


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

| | | |
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|  Accredited to ISO 15189:2012 | Viapath Analytics LLP Issue No: 007 Issue date: 11 May 2021 | |
| | Department of Haematological Medicine Ground Floor Bessemer Wing King's College Hospital Denmark Hill London SE5 9RS United Kingdom | Contact: Nura Ibrahim Tel: +44 (0) 203 299 7685 E-Mail: nura.ibrahim@nhs.net Website: www.viapath.co.uk |
| Testing performed at the above address only | | |

Site activities performed away from the locations listed above:

| Location details | Activity |
|--|--|
| King's College Hospital (Denmark Hill): <ul style="list-style-type: none">• Emergency Department• Liver Theatre• Neuro Theatre• Main Theatres• Nightingale Birth Centre (NBC)• Liver Unit ITU (LITU)• Centenary Wing• Harris Birthright (Windsor Walk) King's College Hospital (Orpington Site): <ul style="list-style-type: none">• Orthopaedic Theatres | Storage & issue of blood & blood products only |



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DETAIL OF ACCREDITATION

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used |
|---|--|---|
| <p>HUMAN TISSUES AND FLUIDS</p> <p>Bone Marrow Peripheral Blood Smears CSF Ascitic fluid Pleural Effusion</p> | <p><u>Cytogenetic analysis for the purpose of clinical diagnosis</u></p> <p>Detection of diagnostically and prognostically relevant cytogenetic abnormalities defined in the WHO Classification of Tumours of Haematopoietic and Lymphoid Tissues (2008 & 2016 revisions)</p> <p>Karyotyping</p> | <p>In house documented methods incorporating manufacturers' instructions as required</p> <p>Culturing of human tissues/cells using: LP-HAE-CYT-Booking In LP-HAE-CYT-SYSMEXAUTO LP-HAE-CYT-Set Up</p> <p>Preparation of cultured cells by manual harvest and G-banding for chromosome analysis using: LP-HAE-CYT-HRVST LP-HAE-CYT-Slide Prep LP-HAE-CYT-GBAND LP-HAE-CYT-MSLOAD</p> <p>Cell separation of CD138+ cells from Multiple Myeloma referrals using: LP-HAE-CYT-PCD</p> <p>Fluorescence In-situ Hybridisation (FISH) using commercial probes and: LP-HAE-CYT-FISH</p> <p>G-banded metaphase analysis using: LP-HAE-CYT-ANALYSIS</p> <p>Fluorescent In-Situ Hybridisation (FISH) analysis using: LP-HAE-CYT-ANALYSIS LP-HAE-CYT-FISHCAP</p> |
| <p>Peripheral Blood</p> | <p>Constitutional analysis to confirm karyotyping findings</p> | <p>G-banded metaphase analysis & FISH analysis using: LP-HAE-CYT-ANALYSIS</p> |



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| <p>HUMAN TISSUES AND FLUIDS (cont'd)</p> <p>Genomic DNA extracted in house from whole blood (unless stated otherwise for specified tests) or received as primary sample type</p> | <p><u>Molecular haematology examinations for the purpose of clinical diagnosis (cont'd)</u></p> <p>Confirmation of HbS and HbC variants</p> <p>Confirmation of HbC variants</p> <p>Confirmation of the HbS mutation</p> <p>Detection of single base changes and microlesions in the HBB, HBA1, HBA2 and HBD genes</p> <p>Detection of large deletions and duplications in the HBB, HBA1 and HBA2 genes</p> | <p>In house documented methods incorporating manufacturers' instructions as required</p> <p>Restriction fragment length polymorphism (RFLP) assay by PCR using: Eppendorf Mastercycler Nexus or Applied Biosystems Veriti™ and Agarose gel electrophoresis LP-HAE-PND013</p> <p>Amplification refractory mutation system (ARMS) assay by PCR using: Eppendorf Mastercycler Nexus or Applied Biosystems Veriti™ Thermal Cycler and Agarose gel electrophoresis LP-HAE-PND014</p> <p>Sanger Sequencing using: Applied Biosystems 3130xl Genetic Analyser LP-HAE-PND039</p> <p>Sanger Sequencing using: Applied Biosystems 3130xl Genetic Analyser LP-HAE-PND118</p> <p>MLPA by PCR and: Applied Biosystems 3130xl Genetic Analyser LP-HAE-PND117</p> |



