### **Schedule of Accreditation**

issued by

## **United Kingdom Accreditation Service**

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



Accredited to

ISO 15189: 2022

## Royal Wolverhampton NHS Trust operating as Black Country Pathology Services

Issue No: 011 Issue date: 25 April 2025

City Hospital Dudley Road Birmingham B18 7QH

Contact: Katy New
Tel: +44 (0)121 507 4227 Ext 4363
E-Mail: katy.new@nhs.net

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  Laboratories City Hospital Dudley Road Birmingham B18 7QH      | Local contact  Katy New BCPS  Quality Manager | Toxicology           | A             |
| Laboratories<br>Sandwell Hospital<br>Lyndon<br>West Bromwich<br>B71 4HJ | As above                                      | Special Biochemistry | В             |

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#### **DETAIL OF ACCR'EDITATION**

| Materials/Products tested  | Type of test/Properties measured/Range of measurement                     | Standard specifications/<br>Equipment/Techniques used   | Location<br>Code |
|----------------------------|---|---|------------------|
| HUMAN BODY FLUIDS (cont'd) | Biochemistry examination activities for the purpose of clinical diagnosis | Documented In-house methods using:  | В                |
| Serum and Urine            | Osmolality  | Vitech Scientific: Freezing point depression SOP: Serum and urine osmolality PROC-CB-F2.1-MAN/16  |                  |
| Whole blood                | HbA1c   | Tosoh G8 HPLC System<br>SOP: Tosoh G8 HPLC HbA1c<br>PROC-CB-F2.1-MAN/45   |                  |
| Urine                      | Urine Calculi   | Thermo Nicolet iS5 by FTIR<br>SOP: Stone analysis by FTIR<br>Spectroscopy<br>PROC-CB-F2.1-FTIR/01   |                  |
| Urine                      | Oxalate   | Ilab Aries: Spectrophotometer Quantification of Urinary Oxalate by Automated Spectrophotometer PROC-CB-F2.1FTIR/03 Chemistry Manuals 1300 |                  |
|                            | Citrate   | Quantification of Citrate in urine by<br>Automated Spectrophotometer<br>Chemistry - Manuals 1300  |                  |
|                            |   |   |                  |
|                            |   |   |                  |

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|----------------------------|--|--|------------------|
| HUMAN BODY FLUIDS (cont'd) | Biochemistry examination activities for the purpose of clinical diagnosis (cont'd) | Documented In-house methods using:   |                  |
|                            | Quantification determination of  |  |                  |
| Faeces                     | Faecal Calprotectin  | ELISA on DS2 Faecal Calprotectin analysis using the DS2 analyser Chemistry Manuals 424 | В                |
| Serum                      | Adalimumab   | Manual ELISA using the Thermo<br>Plate reader and in house method<br>Chem 492          |                  |
|                            | Infliximab   | Manual ELISA using in house<br>method<br>Chem 193                                      |                  |
| Serum/Plasma               | Serum/ Plasma<br>Cholinesterase  | Ilab Aries and in-house method<br>Chem 915   |                  |
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|-------------------------------|--|--|------------------|
| HUMAN BODY FLUIDS<br>(cont'd) | Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)  Quantification determination of (cont'd) | Documented In-house methods using:   |                  |
|                               | Trace Metals   | /Agilent 7700x/Thermo Fisher iCAPRQ by ICPMS   | В                |
| Blood, serum, plasma, urine   | Cobalt<br>Chromium   | Cobalt & chromium in whole blood<br>& serum SPEC/SOP/TM/17<br>Cobalt, chromium, nickel &<br>cadmium in urine<br>SPEC/SOP/TM/40   |                  |
| Blood/Urine                   | Lead Manganese Mercury Arsenic Cadmium Thallium Antimony Bismuth   | Manganese, Lead, Cadmium, Arsenic and Thallium in whole blood SPEC/SOP/TM39  Mercury in whole blood & urine SPEC/SOP/TM/11  Manganese, arsenic, thallium & lead in urine SPEC/SOP/TM/10 Cobalt, chromium, nickel & cadmium in urine SPEC/SOP/TM/40 |                  |
| Whole Blood                   | Barium<br>Silver   | Antimony, barium, bismuth, silver & strontium and nickel in whole blood and Nickel in serum SPEC/SOP/TM41  |                  |
| Serum/Blood/Urine             | Nickel   | SPEC/SOP/TM41<br>SPEC/SOP/TM/40  |                  |
| Plasma/Serum                  | Aluminium  | Aluminium in plasma & serum (PROC-CB-TE/10)  |                  |

