


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

 <p><b>UKAS</b> MEDICAL 9568</p> <p>Accredited to ISO 15189:2012</p>	<h3>Viapath Analytics LLP</h3> <p>Issue No: 002    Issue date: 13 August 2021</p>	
	<p><b>Clinical Transplantation Laboratory (CTL)</b> 3rd Floor Tower Wing Guy's Hospital SE9 1RT</p>	<p><b>Contact: Jeremy Skinner</b> Tel: +44 (0)2071881713 E-Mail: <a href="mailto:jeremy.skinner@viapath.co.uk">jeremy.skinner@viapath.co.uk</a> Website: <a href="http://www.viapath.co.uk">www.viapath.co.uk</a></p>
<p><b>Testing performed at the above address only</b></p>		

### DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
<p>HUMAN TISSUE AND FLUIDS</p> <p>Blood Spleen Lymph node</p> <p>DNA extracted from the sample types listed above</p>	<p><u>Histocompatibility and Immunogenetics examination activities for the purpose of clinical diagnosis:</u></p> <p style="text-align: center;"><u>DNA Tests</u></p>	<p>Examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods:</p> <ol style="list-style-type: none"> <li><u>Automated DNA extraction</u> using: RC2 AA4 DNAP22 DNAP23 DNAP36 DNAP11 DNAP6 RP2 RP3 RP7 RP8 DNAP22 and: Maxwell 16 automated DNA extraction</li> <li>Manual DNA extraction using: Qiagen spin column DNAP21</li> <li><u>DNA quantification</u> using: <u>Nanodrop Lite</u> <u>DNAP29</u></li> <li><u>DNA amplification (PCR)</u> using: DNAP4 and: Applied Biosystems Thermocyclers</li> <li><u>Electrophoresis</u></li> </ol>



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<p>HUMAN TISSUE AND FLUIDS (Cont'd)</p> <p>DNA extracted from the sample types listed above</p>	<p><u>Histocompatibility and Immunogenetics examination activities for the purpose of clinical diagnosis: (cont'd)</u></p>	<p>Examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods:</p> <p>6. <u>SSOP Multiplex bead analysis</u> using: Luminex Liquichip analyser</p> <p>7. <u>Sequencing</u> using: DNAP14 and: 3130xl Genetic Analyser</p> <p>8. <u>HLA typing</u> using: xPonent software MATCHIT! Analysis software for Immucor</p> <p>9. <u>HLA typing</u> using: Unimatch HLA typing software</p> <p>10. <u>HLA typing</u> using: DNAP42 and: uType sequence analysis software</p>
<p>DNA extracted from the sample types listed above</p>	<p>Determination/identification of:</p> <p>Mutations H63D &amp; C282Y in the HFE gene</p> <p>Presence or absence of: HLA-B*27 allelic group</p> <p>Presence or absence of: HLA-B*57:01 allele</p>	<p>Using stated methods listed above:</p> <p>1, 4, 5 DNAP11</p> <p>1, 4, 5 DNAP16</p> <p>1, 4, 5 DNAP25</p>



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<p>HUMAN TISSUE AND FLUIDS (Cont'd)</p> <p>DNA extracted from the sample types listed above</p>	<p><u>Histocompatibility and Immunogenetics examination activities for the purpose of clinical diagnosis: (cont'd)</u></p> <p>HLA Class I &amp; II Typing of: HLA-A HLA-B HLA-C HLA-DRB1/3/4/5 HLA-DQA1 HLA-DQB1</p> <p>HLA Class I typing: HLA-A and/or HLA-B and/or HLA-C</p> <p>HLA Class II typing: HLA-DRB1/3/4/4 and/or HLA-DQB1</p> <p>HLA typing: HLA-A HLA-B HLA-C HLA-DRB/DQB1 HLA-DQA1 HLA-DPB1 HLA-A/B/DRB1</p> <p>HLA typing: HLA-DQA1 HLA-DPB1</p> <p>2<sup>nd</sup> field HLA typing: HLA-A and/or HLA-B and/or HLA-C and/or HLA-DRB1 and/or HLA-DBQ1 and/or HLA-DPB1</p> <p>Determination of the HLA type of a potential deceased donor</p>	<p>Examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods:</p> <p><u>PCR-SSOP</u> 1, 4, 6, 8 DNAP4</p> <p><u>In-house PCR-SSP</u> 1, 4, 5 DNAP4</p> <p><u>In-house PCR-SSP</u> 1, 4, 5 DNAP4</p> <p><u>Invitrogen PCR-SSP</u> 1, 4, 5, 9</p> <p><u>Olerup PCR-SSP</u> 1, 4, 5 DNAP26</p> <p><u>PCR-SBT</u> 2, 3, 4, 5, 7, 10 DNAP41</p> <p><u>Pretype</u> 1, 4, 5, 9 DNAP9</p>