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| <p>HUMAN TISSUES AND FLUIDS (cont'd)</p> <p>Genomic DNA extracted in house from whole blood (unless stated otherwise for specified tests) or received as primary sample type</p> <p>and DNA extracted from: Saliva Dried blood spots Amniotic fluid CVS Cultured amniocytes Fetal blood</p> <p>and DNA extracted from: Whole blood Saliva Dried Blood Spot</p> | <p><u>Molecular haematology examinations for the purpose of clinical diagnosis (cont'd)</u></p> <p>Thalassaemia syndromes genetic analysis: Detection of common deletions in the HBA1 and HBA2 genes known to cause Alpha Thalassaemia</p> <p>Detection of single base changes and microlesions in the HBB, HBA1 and HBA2 genes that cause Thalassaemia syndromes</p> <p>Detection of large deletions and duplications in the alpha globin loci on chromosome 16 and the beta globin loci on chromosome 11</p> <p>Confirmation of Haemoglobin variants</p> <p>Hereditary persistence of fetal haemoglobin (HPFH) genetic analysis: Detection of the most common deletional forms of HPFH caused by large deletions in the beta globin loci</p> | <p>In house documented methods incorporating manufacturers' instructions as required</p> <p>Gap PCR using: Eppendorf Mastercycler Nexus or Applied Biosystems Veriti™ Thermal Cycler and Agarose gel electrophoresis LP-HAE-PND052</p> <p>Sanger Sequencing using: Applied Biosystems 3130xl Genetic Analyser LP-HAE-PND118</p> <p>MLPA by PCR using: Eppendorf Mastercycler Nexus or Applied Biosystems Veriti™ Thermal Cycler Applied Biosystems 3130xl Genetic Analyser LP-HAE-PND117</p> <p>ARMS assay by PCR using: Eppendorf Mastercycler Nexus or Applied Biosystems Veriti™ Thermal Cycler and Agarose gel electrophoresis LP-HAE-PND014</p> <p>MLPA by PCR using: Eppendorf Mastercycler Nexus or Applied Biosystems Veriti™ Thermal Cycler Applied Biosystems 3130xl Genetic Analyser LP-HAE-PND072</p> |



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| <p>HUMAN TISSUES AND FLUIDS (cont'd)</p> <p>Genomic DNA extracted in house from whole blood (unless stated otherwise for specified tests) or received as primary sample type</p> | <p><u>Molecular haematology examinations for the purpose of clinical diagnosis (cont'd)</u></p> <p>Red blood cell disorders and mutations: Membranopathy Red Cell Enzyme Haemoglobinopathies Congenital Erythrocytosis Diamond-Blackfan Anaemia Bone Marrow Failure Thrombocytopenia Neutropenia Porphyria Siderblastic Anaemia Iron Regulation HLH Lymphedema Single Genes (HP, Serpina1, UGTA1) Sex Chromosome Markers</p> <p>Validation of variants from NGS</p> | <p>In house documented methods incorporating manufacturers' instructions as required</p> <p>Beckman Coulter FXP robot to construct sequencing libraries followed by hybridisation to probe targets and amplification. Amplified library sequenced by Next Generation Sequencing (NGS) on Illumina MiSeq. Data analysed using a NIPY pipeline LP-HAE-PND132</p> <p>Sanger Sequencing using: Applied Biosystems 3130xl Genetic Analyser LP-HAE-PND131</p> |