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|----------------------------|--|--|------------------|
| HUMAN BODY FLUIDS (cont'd) | Biochemistry examination activities for the purpose of clinical diagnosis (cont'd) | Documented In-house methods using:   |                  |
|                            | Quantification determination of (cont'd)   |  |                  |
| Serum/Urine/Plasma         | Trace Metals (cont'd)  Copper Selenium Zinc  | /Agilent 7700x/Thermo Fisher iCAPRQ by ICPMS Copper, zinc and selenium in plasma & serum SPEC/SOP/TM16 SPEC/SOP/TM38 Selenium in urine PROC-CB-TE/42 | В                |
| Urine                      | Gallium<br>Indium<br>Iron  | Copper, zinc, selenium and iron in urine by ICP-MS SPEC/SOP/TM/38  |                  |
|                            | Vitamins   |  |                  |
| Serum/Plasma               | D2<br>D3   | Waters Acquity UPLC & Xevo/TQD<br>LC MS-MS<br>Measurement of 25-Hydroxy<br>vitamin D<br>SPEC/SOP/VIT/-003  | В                |
| Blood Spots                | D2<br>D3   | Waters Acquity UPLC & Xevo<br>TQSMS<br>LC MS-MS<br>Measurement of blood spot 25-<br>Hydroxy vitamin D<br>SPEC/SOP/VIT/005                            |                  |
| Serum/Plasma               | Vitamin A<br>Vitamin E<br>β Carotene   | Shimadzu Prominence<br>HPLC<br>Measurement of vitamin A, E and<br>carotenes<br>SPEC/SOP/VIT/004  |                  |
| Whole Blood                | Tacrolimus<br>Sirolimus<br>Cyclosporin   | Waters Acquity/TQS LC MS-MS<br>SPEC/SOP/VIT/022  | В                |

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|----------------------------|--|--|------------------|
| HUMAN BODY FLUIDS (cont'd) | Biochemistry examination activities for the purpose of clinical diagnosis (cont'd) | Documented In-house methods using:   |                  |
| Whole Blood                | Tacrolimus Sirolimus Cyalogogyin   | ABSciex 6500 LC MS-MS<br>SPEC/SOP/VIT/024  | В                |
| Serum and plasma           | Cyclosporin Testosterone Androstenedione 17-hydroxy progesterone DHEAS             |  |                  |
|                            | TPMT   |  |                  |
| Blood                      | Thiopurine methyl transferase (TPMT  | Shimadzu HPLC Measurement of whole blood TPMT activity SPEC/SOP/TPMT/15  | A                |
|                            | TPMT Genotyping  | QIASymphony SP<br>ARMS-PCR<br>SYNGENE InGenius3  | A                |
|                            |  | Extraction of DNA from whole blood using the QIA Symphony SPEC/SOP/TPMT/14 TPMT genotyping by ARMS-PCR SPEC/SOP/TPMT/17 Agarose gel electrophoresis for analysis of TPMT ARMS reaction products SPEC/SOP/TPMT/18 |                  |
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|----------------------------|--|--|------------------|
| HUMAN BODY FLUIDS (cont'd) | Biochemistry examination activities for the purpose of clinical diagnosis (cont'd) | Documented In-house methods using:   |                  |
|                            | TPMT   |  |                  |
| Blood                      | 6-thioguanine (TGN) 6-methylmercaptopurine nucleotides (6MMP)                      | Shimadzu Prominence HPLC<br>Nexera UPLC  |                  |
|                            | , , , , , , , , , , , , , , , , , , ,  | Measurement of whole blood 6-<br>TGN and 6-MMP nucleotides<br>SPEC/SOP/TPMT/24       |                  |
|                            | Red Cell count (RCC)<br>Haematocrit (HCT)  | Sysmex XN-1000 Measurement of Red Blood Cell counts SPEC/SOP/TPMT/9                  | А                |
| Faeces                     | Elastase   | Schebo ELISA kit<br>Measurement of Faecal Pancreatic<br>Elastase<br>SEPC/SOP/TPMT/16 |                  |
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|----------------------------|--|---|------------------|