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HUMAN TISSUE AND FLUIDS (Cont'd)	<p><u>Histocompatibility and Immunogenetics examination activities for the purpose of clinical diagnosis: (cont'd)</u></p> <p>HLA subtyping:            A*68            B*18            B*44            C*03            C*04            DQB1*02            DQB1*03            DQB1*04            DQB1*05            DQB1*06            DRB1*01            DRB1*03            DRB1*04            DRB1*07            DRB1*08            DRB1*09            DRB1*10            DRB1*11            DRB1*12            DRB1*13            DRB1*14            DRB1*15            DRB1*16</p>	<p>Examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods:</p> <p><u>Olerup PCR-SSP</u>            1, 4, 5            DNAP26</p>



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<p>HUMAN TISSUE AND FLUIDS (Cont'd)</p> <p>Blood</p>	<p><u>Histocompatibility and Immunogenetics examination activities for the purpose of clinical diagnosis:</u></p> <p><u>Serology Tests</u></p> <p>HLA-Class I and/or Class II specific antibody detection</p>	<p>Examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods:</p> <p><u>Serological detection</u> using:</p> <p>RC-1 RC-2 SP-1 Pol-7 FCP-30 FCP-16 FCP-20 FCP-22 FCP-15 FCP-26 FCP-31 RP-9 RP-10 RP-2 RP3 and: LABScreen Mixed (OLS) Lifecodes PRA Class I (TEC1) Lifecodes PRA Class II (TEC2) Luminex Liquichip analyser &amp; 100 software HLA Fusion analysis software for OneLambda MATCHIT! Analysis software for Immunocor</p>



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<p>HUMAN TISSUE AND FLUIDS (Cont'd)</p> <p>Blood</p>	<p><u>Histocompatibility and Immunogenetics examination activities for the purpose of clinical diagnosis: (cont'd)</u></p> <p>HLA- Class I and/or Class II specific antibody identification</p>	<p>Examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods:</p> <p><u>Serological identification</u> using:</p> <p>RC-1 RC-2 SP-1 Pol-7 FCP-30 FCP-24 FCP-25 FCP-27 FCP-22 FCP-15 FCP-26 FCP-31 RP-9 RP-10 RP-2 RP-3 and: LABScreen Single Antigen Class I / Class II (OSA1/2) Immucor Single Antigen Class I / Class II (TSA1/2) Luminex Liquichip analyser &amp; 100 software HLA Fusion analysis software for OneLambda MATCHIT! Analysis software for Immucor</p>



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HUMAN TISSUE AND FLUIDS (Cont'd)	<u>Histocompatibility and Immunogenetics examination activities for the purpose of clinical diagnosis: (cont'd)</u>	Examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods:
Blood	Identification of donor specific antibody reactivity and confirm or deny donor/recipient compatibility prior to transplantation	<u>Flow cytometric crossmatching</u> using: RC-1 RC-2 FCP-29 FCp-3 TTP-1 TTP-7 TTP-3 FCP-32 FCP-33 FCP-34 Pol-3 Pol-4 RP-2 RP-10 and: Beckman Coulter FC500 flow Cytometer CXP Cytometer software
	Absolute cell count of subsets: CD3 CD19	<u>Immunemonitoring</u> using: RC-1 RC-2 FCP-32 FCP-9 RP-2 and: Beckman Coulter FC500 flow Cytometer CXP Cytometer software
END		