

Schedule of Accreditation



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|---|---|
| Organisation Name | University Hospital Kerry |
| Trading As | |
| INAB Reg No | 197MT |
| Contact Name | Carol Shanahan |
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| Website | https://www.hse.ie |
| Accreditation Standard | EN ISO 15189 |
| Standard Version | 2012 |
| Date of award of accreditation | 09/09/2008 |
| Scope Classification | Blood Transfusion Science |
| Scope Classification | Haematology |
| Scope Classification | Chemical pathology |
| Services available to the public ¹ | No |

¹ Refer to document on interpreting INAB Scopes of Accreditation

| Sites from which accredited services are delivered | | |
|--|-------------|--|
| (the detail of the accredited services delivered at each site are on the Scope of Accreditation) | | |
| | Name | Address |
| 1 | Head Office | Pathology Department, University Hospital Kerry, Tralee, Kerry |

Scope of Accreditation

Head Office

Blood Transfusion Science

Category: A

| Medical pathology field - Test | Test/assay | Specimen Type | Equipment/Technique | Method (CE/Non-CE/In house developed/based on standard method) | Range of measurement | Std. ref & SOP |
|---|-------------------------------------|------------------|---|--|-------------------------------|--|
| 1020 Transfusion science - .01 Blood grouping including ABO, Rh(D) and other antigens by manual methods | Blood Grouping including ABO (Rh)D | Red Cells Plasma | Automated Grifols Erytra Eflexis system | CE based on standard methods | Refer to associated procedure | [LP-BLO-GRIFOLS] Procedure for Grifols Analyser |
| | | | Manual Method Grifols | CE based on standard methods | Refer to associated procedure | [LP-BLO-GRIFMSC] Procedure for manual Grifols screen |
| | Blood Grouping including ABO, Rh(D) | Red Cell Plasma | Manual Method Ortho, Automated Innova | Ortho BioVue | | LP-BLO-ADODGRP, LP-BLO-AUTOVUE |
| 1020 Transfusion science - .03 Blood group antibody screen | Blood Group antibody screen | Plasma | Manual Method Ortho, Automated Innova | Ortho BioVue | | LP-BLO-MABSCRN, LP-BLO-AUTOVUE |
| | | Red Cells Plasma | Automated Grifols Erytra Eflexis system | CE based on standard methods | Refer to associated procedure | [LP-BLO-GRIFOLS] Procedure for Grifols Analyser |

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| | | | Manual Method Grifols | CE based on standard methods | Refer to associated procedure | [LP-BLO-GRIFMID] Grifols Manual Antibody ID |
| 1020 Transfusion science - .04 Identification of blood group antibodies | Antibody Identification | Plasma | Manual Method Ortho | Ortho BioVue | | LP-BLO-ABIDENT |
| | | Red Cells Plasma | Automated Grifols Erytra Eflexis system | CE based on standard methods | Refer to associated procedure | [LP-BLO-GRIFOLS] Procedure for Grifols Analyser |
| | | | Manual Method Grifols | CE based on standard methods | Refer to associated procedure | [LP-BLO-GRIFMID] Grifols Manual Antibody ID |
| 1020 Transfusion science - .05 Cross match compatible donor units | Compatability Testing | Plasma | Manual Method Ortho | Ortho BioVue | | LP-BLO-COMPATA |
| | Compatibility Testing | Red Cells Plasma | Automated Grifols Erytra Eflexis system | CE based on standard methods | Refer to associated procedure | [LP-BLO-GRIFOLS] Procedure for Grifols Analyser |
| | | | Manual Method Grifols | CE based on standard methods | Refer to associated procedure | [LP-BLO-GRIFMCOM] Procedure on Manual Compatibility Testing |
| 1020 Transfusion science - .06 Red cell phenotyping | Antigen Typing | Red Cells | Automated Grifols Erytra Eflexis system | CE based on standard methods | Refer to associated procedure | [LP-BLO-GRIFOLS] Procedure for Grifols Analyser |
| | | | Manual Method Grifols | CE based on standard methods | Refer to associated procedure | [LP-BLO-GRIFMRHP] Procedure for Grifols Rh Phenotyping Manual Method |
| | | | Manual Method Ortho | Ortho BioVue/Tubes | | LP-BLO-ATGNTYP |
| 1020 Transfusion science - .99 Miscellaneous tests | Direct Coombs Test | | Automated Grifols Erytra Eflexis system | CE based on standard methods | Refer to associated procedure | [LP-BLO-GRIFOLS] Procedure for Grifols Analyser |
| | | | Manual Method Grifols | CE based on standard methods | Refer to associated procedure | [LP-BLO-GRIFMDCT] Grifols Manual Direct Coombs Test |
| | | | Manual Method Ortho, Automated Innova | Ortho BioVue | | LP-BLO-DCOOMBS |