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| <p>HUMAN BODY FLUIDS</p> <p>Blood Bone Marrow</p> | <p><u>Haematology/Immunophenotyping examinations for the purpose of clinical diagnosis</u></p> <p>Immunophenotyping for Chronic T and B lymphoproliferative disorders: LST Tube: CD19 CD20 CD45 Kappa Lambda CD38 CD5 CD4 CD8 CD3 CD56</p> <p>B-cell follow on:</p> <p>Tube 1: CD19 CD81 CD23 CD79b CD10 CD200 CD43 CD45</p> <p>Tube 2: CD19 CD103 CD123 CD11c CD25 ROR1 CD45</p> | <p>In house documented methods incorporating manufacturers' instructions as required</p> <p>Becton Dickinson FACS Canto II Flow Cytometry of fluorescent labelled cells LP-HAE-IM1030 LP-HAE-IM1006 LP-HAE-IM1053</p> |



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| HUMAN BODY FLUIDS (cont'd) | <u>Haematology/Immunophenotyping examinations for the purpose of clinical diagnosis (cont'd)</u> | In house documented methods incorporating manufacturers' instructions as required |
| Blood Bone Marrow | T-cell follow on: Tube 1: CD57 CD2 CD16 CD7 CD25 CD3 HLADR CD45 Tube 2: TCR Alpha/Beta CD30 CD10 TCR Gamma/Delta CD3 CD4 CD45 | Becton Dickinson FACS Canto II Flow Cytometry of fluorescent labelled cells LP-HAE-IM1030 LP-HAE-IM1006 LP-HAE-IM1053 |
| Blood Bone Marrow | Immunophenotyping for diagnosis of acute leukemia: Acute "Screen": CD8 Lambda Kappa CD34 CD33 CD3 HLADR CD117 CD4 CD19 CD45 | Becton Dickinson FACS Canto II Flow Cytometry of fluorescent labelled cells LP-HAE-IM1030 LP-HAE-IM1006 |



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| <p>HUMAN BODY FLUIDS (cont'd)</p> <p>Blood Bone Marrow</p> | <p><u>Haematology/Immunophenotyping examinations for the purpose of clinical diagnosis (cont'd)</u></p> <p>Acute Leukemia Orientation Tube: MPO CD79a CD34 CD19 CD7 CD3 cytCD3 CD45AML 4 Antigen Backbone: CD34 CD117 HLADR CD45</p> <p>Tube 1: CD16 CD13 CD10 CD11b</p> <p>Tube 2: CD14 CD300e CD64</p> <p>Tube 3: CD38, CD56, CD15, CD19</p> <p>Tube 4: CD36 CD105 CD33 CD71</p> <p>Tube 5: CD61/CD42 CD123 CD7 CD4</p> | <p>In house documented methods incorporating manufacturers' instructions as required</p> <p>Becton Dickinson FACS Canto II Flow Cytometry of fluorescent labelled cells LP-HAE-IM1030 LP-HAE-IM1006</p> |



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| HUMAN BODY FLUIDS (cont'd) | <u>Haematology/Immunophenotyping examinations for the purpose of clinical diagnosis (cont'd)</u> | In house documented methods incorporating manufacturers' instructions as required |
| Blood Bone Marrow | <p>B-ALL:</p> <p>Tube 1: CD58 CD66c CD34 CD10 CD38 CD20 CD45 CD19</p> <p>Tube 2: TDT NG2 CD34 CD13 CD19 HLADR CD123 CD45</p> <p>T-ALL</p> <p>Tube 1 TDT CD1A CD5 CD10 CD8 CD3 CD4 CD45</p> <p>Tube 2: CD2 CD99 CD5 CD7 TCR gamma delta CD3 CD123 CD45</p> | <p>Becton Dickinson FACS Canto II Flow Cytometry of fluorescent labelled cells LP-HAE-IM1030 LP-HAE-IM1006</p> |



