


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

 <p>Accredited to ISO 15189:2012</p>	<b>Oncologica UK Limited</b>  <b>Issue No: 002 Issue date: 09 October 2018</b>	
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<b>Testing performed at the above address only</b>		

### DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS/TISSUE  FFPE human samples  FFPE human samples	<u>Preparatory Molecular examination activities for the purpose of clinical diagnosis</u>	In house documented methods incorporating manufacturer's instruction where relevant  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  Histology routine staining (H&E)  <b>Equipment:</b> Leica Autostainer Thermo Fisher ClearVue Cover Slipper  <b>SOPs:</b> LP004 LP005



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<p>HUMAN BODY FLUIDS/TISSUE (cont'd)</p> <p>FFPE human samples</p> <p>FFPE human samples</p> <p>FFPE human samples</p>	<p><u>Preparatory Molecular examination activities for the purpose of clinical diagnosis (cont'd)</u></p> <p><u>Molecular pathological examination activities for the purpose of clinical diagnosis</u></p> <p>Protein Levels of PD-L1 in tumour cells and immune cell infiltrates to predict response to anti-PD1 and PD-L1 directed therapies.</p>	<p>In house documented methods incorporating manufacturer's instruction where relevant</p> <p>Tumour assessment / microdissection</p> <p>Olympus BX51 Microscope</p> <p><b>SOP:</b> LP034</p> <p>Manual extraction of DNA &amp; RNA (including reverse transcription to cDNA) from curls or slides Manufactured kit using glass fibre filter technology – Thermo Fisher Scientific</p> <p><b>SOP:</b> LP013</p> <p>In house documented methods incorporating manufacturer's instruction where relevant</p> <p><b>Immunofocus Test</b></p> <p><b>Antibody:</b> PD-L1</p> <p><b>Equipment:</b> Leica Bond III Leica Autostainer Thermo Fisher ClearVue Cover Slipper</p> <p><b>SOPs:</b> LP018 LP004 LP005</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>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 1.0)</p> <p>Mutation detection of sequence variants using Next-generation sequencing for 237 gene targets:</p> <p><b>Kits/Equipment:</b> Manufactured Next-Generation sequencing kit Manufactured Library kit – Oncofocus version 1.0</p> <p>Ion AmpliSeq Library kit 2.0 Superscript VILO cDNA synthesis kit</p> <p>Manufactured qPCR Quantitation kit - TaqMan quantitation kit StepOne Plus RT PCR Ion OneTouch 2 Emulsion PCR Instrument One Touch ES Enrichment Instrument Ion Torrent S5 Next-generation sequencing instrument Micro-centrifuges Qubit Fluorometer</p> <p><b>SOPs: LP022, LP009, LP055, LP056, LP052</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>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>Mutation detection of sequence variants using Next-generation sequencing for 505 gene targets :</p> <p><b>Kits/Equipment:</b> Manufactured Next-Generation sequencing kit Manufactured Library kit – Oncofocus version 3.0 Manufactured qPCR Quantitation kit - Ion Library Equaliser Kit 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 Micro-centrifuges Qubit Fluorometer</p> <p><b>SOPs: LP022, LP009, LP056, LP052</b></p>
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