


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

|  |  |  |
|--|--|--|
|  <p><b>UKAS</b><br/>TESTING</p> <p><b>10641</b></p> <p>Accredited to<br/>ISO/IEC 17025:2017</p> | <p><b>PURA Diagnostics Ltd</b></p> <p>Issue No: 004      Issue date: 19 October 2021</p> |  |
|  | <p>Unit D5<br/>Churcham Business Park<br/>Churcham<br/>Gloucestershire<br/>GL2 8AX</p>   | <p>Contact: Laboratory Director<br/>Tel: +44 (0)145 222 6125<br/>E-Mail: info@puradx.com<br/>Website: www.puradx.com</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>Whole blood</p> | <p><u>Haematology examination activities for the purposes of clinical diagnosis:</u></p> <p><b>Full Blood Count</b></p> <p>Red Blood Cells (RBC)</p> <p>Haematocrit (HCT)</p> <p>Mean Cell Volume (MCV)</p> <p>Mean Cell Haemoglobin (MCH)</p> <p>Haemoglobin Concentration (MCH)</p> <p>White Blood Cells (WBC)</p> <p>Neutrophils (NEUT)</p> <p>Lymphocytes (LYMP)</p> <p>Monocytes (MONO)</p> <p>Eosinophils (EOSO)</p> <p>Basophils (BASO)</p> | <p>Documented in house methods and manufacturer's instructions for:</p> <p><b>Beckman Coulter Unicel DxH 900 AIM technology incorporating fluorescence flow cytometry, electrical impedance, RBC pulse height detection method, sheath flow direct current (DC) detection method and calculated red cell parameters</b></p> <p><b>SOP 7.2.3.1</b></p> |



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|----------------------------|--|--|
| HUMAN BODY FLUIDS (cont'd) | <u>Biochemistry examination activities for the purposes of clinical diagnosis:</u> | Documented in house methods and manufacturer's instructions for: |
| Serum                      | <b>Quantitative analysis of:</b>   | <b>Beckman Coulter AU 480/700</b>                                |
|                            |  | <b>SOP 7.2.1.2</b>   |
|                            |  | <b>SOP 7.2.1.3</b>   |
|                            |  | <b>SOP 7.2.1.4</b>   |
|                            |  | <b>SOP 7.2.1.5</b>   |
|                            |  | <b>SOP 7.2.1.6</b>   |
|                            | Bilirubin  | Diazo  |
|                            | Hs CRP   | Latex  |
|                            | Urea   | Urease Kinetic   |
|                            | Creatinine   | Enzymatic  |
|                            | Transferrin  | Immunoturbidometric  |
|                            | Glucose  | Hexokinase   |
|                            | Total Protein  | Biuret – end point   |
|                            | Albumin  | BCG  |
|                            | Globulin   | BCG/Biuret End Point   |
|                            | Urate  | Uricase/Peroxidase   |
|                            | AST  | IFCC with PLP  |
|                            | ALT  | IFCC with PLP  |
|                            | ALP  | IFCC (AMP with Zn.Mg)  |
|                            | GGT  | IFCC (carboxy-nitroaniline)                                      |
|                            | Iron   | TPTZ   |
|                            | Cholesterol  | Cholesterol Oxidase  |
|                            | Triglyceride   | GK/GOP-PAP   |
|                            | HDL  | Elimination  |



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|---|--|---|
| HUMAN BODY FLUIDS (cont'd)  | <u>Biochemistry examination activities for the purposes of clinical diagnosis:</u><br>(cont'd) | Documented in house methods and manufacturer's instructions for:  |
| Whole blood   | <b>Quantitative analysis of</b> (cont'd)   | <b>Beckman Coulter Unicel DxH 480/700</b><br><b>SOP 7.2.1.2</b><br><b>SOP 7.2.1.3</b><br><b>SOP 7.2.1.4</b><br><b>SOP 7.2.1.5</b><br><b>SOP 7.2.1.6</b> |
|   | HbA1C  | Turbidimetric immuno-inhibition   |
| HUMAN BODY FLUIDS   | <u>Serological examination activities for the purposes of clinical diagnosis:</u>              | Documented in house methods and manufacturer's instructions   |
| Venous and capillary serum (fingerprick). For the purpose of testing under the National Covid Prevalence Testing Programme; Clinical Trials and to Healthcare organisations only: | Qualitative detection of SARS-CoV-2 (COVID-19) Total antibodies (IgM/IgG)                      | Elecsys Anti-SARS-CoV-2 S (qualitative) assay on the Roche Cobas on the 411 and 602<br>SOP 7.5.1<br>SOP 7.5.3<br>SOP 7.1.6                              |
|   | Quantitative determination of SARS-CoV-2 Spike antibodies                                      |   |
| END   |  |   |