


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

 Accredited to ISO 15189:2012	Oncologica UK Limited Issue No: 008 Issue date: 05 August 2021	
	Suite 2 The Newnham Building Chesterford Research Park Little Chesterford Cambridge CB10 1XL United Kingdom	Contact: Pamela Clarke Tel: +44 (0)1223 627098 E-Mail: Pamela.Clarke@oncologica.com Website: www.oncologica.com

Testing performed by the Organisation at the locations specified below

Locations covered by the organisation and their relevant activities

Laboratory locations:

Location details	Activity	Location code
Address Suite 2 The Newnham Building Chesterford Research Park Little Chesterford Cambridge CB10 1XL	Local contact Pamela Clarke	Molecular
		Suite 2

Site activities performed away from the locations listed above:

Location details	Activity
Portakabin Address – as main site, above	As Above
	Unpacking of deactivated Coronafocus Samples



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DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS/TISSUE	<u>Preparatory Molecular examination activities for the purpose of clinical diagnosis</u>	In house documented methods incorporating manufacturer's instruction where relevant	Suite 2
FFPE human samples		Preparation of tissue sections: Re-embedding FFPE blocks Cutting sections for H&E staining Cutting curls for DNA/RNA extraction Equipment: <ul style="list-style-type: none"> • Leica Microtome • Leica Embedding centre SOPs: LP003 LP002	
FFPE human samples		Histology routine staining (H&E) Equipment: Leica Autostainer Thermo Fisher ClearVue Cover Slipper SOPs: LP004 LP005	



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HUMAN BODY FLUIDS/TISSUE (cont'd)	<u>Preparatory Molecular examination activities for the purpose of clinical diagnosis (cont'd)</u> <u>Molecular pathological examination activities for the purpose of clinical diagnosis</u>	In house documented methods incorporating manufacturer's instruction where relevant	Suite 2
FFPE human samples		Tumour assessment / macrodissection Olympus BX51 Microscope SOP: LP034	
FFPE human samples		Manual extraction of DNA & RNA (including reverse transcription to cDNA) from curls or slides Manufactured kit using glass fibre filter technology – Thermo Fisher Scientific SOP: LP013	
FFPE human samples	Protein Levels of PD-L1 in tumour cells and immune cell infiltrates to predict response to anti-PD1 and PD-L1 directed therapies.	Immunofocus Test Antibody: PD-L1 Equipment: Leica Bond III Leica Autostainer Thermo Fisher ClearVue Cover Slipper SOPs: LP018 LP005	Suite 2



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<p>HUMAN BODY FLUIDS/TISSUE (cont'd)</p> <p>Extracted DNA and RNA samples (in house, from the sample types mentioned above)</p>	<p><u>Molecular pathological examination activities for the purpose of clinical diagnosis (cont'd)</u></p> <p>Oncogenes, fusion genes, genes susceptible to copy number variation, SNP hotspots, DNA repair genes and tumour suppressors linked to anti-cancer targeted therapies,</p>	<p>In house documented methods incorporating manufacturer's instruction where relevant</p> <p>Oncofocus test version 3.0</p> <p>Manual Mutation detection of sequence variants using Next-generation sequencing for 505 gene targets :</p> <p>Kits/Equipment: Manufactured Next-Generation sequencing kit Manufactured Library kit – Oncofocus version 3.0</p> <p>Manufactured qPCR Quantitation kit - TaqMan quantitation kit</p> <p>Ion Ampliseq library kit plus Micro-centrifuges Vortexes Thermalcyclers Qubit Fluorometer StepOne Plus RT PCR Ion OneTouch 2 Emulsion PCR Instrument One Touch ES Enrichment Instrument Ion Torrent S5 Next-generation sequencing instrument</p> <p>SOPs: LP022, LP009, LP056, LP052</p> <p>Automated Ion Chef System (automated template preparation and chip loading) Ion Torrent S5 Next-generation sequencing instrument</p> <p>SOP's: LP064</p>	<p>Suite 2</p>



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<p>HUMAN BODY FLUIDS/TISSUE (cont'd)</p> <p>Extracted DNA and RNA samples (in house, from the sample types mentioned above)</p>	<p><u>Molecular pathological examination activities for the purpose of clinical diagnosis (cont'd)</u></p> <p>Immunofocus Tumour Mutation Burden</p>	<p>In house documented methods incorporating manufacturer's instruction where relevant</p> <p>Manual Micro-centrifuges Vortexes Thermalcyclers Qubit Fluorometer Ion Ampliseq library kit plus StepOne Plus RT PCR Ion OneTouch 2 Emulsion PCR Instrument One Touch ES Enrichment Instrument Ion Torrent S5 Next-generation sequencing instrument</p> <p>SOP's LP063, LP056</p> <p>Automated Immunofocus Ion Chef System (automated template preparation and chip loading) Ion Torrent S5 Next-generation sequencing instrument</p> <p>SOP's: LP064</p>	<p>Suite 2</p>



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HUMAN BODY FLUIDS/TISSUE (cont'd)	<u>Molecular examination activities for the purpose of clinical diagnosis</u>	Documented in house methods including DHSC requirements for private providers of Covid-19 testing, to include: <ul style="list-style-type: none"> • General Population Testing, • Test to Release Testing • Day 2 & 8 International Arrival Testing 	Suite 2
Upper respiratory and Nasopharyngeal swabs in Viral Transport Medium (VTM)	Detection of SARS-CoV-2 virus RNA (COVID-19) specifically ORF1ab, N and S gene	RNA Extraction using Applied Biosciences MagMax kits either manually or using a Kingfisher automated purification and extraction instrument SOP's: LP072 Q-PCR using the Thermofisher MagMax CE-IVD RT-PCR kit for SARS CoV2 using Thermofisher Quant Studio 5 Flex system SOP's LP073	Suite 2
Extracted RNA from the samples listed above and received from external laboratories approved for DHSC day 2/8 testing	Whole genome sequencing of SARS-CoV-2 virus	Day 2 international arrival testing only: Targeted Next Generation Sequencing (NGS) Using Ion Ampliseq™ SARS-CoV-2 Panel and Ion GeneStudio S5 Prime Sequencing System SOP's: LP084, LP064	Suite 2
END			