


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 <p>UKAS MEDICAL 9093</p> <p>Accredited to ISO 15189:2012</p>	<h3>Viapath Analytics LLP</h3> <p>Issue No: 011 Issue date: 15 October 2021</p>	
	<p>Biochemical Sciences 4th & 5th Floors North Wing St. Thomas' Hospital Westminster Bridge Road London SE1 7EH</p>	<p>Contact: Dr Rachel Carling Tel: +44 (0) 2071881283 Fax: +44 (0) 2071881269 E-Mail: Rachel.carling@viapath.co.uk Website: www.viapath.co.uk</p>
<p>Testing performed at the above address only</p>		

DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
<p>HUMAN BODY FLUIDS</p> <p>Serum/plasma Whole blood Dried bloodspot Urine Cerebrospinal fluid Faeces</p>	<p><u>Biochemistry examination activities for the purpose of clinical diagnosis</u></p> <p>Biochemical compounds (qualitative & quantitative)</p>	<p>In-house documented methods incorporating manufacturers' instructions as required</p> <p>Flexible scope protocols: SLM-P-3 Management of UKAS Flexible Scope using: Mass Spectrometry technologies:</p> <ul style="list-style-type: none"> • Single quadrupole mass spectrometry (MS) • Triple quadrupole mass spectrometry (MS/MS) <p>and associated technologies:</p> <ul style="list-style-type: none"> • Flow injection analysis (FIA) • Liquid chromatography (LC) • Ultra-high performance liquid chromatography (UHPLC) • Gas chromatography (GC) • Automated sample preparation technologies <p>Flexible scope limited to the application of these methods for the detection of additional biochemical compounds listed in SLM-QF-139 Biochemical Sciences record of changes within flexible scope</p>



9093
Accredited to
ISO 15189:2012

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Viapath Analytics LLP
Issue No: 011 Issue date: 15 October 2021

Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS	<u>Newborn Bloodspot screening</u>	In-house documented methods incorporating manufacturers' instructions as required
Bloodspot	C8 C10 Phenylalanine Tyrosine C5DC C5 Methionine Leucine	Documented in-house methods to meet the requirements of the Newborn blood spot screening programme as defined in the July 2018 Newborn blood spot screening: Laboratory QA evidence requirements Sciex 4500 FIA-MSMS with Exion UPLC (included within flexible scope protocols SLM-P-3) using: SLMN-LP-25 Expanded Screening by LC-MSMS
Blood spot	Total homocysteine	Waters Premier & TQD MSMS (included within flexible scope protocols SLM-P-3) using: SLMN-LP-27 Bloodspot homocysteine
Bloodspot	IRT TSH	Perkin Elmer AutoDELFIA (Immunoassay) using: SLMN-LP-36 Bloodspot IRT analysis SLMN-LP-37 Bloodspot TSH analysis
Bloodspot	Haemoglobin variants S,C,D,E,O-Arab	Waters FIA-MSMS (Xevo TQ-S) (included within flexible scope protocols SLM-P-3) using: SLMN-LP-39 Bloodspot Sickle Screening by FIA-MSMS



9093
Accredited to
ISO 15189:2012

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Viapath Analytics LLP
Issue No: 011 Issue date: 15 October 2021

Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
<p>HUMAN BODY FLUIDS (cont'd)</p> <p>Urine</p> <p>Plasma</p> <p>Dried bile (post-mortem)</p>	<p><u>Inherited Metabolic Diseases</u></p> <p>Organic acids (qualitative interpretation of profile) MMA Orotic acid</p> <p>Very Long Chain Fatty Acids: Phytanate Pristanate C22 C24 C26</p> <p>Qualitative interpretation of profile with quantitation of clinically relevant Acylcarnitines</p>	<p>In-house documented methods incorporating manufacturers' instructions as required</p> <p>Agilent GCMS using: SLMM-LP-35 Urine Organic acid analysis SLMM-LP-54 Interpretation and Reporting of UORG</p> <p>Agilent GCMS using: SLMM-LP-19 Determination of VLCFA by GCMS SLMM-LP-33 Duty Biochemist reporting SOP</p> <p>Waters MSMS (Xevo TQS) using: SLMM-LP-17 Analysis of blood spot Acylcarnitines SLMM-LP-33 Duty Biochemist reporting SOP</p>