| HUMAN BODY FLUIDS (cont'd) | Biochemistry examination activities for the purpose of clinical diagnosis (cont'd) | Documented In-house methods using:  |                  |
|                            | TMPT (cont'd)  |   |                  |
| Blood                      | Uridine diphosphoglucose glucuronosyltransferase enzyme (UGT1A1) for               | QIASymphony SP<br>Real-Time PCR   | A                |
|                            | Gilbert's syndrome   | Extraction of DNA from whole blood using the QIASymphony SPEC/SOP/TPMT/14                                 |                  |
|                            |  | Gilbert's syndrome: genotyping of UGT1A1 by Real-Time PCR SPEC/SOP/TPMT/21                                |                  |
|                            | Quantification determination of  |   | А                |
|                            | Toxicology   |   |                  |
| Blood                      | Levetiracetam  | HPLC-DAD Dionex Target Absorption/RT Quantitative analysis of drugs in plasma by HPLC-DAD SPEC/SOP/TOX/83 |                  |
| Blood                      | Amitriptyline<br>Nortriptyline   | HPLC-DAD Dionex Target Absorption/RT Quantitative analysis of drugs in plasma by HPLC-DAD                 |                  |
| Blood                      | Clozapine & norclozapine<br>Lamotrigine  | HPLC-UV Prominence<br>Absorption maxima/RT  |                  |
|                            |  | Quantitative analysis of clozapine, norclozapine & lamotrigine by Shimadzu HPLC-UV SPEC/SOP/TOX/71        |                  |
|                            |  |   |                  |
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|----------------------------|--|---|------------------|
| HUMAN BODY FLUIDS (cont'd) | Biochemistry examination activities for the purpose of clinical diagnosis (cont'd) | Documented In-house methods using:  |                  |
|                            | Quantification determination of (cont'd)   |   |                  |
|                            | Toxicology (cont'd)  |   | А                |
| Blood/Urine                | Ethanol screening & confirmation Methanol screening                                | Shimadzu headspace- GC-FID<br>Target ions   |                  |
|                            | Wethanor sorcerning  | Quantitative analysis of ethanol & methanol SPEC/SOP/TOX/81   |                  |
| Blood                      | TDM: Quetiapine<br>TDM: Olanzapine   | Waters Aquity UPLC-MS/MS<br>Semi-quantitative MRM   |                  |
|                            |  | Quantitative analysis of plasma<br>Olanzapine & Quetiapine by<br>Waters LC-MS/MS<br>SPEC/SOP/TOX/85 |                  |
| Blood                      | Ethylene glycol screening  | Shimadzu GC 2020 plusGC-FID Target ions   |                  |
|                            |  | Quantitative analysis of ethylene glycol by Shimadzu GC-FIC SPEC/SOP/TOX/88                         |                  |
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|--|---|--|------------------|
| HUMAN BODY FLUIDS (cont'd)                   | Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)  | Documented In-house methods using:   |                  |
|  | Quantification determination of (cont'd)  |  |                  |
|  | Toxicology (cont'd)   |  | A                |
| Oral Fluid using Salivette Collection Device | Drugs of abuse screening: Morphine, Codeine   | Waters Acquity UPLC-MS/MS Semi-quantitative MRM                                |                  |
|  | Dihydrocodeine, 6MAM, Methadone EDDP Buprenorphine Norbuprenorphine Cocaine, Benzoylecgnonine Amphetamine Methamphetamine MDA, MDMA, Diazepam Nordiazepam Oxazepam Temazepam Lorazepam Thebaine Ketamine Tramadol Mephedrone, 4-MEC Ethylphenidate Methiopropamine Adamantyl-NOID | Analysis of Oral Fluid Drugs of<br>Abuse by Waters LC-MS/MS<br>SPEC/SOP/TOX/90 |                  |
|  |   |  |                  |