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| | Kleihauer Testing | | Manual Stain | Kleihauer Blake | | LP-BLO-KLEIHAU |
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The hospital blood bank has been assessed and is competent to comply with Articles 14 and 15 of the EU Directive 2002/98/EC (S.I. 360/2005 and S.I. 547/2006).

Chemical Pathology

Category: A

| Medical pathology field - Test | Test/assay | Specimen Type | Technique | Equipment/Range of Measurement | Method (CE/Non-CE/In house developed/based on standard method) | Std. Ref & SOP |
|---|------------------------------|---------------|-------------|--------------------------------|--|----------------|
| 1061 Clinical Chemistry - .01 Analytes in general use in cardiac, liver function, lipid, renal and other profiles and metabolic studies | 24 hour creatinine clearance | Urine | Calculation | Beckman Coulter AU5812 | CE | LP-BIO-AU5812 |
| | 24 hour urinary amylase | | Calculation | Beckman Coulter AU5812 | CE | LP-BIO-AU5812 |
| | 24 hour urinary calcium | | Calculation | Beckman Coulter AU5812 | CE | LP-BIO-AU5812 |
| | 24 hour urinary chloride | | Calculation | Beckman Coulter AU5812 | CE | LP-BIO-AU5812 |
| | 24 hour urinary creatinine | | Calculation | Beckman Coulter AU5812 | CE | LP-BIO-AU5812 |
| | 24 hour urinary magnesium | | Calculation | Beckman Coulter AU5812 | CE | LP-BIO-AU5812 |
| | 24 hour urinary phosphate | | Calculation | Beckman Coulter AU5812 | CE | LP-BIO-AU5812 |
| | 24 hour urinary potassium | | Calculation | Beckman Coulter AU5812 | CE | LP-BIO-AU5812 |
| | 24 hour urinary sodium | | Calculation | Beckman Coulter AU5812 | CE | LP-BIO-AU5812 |
| | 24 hour urinary urate | | Calculation | Beckman Coulter AU5812 | CE | LP-BIO-AU5812 |
| | 24 hour urinary urea | | Calculation | Beckman Coulter AU5812 | CE | LP-BIO-AU5812 |

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| Albumin | Serum | Colorimetric | Beckman Coulter AU680 | Bromocresol Green | LP-BIO-AU680 |
| | | Colorimetric - BCG | Beckman Coulter AU5812 | CE | LP-BIO-AU5812 |
| Alkaline Phosphatase | Serum | Enzymatic | Beckman Coulter AU680 | AMP optimised to IFCC | LP-BIO-AU680 |
| | | Enzymatic AMP optimised to IFCC | Beckman Coulter AU5812 | CE | LP-BIO-AU5812 |
| ALT | Serum | Enzymatic | Beckman Coulter AU680 | Beckman Mod. IFCC Ref without PSP | LP-BIO-AU680 |
| | | Enzymatic - IFCC without PSP | Beckman Coulter AU5812 | CE | LP-BIO-AU5812 |
| Amylase | Serum | Enzymatic | Beckman Coulter AU680 | Beckman Olympus blocked pNPG7 | LP-BIO-AU680 |
| | Serum and Urine | Enzymatic - blocked pNPG7 | Beckman Coulter AU5812 | CE | LP-BIO-AU5812 |
| AST | Serum | Enzymatic | Beckman Coulter AU680 | Tris Buffer without PSP | LP-BIO-AU680 |
| | | Enzymatic - Tris buffer without PSP | Beckman Coulter AU5812 | CE | LP-BIO-AU5812 |
| Bicarbonate | Serum | Enzymatic | Beckman Coulter AU5812 | CE | LP-BIO-AU5812 |
| | | Enzymatic | Beckman Coulter AU680 | Enzymatic | LP-BIO-AU680 |
| Bilirubin, Direct | Serum | Enzymatic | Beckman Coulter AU680 | Dichlorophenyl Diazonium | LP-BIO-AU680 |
| | | Enzymatic - DCP Diazonium | Beckman Coulter AU5812 | CE | LP-BIO-AU5812 |
| Bilirubin, Total | Serum | Colorimetric | Beckman Coulter AU680 | DPD (Beckman AU) | LP-BIO-AU680 |
| | | Colorimetric - DPD | Beckman Coulter AU5812 | CE | LP-BIO-AU5812 |
| Calcium | Serum | Colorimetric | Beckman Coulter AU680 | Arsenazo | LP-BIO-AU680 |
| | Serum and Urine | Colorimetric - Arsenazo | Beckman Coulter AU5812 | CE | LP-BIO-AU5812 |