9093
Accredited to
ISO 15189:2012

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Viapath Analytics LLP
Issue No: 011 Issue date: 15 October 2021

Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
<p>HUMAN BODY FLUIDS (cont'd)</p> <p>Cerebrospinal fluid (CSF) Urine</p>	<p><u>Inherited Metabolic Diseases</u> (cont'd)</p> <p>Amino Acids: Taurine Threonine Serine Glutamine Glutamate Proline Glycine Alanine Citrulline Cystine Phenylalanine Tyrosine Isoleucine Leucine Valine Methionine Lysine Histidine Ornithine Arginine</p>	<p>In-house documented methods incorporating manufacturers' instructions as required</p> <p>Biochrom Ion Exchange amino acid analysers using: SLMM-LP-38 Amino acid preparation and analysis SLMM-LP-33 Duty Biochemist reporting SOP</p>



9093
Accredited to
ISO 15189:2012

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Viapath Analytics LLP
Issue No: 011 Issue date: 15 October 2021

Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
<p>HUMAN BODY FLUIDS (cont'd)</p> <p>Plasma / CSF</p>	<p><u>Inherited Metabolic Diseases</u> (cont'd)</p> <p>Glycine ratio</p>	<p>In-house documented methods incorporating manufacturers' instructions as required</p> <p>Calculated ratio from: Biochrom Ion Exchange CSF result using: SLMM-LP-38 Amino acid preparation and analysis and Waters MSMS (Xevo TS-S with Acquity LC Plasma result (included within flexible scope protocols SLM-P-3) using: SLMM-LP-52 Plasma AA by LC-MSMS</p>



9093
Accredited to
ISO 15189:2012

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Viapath Analytics LLP
Issue No: 011 Issue date: 15 October 2021

Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	<u>Purine Research Laboratory</u>	In-house documented methods incorporating manufacturers' instructions as required
Urine Plasma	Purine and pyrimidine (qualitative interpretation of profile) including quantitative: Uracil Psuedouridine Uric Acid Hypoxanthine Xanthine Thymine Succinyladenosine SAICAr Deoxyuridine Thymidine Guanosine Inosine Deoxyguanosine Deoxyinosine Adenine Deoxyadenosine	Waters Acquity UPLC with PDA Perkin Elmer Spectrophotometer Lambda 35 using: SLMP-LP-62 Purine and pyrimidine metabolites in urine and plasma SLMP-LP-51 Use of Waters UPLC SLMP-LP-20 –Measurement of Absorbance using the Lambda 35 Spectrophotometer
Blood	Thioguanine / Methylmercaptapurine	Waters Acquity UPLC with PDA using: SLMP-LP-17. Assay of TGN in whole blood SLMP-LP-51 Use of Waters UPLC
Blood Serum	Methotrexate polyglutamates	Waters Alliance HPLC with Fluorescence detection using: SOP SLMP-LP-46 Red blood cell MTX polyglutamate assay SLMP-LP-22 Use of Waters HPLC



9093
Accredited to
ISO 15189:2012

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Viapath Analytics LLP
Issue No: 011 Issue date: 15 October 2021

Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
<p>HUMAN BODY FLUIDS (cont'd)</p> <p>Blood Plasma</p>	<p><u>Purine Research Laboratory</u> (cont'd)</p> <p>Butyrylcholinesterase genotyping</p>	<p>In-house documented methods incorporating manufacturers' instructions as required</p> <p>Manual or QIAcube automated DNA extraction and Agilent AriaMx Real time PCR using: SLMP-LP-54 TaqMan assay for BCHE variants</p>



9093
Accredited to
ISO 15189:2012

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Viapath Analytics LLP
Issue No: 011 Issue date: 15 October 2021

Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
Blood	Purine Disorder Mutation analysis HPRT mutation analysis <u>Genes</u> DPYS DPYD PNP ADSL APRT Gephyrin MOCS1 MOCS2 PRPS1 Thymidine Phosphorylase ADA HNF1B REN SUOX UMOD UMPS BCHE	Manual or QIAcube automated DNA extraction and ABI PRISM 3130xl Genetic Analyser using: SLMP-LP-6. Extraction of DNA from blood SLMP-LP-12. PCR SLMP-LP-7 DNA sequencing SLMP-LP-28 HPRT mutation analysis SLMP-LP-31 DPYS gene sequencing SLMP-LP-32 DPYD gene sequencing SLMP-LP-33 PNP gene sequencing SLMP-LP-34 ADSL gene sequencing SLMP-LP-35 APRT gene sequencing SLMP-LP-36 Gephyrin gene sequencing SLMP-LP-37 MOCS1 gene sequencing SLMP-LP-38 MOCS2 gene sequencing SLMP-LP-40 PRPS1 gene sequencing SLMP-LP-41 Thymidine Phosphorylase sequencing SLMP-LP-43 ADA gene sequencing SLMP-LP-55 HNF1B gene sequencing SLMP-LP-SLMP-LP-56 REN gene sequencing SLMP-LP-57 SUOX gene sequencing SLMP-LP-58 UMOD gene sequencing SLMP-LP-59 UMPS gene sequencing SLM-LP-63 Agarose gel electrophoresis SLMP-LP-69 BCHE Sequencing



9093
Accredited to
ISO 15189:2012

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Viapath Analytics LLP
Issue No: 011 Issue date: 15 October 2021

Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	<u>Purine Research Laboratory</u> (cont'd)	In-house documented methods incorporating manufacturers' instructions as required
HUMAN BODY FLUIDS (cont'd)	<u>Reference Chemistry</u>	In-house documented methods incorporating manufacturers' instructions as required
Serum Urine	Paraprotein quantitation Alkaline phosphatase isoenzyme Lipoprotein	Electrophoresis, Immunotyping (serum only), & Immunofixation using: Sebia Capillarys Sebia Hydrasys using: SLMC-LP-22 Procedure for Sebia Capillarys Electrophoresis & Immunotyping SLMC-LP-23 Protein Electrophoresis and Immunofixation using Sebia Hydrasys Automated Electrophoresis System SLMC-LP-35 Measurement of Serum Lipoproteins using Sebia Hydrasys Automated Electrophoresis system SLMC-LP-4 Alkaline Phosphatase Isoenzymes
Renal Calculi	Qualitative measurement of inorganic and organic compounds	Nicolet iS5 FT IR Spectrometer using: SLMC-LP-41 Stone (calculi) analysis using Nicolet iS5 Mid FT-IR spectrometer SLMC-LP-42 Visual guide Stone (calculi) analysis using Nicolet iS5 Mid FT-IR spectrometer
Serum	Macroenzyme (ALP) detection	PEG precipitation using: SLMC-LI-21 Macroenzyme (ALP) detection by PEG precipitation Laboratory instruction



9093
Accredited to
ISO 15189:2012

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Viapath Analytics LLP
Issue No: 011 Issue date: 15 October 2021

Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS (cont'd)	<u>Reference Chemistry</u> (cont'd)	In-house documented methods incorporating manufacturers' instructions as required
Serum Plasma	Semi quantitative determination of Cryoglobulins: Cryoglobulin precipitate as % of serum	Wintrobe haematocrit (Cryocrit) tubes using: SLMC-LP-10 Cryoglobulin Analysis
Sweat	Chloride	Macroduct Sweat Collection System Corning 925 Chloride Analyser Coulometry using: SLMC-LP-24 Sweat Testing for Cystic Fibrosis
Serum	Cholinesterase total activity Cholinesterase phenotyping	Cobas Mira S using: SLMC-LP-9 Cholinesterase (Butylcholinesterase) Analysis on Cobas Mira S
Serum	Anti-TNF drugs: Adalimumab and anti-drug antibodies Adalimumab biosimilar trade name Humira and anti-drug antibodies	LISA-TRACKER ELISA analysis Dynex DS2 using: SLMC-LP-48 LISA-TRACKER ELISA analysis using the Dynex DS2
Urine Fluid	pH	pH meter hydrogen ion ISE using: SLMC-LP-37 Mettler Toledo pH meter SG2
Urine	Sampling with subsequent analysis by an ISO 15189:2012 accredited laboratory: Intestinal permeability / disaccharide testing	Sample collection using: Intestinal permeability test instructions for patients Intestinal disaccharidase and permeability test instructions
END		