


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

 <b>Accredited to ISO 15189:2012</b>	<b>Oncologica UK Limited</b> <b>Issue No: 010 Issue date: 15 March 2022</b>	
	<b>Suite 2 The Newnham Building Chesterford Research Park Little Chesterford Cambridge CB10 1XL United Kingdom</b>	<b>Contact: Pamela Cornwell Tel: +44 (0)1223 627098 E-Mail: Pamela.Cornwell@oncologica.com Website: www.oncologica.com</b>

**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
<b>Address</b> Suite 2 The Newnham Building Chesterford Research Park Little Chesterford Cambridge CB10 1XL	<b>Local contact</b> Pamela Cornwell	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  <b>Equipment:</b> <ul style="list-style-type: none"> <li>• Leica Microtome</li> <li>• Leica Embedding centre</li> </ul> <b>SOPs:</b> LP003 LP002	
FFPE human samples		Histology routine staining (H&E)  <b>Equipment:</b> Leica Autostainer Thermo Fisher ClearVue Cover Slipper  <b>SOPs:</b> 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>	In house documented methods incorporating manufacturer's instruction where relevant	Suite 2
FFPE human samples		Tumour assessment / macrodissection  Olympus BX51 Microscope  <b>SOP:</b> LP034 LP042	
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  <b>SOP:</b> LP013	
FFPE human samples	<u>Molecular pathological examination activities for the purpose of clinical diagnosis</u>  Quantification of PD-L1 expression (Tumour Proportion Score) and area occupied by tumour infiltrating PD-L1 immune cells	In house documented methods incorporating manufacturer's instruction where relevant  <b>Immunofocus Test</b>  <b>Antibody:</b> PD-L1  <b>Equipment:</b> Leica Bond III Leica Autostainer Thermo Fisher ClearVue Cover Slipper  <b>SOPs:</b> LP018 LP005 LP069	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><b>Manual</b> Mutation detection of sequence variants using Next-generation sequencing for 505 gene targets :</p> <p><b>Kits/Equipment:</b> Manufactured Next-Generation Oncofocus version 3.0 sequencing kit</p> <p>Manufactured qPCR Library Taqman Quantitation kit</p> <p>Ion Ampliseq library kit plus Micro-centrifuges Vortexes Thermalcyclers Qubit Fluorometer StepOne Plus RT PCR QuantStudio 5 real-time PCR system Ion GeneStudio™ S5 System Ion GeneStudio™ S5 Prime System</p> <p><b>SOPs: LP022, LP009, LP056, LP052</b></p>	<p>Suite 2</p>



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		<p><b>Automated</b></p> <p>Mutation detection of sequence variants using Next-generation sequencing for 505 gene targets :</p> <p><b>Using Oncofocus version 3.0 sequencing kit and</b></p> <p>Ion Chef System (automated template preparation and chip loading) Ion GeneStudio™ S5 System Ion GeneStudio™ S5 Prime System</p> <p><b>SOP's: LP064</b></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><b>Manual</b></p> <p>Manufactured Next-Generation Tumour mutation burden sequencing kit</p> <p>Manufactured qPCR Library Taqman Quantitation kit</p> <p>Micro-centrifuges Vortexes Thermalcyclers Qubit Fluorometer Ion Ampliseq library kit plus StepOne Plus RT PCR QuantStudio 5 real-time PCR system Ion Torrent S5 Next-generation sequencing instrument</p> <p><b>SOP's LP022, LP063, LP055,</b></p> <p><b>Automated</b> Immunofocus Ion Chef System (automated template preparation and chip loading) Ion GeneStudio™ S5 System</p> <p><b>SOP's: LP064</b></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"> <li>General Population Testing,</li> <li>Day 2 International Arrival Testing</li> </ul>	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 Flex automated purification and supporting automated platforms including Apricot, Multidrop, Integra Assist Plus and Hamilton Starlet liquid handling systems  <b>SOP's: LP072, LP089, LP091, LP092, LP097</b>  Q-PCR using the Thermofisher Taqpath CE-IVD RT-PCR kit for SARS CoV2 using Thermofisher Quant Studio 5 or 7 Flex system and supporting automated platforms including the Hamilton STAR ad Integra Assist Plus liquid handling systems  <b>SOP's LP073 , LP082, LP090, LP094, LP095</b>	Suite 2



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<p>HUMAN BODY FLUIDS/TISSUE (cont'd)</p> <p>Extracted RNA from the samples listed above and received from external laboratories approved for DHSC day 2/8 testing</p>	<p><u>Molecular examination activities for the purpose of clinical diagnosis</u></p> <p>Whole genome sequencing of SARS-CoV-2 virus</p>	<p>Documented in house methods including DHSC requirements for private providers of Covid-19 testing</p> <p>Day 2 international arrival testing only:</p> <p>Manual and Automated selection of RT-PCR positive SARS-CoV-2 samples for Whole genome Next Generation Sequencing (NGS)</p> <p><b>Kits/Equipment:</b> Manufactured Next-Generation SARS-Cov-2 whole genome sequencing kit</p> <p>Manufactured qPCR Library Taqman Quantitation kit</p> <p>Ion Ampliseq library kit plus Micro-centrifuges Vortexes Thermalcyclers StepOne Plus RT PCR QuantStudio 5 real-time PCR Ion GeneStudio™ S5 System Ion GeneStudio™ S5 Prime System</p> <p><b>SOP's: LP084, LP088, LP055</b></p> <p><b>Automated</b> Ion Chef System (automated template preparation and chip loading)</p> <p>Ion GeneStudio™ S5 System Ion GeneStudio™ S5 Prime System</p> <p><b>SOP's: LP064</b></p>	<p>Suite 2</p>
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