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| <p>HUMAN BODY FLUIDS (cont'd)</p> <p>Blood Bone Marrow</p> | <p><u>Haematology/Immunophenotyping examinations for the purpose of clinical diagnosis (cont'd)</u></p> <p>Minimal Residual Disease (MRD) assessment of: B-acute lymphoblastic leukaemia: CD58 CD66c CD34 CD10 CD38 CD20 CD45 CD19</p> <p>Chronic lymphocytic leukaemia: CD81 CD79b CD5 ROR 1 CD19 CD20 CD43 CD45</p> <p>Acute myeloid leukaemia: CD34 CD117 CD45 HLADR CD13 CD33 CD11b CD2 CD5 CD38 CD123 CD19 CD36 CD56 CD7 CD64</p> | <p>In house documented methods incorporating manufacturers' instructions as required</p> <p>Becton Dickinson FACS Canto II Flow Cytometry of fluorescent labelled cells LP- HAE-IM1123 LP-HAE-IM1122</p> <p>LP-HAE-IM-1125</p> |



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| <p>HUMAN BODY FLUIDS (cont'd)</p> <p>Blood Bone Marrow</p> <p>Blood Bone Marrow</p> | <p><u>Haematology/Immunophenotyping examinations for the purpose of clinical diagnosis (cont'd)</u></p> <p>Immunophenotyping for the diagnosis of Plasma cell disorders: CD27 CD56 CD5 CD138 CD38 CD20 CD45 CD19</p> <p>Cyt Kappa / Cyt Lambda CD117 CD138 CD38 CD45 CD19</p> <p>Testing for Paroxysmal Nocturnal Haemoglobinuria (PNH): WBC: CD157 FLAER CD64 CD15 CD45</p> <p>RBC: CD59 CD235a</p> | <p>In house documented methods incorporating manufacturers' instructions as required</p> <p>Becton Dickinson FACS Canto II Flow Cytometry of fluorescent labelled cells LP-HAE-IM1108</p> <p>Becton Dickinson FACS Canto II Flow Cytometry of fluorescent labelled cells LP-HAE-IM1030 LP-HAE-IM1006</p> |



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| <p>HUMAN BODY FLUIDS (cont'd)</p> <p>Blood Bone Marrow</p> | <p><u>Haematology/Immunophenotyping examinations for the purpose of clinical diagnosis (cont'd)</u></p> <p>Immunophenotyping for Myelodysplastic Syndrome (MDS) assessmenty</p> <p>CD34 CD117 CD45 HLADR CD16 CD10 CD11b CD13 CD14 CD64 IREM2 CD38 CD19 CD56 CD15 CD71 CD36 CD33 CD7 CD123 CD4</p> | <p>In house documented methods incorporating manufacturers' instructions as required</p> <p>Becton Dickinson FACS Canto II Flow Cytometry of fluorescent labelled cells LP-HAE-IM1126</p> |



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| <p>HUMAN BODY FLUIDS (cont'd)</p> <p>Blood</p> <p>Blood</p> | <p><u>Haematology examinations for the purpose of clinical diagnosis</u></p> <p>Full Blood Count (FBC): WBC RBC HGB PCV(HCT) MCV MCH MCHC RDW-CV PLT MPV #NEUT #LYMP #MONO #EOS #BASO #NRBC Metamyelocyte count Myleocyte count Promyelocyte count Blasts Blast Flag Immature Granulocyte Flag Platelet Clump Flag Atypical Lymphocyte Flag</p> <p>Reticulocytes: Retic absolute Retic Percentage LFR MFR HFR Retic RBC IRF %HYPO Ret-He</p> | <p>In house documented methods incorporating manufacturers' instructions as required</p> <p>Sysmex XN-9100 series – XN10 Optical Analysis (Flow Cytometry) LP-BS-HA001</p> <p>Sysmex XN-9100 series – XN10 Optical Analysis (Flow Cytometry) LP-BS-HA001</p> |