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| Chloride | Serum | Ion Specific Electrode | Beckman Coulter AU680 | ISE Indirect | LP-BIO-AU680 |
| | Serum and Urine | Ion Specific Electrode - Indirect | Beckman Coulter AU5812 | CE | LP-BIO-AU5812 |
| Cholesterol | Serum | Enzymatic | Beckman Coulter AU680 | Cholesterol Oxidase Abel Kendall | LP-BIO-AU680 |
| | | Enzymatic - Cholesterol Oxidase | Beckman Coulter AU5812 | CE | LP-BIO-AU5812 |
| Creatine Kinase | Serum | Colorimetric | Beckman Coulter AU680 | CK-NAC (IFCC) | LP-BIO-AU680 |
| | | Colorimetric - CK-NAC (IFCC) | Beckman Coulter AU5812 | CE | LP-BIO-AU5812 |
| Creatinine | Serum | Enzymatic | Beckman Coulter AU680 | Creatinine PAP Method | LP-BIO-AU680 |
| | Serum and Urine | Enzymatic - PAP | Beckman Coulter AU5812 | CE | LP-BIO-AU5812 |
| CSF-Glucose | CSF | Colorimetric - Hexokinase | Beckman Coulter AU5812 | CE | LP-BIO-AU5812 |
| GGT | Serum | Enzymatic | Beckman Coulter AU5812 | CE | LP-BIO-AU5812 |
| | | Enzymatic | Beckman Coulter AU680 | Gamma Glut 3-carb-4-nitro (IFCC) | LP-BIO-AU680 |
| Glucose (Fasting and Random) | Plasma | Enzymatic | Beckman Coulter | Hexokinase | LP-BIO-AU680 |
| | Plasma and Urine | Enzymatic - Hexokinase | Beckman Coulter AU5812 | CE | LP-BIO-AU5812 |
| HDL Cholesterol | Serum | Enzymatic | Beckman Coulter AU680 | Direct HDL immunoseparation | LP-BIO-AU680 |
| HDL Cholesterol | | Enzymatic - Direct HDL | Beckman Coulter AU5812 | CE | LP-BIO-AU5812 |
| Inorganic Phosphate | | Serum | Colorimetric | Beckman Coulter AU680 | Phosphomolybdate UV |
| | Serum and Urine | Colorimetric - Phosphomolybdate | Beckman Coulter AU5812 | CE | LP-BIO-AU5812 |
| LDH | Serum | Enzymatic | Beckman Coulter AU680 | P to L Scandanavian & Dutch | LP-BIO-AU680 |

