisseria gonorrhoeae (GC) to aid in the diagnosis of gonococcal urogenital disease using the Panther™ system.	Y	n/a

NATIONAL MRSA REFERENCE LABORATORY (NMRSARL)

Device identification (e. g. name, description)	Device Type (IVD/MD)	Risk Class of the Device	Intended Purpose	Applicable GSPR Fully Met? Y/N	Information on & justification for applicable GSPR that are not fully met (using the numbering as in Annex 1 of the IVDR)
Detection of resistance and virulence genes in S. aureus	IVD	B	To detect resistance and virulence genes in S. aureus	Y	n/a
Detection of linezolid resistance genes	IVD	B	To detect resistance genes in Staphylococci and Enterococci	Y	n/a
Whole Genome Sequencing (Bacterial)	IVD	B	To detect resistance genes in Staphylococci and Enterococci, epidemiological typing, surveillance and outbreak investigations	Y	n/a
Whole Genome Sequencing (Covid)	IVD	B	Surveillance of SARS-CoV-2	Y	n/a
Protect Microorganism Preservation system	IVD	A (Class 1s-FDA)	Used to store microorganisms at low temperature, long term storage of stock and QC microorganisms	Y	n/a
Broth Microdilution using custom plates	IVD	A	Susceptibility testing of Enterococci and Staphylococci	Y	n/a

VIROLOGY LABORATORY

Device indentification (e.g. name, description)	Device Type (IVD/MD)	Risk Class of the Device	Intended Purpose	Applicable GSPR Fully Met? Y/N	Information on & justification for applicable GSPR that are not fully met (using the numbering as in Annex 1 of the IVDR)
Abbott Alinity HepA IgG	IVD	C	To diagnose infection / check vaccination status for HAV	Y	n/a
Abbott Alinity HBsAg	IVD	D	To diagnose infection with HBV	Y	n/a
Abbott Alinity anti-HBs	IVD	D	To diagnose infection / check vaccination status for HBV	Y	n/a
Abbott Alinity anti-HBc	IVD	D	To diagnose infection / previous exposure to HBV	Y	n/a
Abbott Alinity HCV Ab	IVD	D	To diagnose infection /previous exposure to HCV	Y	n/a
Abbott Alinity HIV Ag/Ab	IVD	D	To diagnose infection with HIV-1 or HIV-2	Y	n/a
Abbott Alinity Syphilis Ab	IVD	C	To diagnose infection / previous exposure to T. pallidum	Y	n/a
Abbott Alinity EBV VCA IgM	IVD	C	To diagnose infection / previous exposure to	Y	n/a
ASI RPR	IVD	C	to diagnose T. pallidum infection / monitor response to treatment	Y	n/a
Fortress TPHA	IVD	C	To diagnose T. pallidum infection	Y	n/a
Detection of HBV Antiviral Resistance Determinants	IVD	D	To detect mutations associated with antiviral resistance in HBV	Y	n/a
HHV-8 Real-Time PCR Assay	IVD	C	To detect HHV-8 DNA in plasma samples	Y	n/a
Toxoplasma gondii Real-Time PCR Assay	IVD	C	To detect T. gondii DNA in whole blood and CSF samples	Y	n/a
BKV Real-Time PCR Assay	IVD	C	To detect BKV DNA in urine samples	Y	n/a
Argene CMV, EBV and ADV assays	IVD	D	To detect CMV, EBV and ADV DNA in plasma samples and BALs (CMV only)	Y	n/a
HSV Detection and Typing & VZV Real-time PCR Qualitative Assays	Y	C	To detect HSV-1, HSV-2 and VZV DNA in viral swabs from clinical sites	Y	n/a
LGV Real-Time PCR Assay	IVD	C	To detect C. trachomatis LGV Strain DNA in clinical samples	Y	n/a

Device indentification (e.g. name, description)	Device Type (IVD/MD)	Risk Class of the Device	Intended Purpose	Applicable GSPR Fully Met? Y/N	Information on & justification for applicable GSPR that are not fully met (using the numbering as in Annex 1 of the IVDR)
Hepatitis E Real-Time PCR Assay	IVD	C	To detect HEV RNA in serum samples	Y	n/a
Pneumocystis jirovecii Real-Time PCR Assay	IVD	C	To detect P. jirovecii DNA in BAL samples	Y	n/a
Bronchoalveolar lavage (BAL) sample type tested using Mutaplex SARS-CoV-2 Real-Time PCR Assay on Panther Testing system (Hologic)	IVD	D	To detect SARS-CoV-2 RNA in clinical BAL samples	Y	n/a
Bronchoalveolar lavage (BAL) sample type tested using GeneXpert and Xpert Xpress SARS-CoV-2/Flu Assays (combined / individual tests)	IVD	D	To detect SARS-CoV-2 RNA /Flu / RSV in clinical BAL samples	Y	n/a
Bronchoalveolar lavage (BAL) sample type tested using Aptima SARS-CoV-2 Assay on the Panther Testing system (Hologic)	IVD	D	To detect SARS-CoV-2 in clinical BAL samples	Y	n/a
Bronchoalveolar lavage (BAL) sample type tested using ePlex RP2 Assay for the Detection of Respiratory Pathogens on ePlex testing system	IVD	D	To detect respiratory viruses in clinical BAL samples	Y	n/a
Bronchoalveolar lavage (BAL) sample type tested using Panther Fusion Respiratory Assays (Hologic)	IVD	C/D	To detect respiratory viruses in clinical BAL samples	Y	n/a
Panther Fusion Orthopox & SJH Mpox Real-Time PCR Assay on Panther Testing system (Hologic)	IVD	C	To detect Mpox DNA in clinical samples	Y	n/a