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| HUMAN BODY FLUIDS (cont'd) | <u>Haematology examinations for the purpose of clinical diagnosis</u> (cont'd) | In house documented methods incorporating manufacturers' instructions as required |
| Blood | Detection and speciation of Malaria parasites: <i>Plasmodium falciparum</i> , <i>P. vivax</i> , <i>P. ovale</i> , <i>P. malariae</i> , <i>P. knowlesi</i> , trypanosomes, microfilariae, <i>Leishmania</i> spp. <i>P. falciparum</i> -specific HRP II antigen Pan-malarial antigen of: <i>P. falciparum</i> , <i>P. vivax</i> , <i>P. ovale</i> , <i>P. malariae</i> | Wright-Giemsa & Giemsa R66 staining followed by Light Microscopy ML008, ML009 BINAX NOW ICT Immunochromatographic assay ML009 |
| Blood (Thin blood films) | Detection of <i>Plasmodium</i> spp. | Pathway Diagnostics Quantitative Buffy Coat (QBC) kit & Fluorescence microscopy ML009 |
| Blood | Morphological analysis & differential cell count | Light Microscopy ML007, ML018 |
| Blood | Erythrocyte Sedimentation Rate (ESR) | Sysmex Starrsed Interrliner XN FRL Westergren method LP-BS-HA002 |
| Blood | Infectious Mononucleosis screen: Detection of the heterophile antibody | Accusay Mono Solid-phase immunoassay and: ML003 |



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| HUMAN BODY FLUIDS (cont'd) | <u>Haematology examinations for the purpose of clinical diagnosis</u> (cont'd) | In house documented methods incorporating manufacturers' instructions as required |
| Blood | Prothrombin/ INR Activated partial thromboplastin time/APTT Clauss Fibrinogen Thrombin Time Factor Assays: FII FV FVII FVIII FIX FX FXI FXII | Sysmex CS-5100 Clot method LP-BS-HT001 |
| Blood | Reptilase Time DRVV Activated Protein C Resistance | Sysmex CS-5100 Snake Venom Assays LP-HAE-HT004, HT070, HT073 |
| Blood | DDimer VWF Antigen Free Protein S | Sysmex CS-5100 Latex bead Immunoturbidimetric Assay LP-HAE-HT077, HT087, HT025 |
| Blood | Anti-Xa: Heparin Rivaroxaban Apixaban Edoxaban Antithrombin Activity Protein C Activity | Sysmex CS-5100 Chromogenic method LP-HAE-HT075, HT072 |
| Blood | Ecarin Time - Dabigatran | Sysmex CS-5100 Chromogenic Ecarin Time LP-HAE- HT096 |



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| HUMAN BODY FLUIDS (cont'd) | <u>Haematology examinations for the purpose of clinical diagnosis</u> (cont'd) | In house documented methods incorporating manufacturers' instructions as required |
| Blood | Haemoglobinopathy Screening (inc. Antenatal, Pre-anaesthetic, Sickle Cell and Thalassaemia Screening by detection of haemoglobin variants: Haemoglobins S, C, D, E, O-Arab, Lepore | Documented in-house methods to meet the requirements of the Sickle Cell and Thalassaemia screening programme(s) as defined in the July 2018 'Sickle Cell and Thalassaemia screening: laboratory QA evidence requirements' Bio-Rad Variant II HPLC LP-HAE-RC-HB003 Helena Acid Agarose Gel Electrophoresis LP-HAE-RC-HB005 Perkin Elmer Iso-Electric focussing system LP-HAE-RC-NNS012 |
| Blood | Sickle cell solubility | Microgen Sickle solubility test LP-HAE-RC-HB002 |
| Dry Blood Spot | Newborn Screening confirmation of haemoglobin variants: Haemoglobins S, C, D, E, O-Arab | Manual DBS punching and Perkin Elmer Iso-Electric focussing system LP-HAE-RC-NNS012 |
| Blood | Haemoglobin H bodies identification | Supra-vital staining with brilliant Cresyl blue and microscopic examination LP-HAE-RC-HB009 |
| Blood | Haemoglobin S and Haemoglobin F quantification | Bio-Rad Variant II HPLC analyser LP-HAE-RC-HB003 |
| Blood | Investigation for Hereditary Spherocytosis | EMA dye binding to red blood cells and flow cytometry analysis on Becton Dickinson FACS Canto II LP-HAE-RC-NEH-007 |