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| | | Enzymatic - P to L Scandanavian & Dutch | Beckman Coulter AU5812 | CE | LP-BIO-AU5812 |
| LDL | | Calculated | Beckman Coulter AU680 | Calculated | LP-BIO-AU680 |
| | | Calculation | Beckman Coulter AU5812 | CE | LP-BIO-AU5812 |
| Magnesium | | Colorimetric | Beckman Coulter AU680 | Xylidyl Blue | LP-BIO-AU680 |
| | Serum and Urine | Colorimetric - Xylidile Blue | Beckman Coulter AU5812 | CE | LP-BIO-AU5812 |
| Microalbumin creatinine ratio | Urine | Calculation | Beckman Coulter AU5812 | CE | LP-BIO-AU5812 |
| Potassium | Serum | Ion Specific Electrode | BEckman Coulter AU680 | ISE Indirect | LP-BIO-AU680 |
| | Serum and Urine | Ion Specific Electrode - Indirect | Beckman Coulter AU5812 | CE | LP-BIO-AU5812 |
| Sodium | Serum | Ion Specific Electrode | Beckman Coulter AU680 | ISE Indirect | LP-BIO-AU680 |
| | Serum and Urine | Ion Specific Electrode - Indirect | Beckman Coulter AU5812 | CE | LP-BIO-AU5812 |
| Sodium, Potassium, Chloride | Serum | Indirect ISE | Beckman Coulter AU680 | CE | |
| | Serum and Urine | Ion Specific Electrode - Indirect | Beckman Coulter AU5812 | CE | LP-BIO-AU5812 |
| Total protein | Serum | Colorimetric | Beckman Coulter AU680 | Biuret Reaction | LP-BIO-AU680 |
| | Serum and Urine | Colorimetric - Biuret | Beckman Coulter AU5812 | CE | LP-BIO-AU5812 |
| Triglyceride Total | Serum | Enzymatic | Beckman Coulter AU680 | Lipase GK UV no correction | LP-BIO-AU680 |
| | | Enzymatic - Lipase GK UV no correction | Beckman Coulter AU5812 | CE | LP-BIO-AU5812 |
| Urea | | Enzymatic | Beckman Coulter AU680 | Urease Kinteric | LP-BIO-AU680 |
| | Serum and Urine | Enzymatic - Urease | Beckman Coulter AU5812 | CE | LP-BIO-AU5812 |

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| | Uric Acid | Serum | Enzymatic | Beckman Coulter AU680 | Uricase Perox. with ascorb. ox. | LP-BIO-AU680 |
| | | Serum and Urine | Enzymatic - Uricase Perox with ascorb. Ox. | Beckman Coulter AU5812 | CE | LP-BIO-AU5812 |
| 1061 Clinical Chemistry - .02 Proteins, quantitative analysis | 24 hour urinary total protein | Urine | Calculation | Beckman Coulter AU5812 | CE | LP-BIO-AU5812 |
| | CRP | Serum | Immunoturbidimetric | Beckman Coulter AU5812 | CE | LP-BIO-AU5812 |
| | | | Immunoturbidimetric | Beckman Coulter AU680 | Beckman Turb Latex IFCC Cal | LP-BIO-AU680 |
| | CSF-Total Protein | CSF and Urine | Colorimetric - Pyrogallol Red | Beckman Coulter AU5812 | CE | LP-BIO-AU5812 |
| | Microalbumin | Urine | Turbidimetric measure of Albumin | Beckman Coulter AU5812 | CE | LP-BIO-AU5812 |
| | Protein creatinine ratio | | Calculation | Beckman Coulter AU5812 | CE | LP-BIO-AU5812 |
| | Rheumatoid Factor | Serum | Immunoturbidimetric | Beckman Coulter AU680 | Non IFCC Cal | LP-BIO-AU680 |
| Immunoturbidimetric - Non IFCC | | | Beckman Coulter AU5812 | CE | LP-BIO-AU5812 | |
| Colorimetric | | | Beckman Coulter AU5812 | CE | LP-BIO-AU5812 | |
| 1061 Clinical Chemistry - .10 Drugs for therapeutic monitoring | Lithium | | Colorimetric | Beckman Coulter AU680 | Spectrophotometric | LP-BIO-AU680 |
| | | | Enzymatic | Beckman Coulter AU680 | Emit Tox assay | LP-BIO-AU680 |
| | Paracetamol | | Enzymatic - Emit Tox Assay | Beckman Coulter AU5812 | CE | LP-BIO-AU5812 |
| | | | Enzymatic | Beckman Coulter AU680 | Dri-Ethyl Alcohol | LP-BIO-AU680 |
| | | | Enzymatic - Dri ethyl alcohol | Beckman Coulter AU5812 | CE | LP-BIO-AU5812 |
| 1061 Clinical Chemistry - .14 Alcohol for non-legal purposes | Alcohol | | Enzymatic | Beckman Coulter AU680 | Dri-Ethyl Alcohol | LP-BIO-AU680 |
| | | | Enzymatic - Dri ethyl alcohol | Beckman Coulter AU5812 | CE | LP-BIO-AU5812 |