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|----------------------------|---|--|------------------|
| HUMAN BODY FLUIDS (cont'd) | Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)  | Documented In-house methods using:   |                  |
|                            | Quantification determination of (cont'd)  |  |                  |
|                            | Toxicology (cont'd)   |  | Α                |
| Urine                      | Drugs of abuse screening: Morphine Codeine Dihydrocodeine 6MAM Methadone EDDP Buprenorphine Norbuprenorphine Benzoylecgnonine Amphetamine Methamphetamine MDMA Diazepam Nordiazepam Oxazepam Temazepam Lorazepam Thebaine Ketamine N-desmethyltramadol Mephedrone Clonazepam Alprazolam Etizolam Zopiclone Pregabalin Gabapentin Mirtazapine Promethazine Quetiapine Fentanyl | Waters UPLC-MS/MS Semi-quantitative MRM  Analysis of urine drugs of abuse by Waters LC-MS/MS SPEC/SOP/TOX/86 |                  |

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|----------------------------|---|---|------------------|
| Materials/Products tested  | Type of test/Properties<br>measured/Range of<br>measurement                                 | Standard specifications/<br>Equipment/Techniques used           | Location<br>Code |
| HUMAN BODY FLUIDS (cont'd) | Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)          | Documented In-house methods using:                              |                  |
|                            | Quantification determination of (cont'd)  |   |                  |
|                            | Toxicology (cont'd)   |   | A                |
| Plasma and Urine           | Detection and quantitation of synthetic cannabinoids:                                       | Documented In-house methods using:                              |                  |
|                            | AMB-FUBINACA<br>5F-ADB<br>5F-MDMB-PICA<br>4F-MDMB-BINACA<br>MDMB-4en-PINACA<br>ADB-BUTINACA | Waters Acquity /Xevo TQD Micro<br>UPLC MS-MS<br>SPEC/SOP/TOX/37 |                  |
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|----------------------------|--|--|------------------|
| HUMAN BODY FLUIDS (cont'd) | Biochemistry examination activities for the purpose of clinical diagnosis (cont'd) | Documented In-house methods using:   |                  |
|                            | Quantification determination of (cont'd)   |  |                  |
|                            | Toxicology (cont'd)  |  | А                |
| Urine                      | Drugs of Abuse Confirmation  | Shimadzu QP2010 GC-MS<br>Target Ions   |                  |
|                            | Heroin metabolite<br>6-Monoacetylmorphine<br>(6MAM)                                | Quantitative analysis of 6-MAM in urine by Shimadzu GC-MS SPEC/SOP/TOX/75  |                  |
|                            | Benzodiazepines Diazepam Nordiazepam Temazepam Oxazepam Lorazepam                  | Quantitative analysis of<br>Benzodiazepines: Diazepam,<br>Nordiazepam, Oxazepam,<br>Temazepam and Lorazepam in<br>Urine by Shimadzu GC-MS<br>SPEC/SOP/TOX/52 |                  |
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|----------------------------|--|--|------------------|
| HUMAN BODY FLUIDS (cont'd) | Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)     | Documented In-house methods using:   |                  |
|                            | Quantification determination of (cont'd)   |  |                  |
|                            | Toxicology (cont'd)  |  | А                |
|                            | Opiates Morphine Codeine Dihydrocodeine  | Quantitative analysis of Opiates:<br>Morphine, Codeine and<br>Dihydrocodeine in Urine by<br>Shimadzu GC-MS<br>SPEC/SOP/TOX/76  |                  |
|                            | Cannabis metabolite 11-nor-9-carboxy-delta-9- tetrahydrocannbinol (THC- COOH)          | Quantitative Analysis of Cannabis<br>Metabolite (11-nor-9-carboxy-delta-<br>9-tetrahydrocannabinol, THC-<br>COOH) in Urine by Shimadzu GC-<br>MS<br>SPEC/SOP/TOX/113 |                  |
|                            |  | Waters Acquity LC-MS/MS Target Ions  |                  |
| Urine                      | Cannabis metabolite<br>11-nor-9-carboxy-delta-9-<br>tetrahydrocannbinol (THC-<br>COOH) | Waters Acquity/Xevo TQD3 UPLC MS-MS SPEC/SOP/TOX/69  |                  |
| Urine                      | Ethyl glucuronide (EtG)  | Waters Acquity/Xevo TQD4 Micro UPLC MS-MS  |                  |
|                            | Ethyl sulphate (EtS)   | SPEC/SOP/TOX/117   |                  |
| Whole Blood                | Phosphatidylethanol (PEth)   | Waters Acquity/Xevo TQD4 Micro UPLC MS-MS SPEC/SOP/TOX/118   |                  |
|                            | Amphetamines<br>Amphetamine<br>Methamphetamine<br>MDMA                                 | Quantification of Amphetamine (amphetamine, methamphetamine, MDMA, MDA) Methadone, EDDP and Benzoylecgonine in urine by Waters LC-MS/MS SPEC/SOP/TOX/72              |                  |

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|-------------------------------|---|--|------------------|--|--|
| HUMAN BODY FLUIDS<br>(cont'd) | Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)  | Documented In-house methods using:   |                  |  |  |
|                               | Toxicology (cont'd)   |  | А                |  |  |
| Urine (cont'd)                | Drugs of Abuse Confirmation (cont'd)  | Waters Acquity LC-MS/MS<br>Target Ions   |                  |  |  |
|                               | Methadone and metabolite<br>Methadone<br>EDDP   |  |                  |  |  |
|                               | Cocaine metabolite<br>Benzoylecgonine   |  |                  |  |  |
| Biological material           | Unknown toxicology screen:<br>General drugs screen (positive<br>electrospray) as per Waters<br>(Masslynx 4.1 TOF TOX<br>database 1) | Waters Xevo UPLC-MS/TOF<br>Exact mass/RT<br>Toxicology screening using the<br>Waters Xevo G2 TOF: General<br>drug screening method with<br>positive electrospray<br>SPEC/SOP/TOX/106 |                  |  |  |
|                               | Unknown toxicology screen:<br>General drugs screen<br>(negative electrospray) as per<br>Waters (Neg-ion-library-<br>201115)         | Toxicology screening using the Waters Xevo G2 TOF: General drug screening method with negative electrospray SPEC/SOP/TOX/107   |                  |  |  |
| END                           |   |  |                  |  |  |

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