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| HUMAN BODY FLUIDS (cont'd) | <u>Haematology examinations for the purpose of clinical diagnosis</u> (cont'd) | In house documented methods incorporating manufacturers' instructions as required |
| Blood | Red Cell Enzymes: Glucose-6-Phosphate Dehydrogenase (G6PD) Pyruvate Kinase Hexokinase Glucose Phosphate Isomerase Phospho-glycerate Kinase Triose-phosphate Isomerase Aldolase Glutathione Reductase Methaemoglobin Reductase | Analysis of prepared red cell lysate by spectrophotometric measurement of rate of reduction of NADP or oxidation of NADH using Glock and McLean method LP-HAE-RC-MET013 LP-HAE-RC-MET015 LP-HAE-RC-MET014 LP-HAE-RC-MET017 LP-HAE-RC-MET019 LP-HAE-RC-MET020 LP-HAE-RC-MET016 LP-HAE-RC-MET022 LP-HAE-RC-MET021 |
| Blood | Glucose-6-Phosphate Dehydrogenase deficiency screen | BinaxNOW G6PD kit LP-HAE-RC-MET023 |
| Bone marrow | Morphological analysis | May-Grunwald and Giemsa staining followed by microscopy LP-HAE-IM1005 |
| | Blood transfusion examinations for the purpose of clinical diagnosis | In house documented methods incorporating manufacturers' instructions as required |
| Blood | ABO / RhD Blood Group antigens: A, B & D | Automated using: Biorad IH1000 Biorad Gelstation LP-HAE-BT2-001, BT-3-A |
| Blood | Antibody Screen for: D, C, Cw, E, c, e, K, Fya, Fyb, Jka, Jkb, S, s, Lea, Leb, M,N & Lua | Automated using: Biorad IH1000 Biorad Gelstation LP-HAE-BT2-001, BT3-A |



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| HUMAN BODY FLUIDS (cont'd) | <u>Blood transfusion examinations for the purpose of clinical diagnosis</u> | In house documented methods incorporating manufacturers' instructions as required |
| Blood | DAT (polyspecific, monospecific) | Automated using: Biorad IH1000 Biorad Gelstation LP-HAE-BT2-001, BT2-05, BT3-D |
| Blood | RHK phenotype antigens: D,C,c, E, e, K | Automated using: Biorad IH1000 Biorad Gelstation LP-HAE-BT2-001, BT2-003 |
| Blood | Non-RHK phenotype antigens: Jka, Jkb, Lea, Leb, S, s, M/N, Fya, Fyb | Automated (except Fya/Fyb) using: Biorad Gelstation, ID- Incubator 37 SI, ID-Centrifuge 12 S, DiaCent-12 LP-HAE-BT2-003, BT3-008 |
| Blood | Antibody Titres of: Anti-A Anti-B | Manual using: BioRad cards/gels, ID-Centrifuge 12, ID-Incubator 37I LP-HAE-BT5-033 |
| Blood | Foetal maternal haemorrhage | Kleihauer acid elution test using Microscopy LP-HAE-BT3-J |
| Blood | Antibody identification of: D, C, Cw, E, c, e, K, Fya, Fyb, Jka, Jkb, S, s, Lea, Leb, M, N & Lua | Automated or manual using: Biorad Gelstation, ID-Incubator 37 SI, ID-Centrifuge 12 S LP-HAE-BT2-002, BT3-B |
| Blood | Baby ABO / RhD Blood Group antigens: A, B, AB & D | Automated using: Biorad IH1000 Biorad Gelstation LP-HAE-BT3-A, BT2-001 |
| Blood | ABO / RhD Blood Group antigens: A, B & D | Manual using: BioRad cards/gels, DiaCent 12 Centrifuge LP-HAE-BT4-008 |

END