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| 1061 Clinical Chemistry - .15 Drugs for toxicological purposes | Salicylate | | Enzymatic | Beckman Coulter AU680 | Emit Tox Assay | LP-BIO-AU680 |
| | | | Enzymatic - Emit Tox Assay | Beckman Coulter AU5812 | CE | LP-BIO-AU5812 |
| 1061 Clinical Chemistry - .40 Iron studies | Iron | | Colorimetric | Beckman Coulter AU680 | Without ppt | LP-BIO-AU680 |
| | | | Colorimetric without ppt | Beckman Coulter AU5812 | CE | LP-BIO-AU5812 |
| | Transferrin | | Immunoturbidimetric | Beckman Coulter AU5812 | CE | LP-BIO-AU5812 |
| | | | Immunoturbidimetric | Beckman Coulter AU680 | IFCC Cal | LP-BIO-AU680 |
| | | | Immunoturbidimetric | Beckman Coulter AU5812 | CE | LP-BIO-AU5812 |
| | | | Immunoturbidimetric | Beckman Coulter AU680 | IFCC Cal | LP-BIO-AU680 |
| 1061 Clinical Chemistry - .80 Quantitative investigation of immunoglobulins G, A, M and in body fluids | IgA | | Immunoturbidimetric | Beckman Coulter AU5812 | CE | LP-BIO-AU5812 |
| | | | Immunoturbidimetric | Beckman Coulter AU680 | IFCC Cal | LP-BIO-AU680 |
| | IgG | | Immunoturbidimetric | Beckman Coulter AU5812 | CE | LP-BIO-AU5812 |
| | | | Immunoturbidimetric | Beckman Coulter AU680 | IFCC Cal | LP-BIO-AU680 |
| | IgM | | Immunoturbidimetric | Beckman Coulter AU5812 | CE | LP-BIO-AU5812 |
| | | | Immunoturbidimetric | Beckman Coulter AU680 | IFCC Cal | LP-BIO-AU680 |
| 1061 Clinical Chemistry - .99 Miscellaneous tests | CSF-Glucose | CSF | Colorimetric | Beckman Coulter AU680 | Hexokinase | LP-BIO-AU680 |
| | CSF-Total Protein | | Colorimetric | Beckman Coulter AU680 | Pyrogallol Red | LP-BIO-AU680 |

Category: A

| Medical pathology field - Test | Test/Assay | Specimen Type | Technique | Range of Measurement/Equipment | Method (CE/Non-CE/In house developed/based on standard method) | Std. Ref & SOP |
|---|----------------------------------|------------------|-----------------------------|--------------------------------|--|--|
| 1030 Haematology - .01 Blood counts | Full Blood Counts | EDTA Whole Blood | Automated Sysmex | XN-9000 | CE | LP-HAEM-XNQC, LP-HAEM-AUTHFBC, LP-HAEM-XNMAINT, LP-HAEM-XNOPER |
| | | | Optimal flow cytometry | XN-9000 | CE | LP-HAEM-XNQC, LP-HAEM-AUTHFBC, LP-HAEM-XNMAINT, LP-HAEM-XNOPER |
| 1030 Haematology - .02 Visual examination of blood films | Visual Examination of Blood Film | | Automated Sysmex | SP-10 Hematek | CE | LP-HAEM-SP10, LP-HAEM-HEMATEK, LP-HAEM-BLDFLM |
| | | | Staining microscopy | SP-50 Stainer and RAL | CE | LP-HAEM-SP50, LP-HAEM-RAL, LP-HAEM-BLDFILM |
| 1030 Haematology - .05 Automated differential leucocyte counts | Automated Differential | | Automated Sysmex | XN-9000 | CE | LP-HAEM-XNQC, LP-HAEM-AUTHFBC, LP-HAEM-XNMAINT, LP-HAEM-XNOPER |
| | | | Fluorescence Flow cytometry | XN-9000 | CE | LP-HAEM-XNQC, LP-HAEM-AUTHFBC, LP-HAEM-XNMAINT, LP-HAEM-XNOPER |
| 1030 Haematology - .06 Automated reticulocyte counts | Automated reticulocyte count | | Automated Sysmex | XN-9000 | CE | LP-HAEM-XNQC, LP-HAEM-AUTHFBC, LP- |

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| | | | | | | HAEM-XNMAINT, LP-HAEM-XNOPER |
| | | | Fluorescence Flow cytometry | XN-9000 | CE | LP-HAEM-XNQC, LP-HAEM- AUTHFBC, LP- HAEM-XNMAINT, LP-HAEM-XNOPER |
| 1030 Haematology - .09 Examination of malarial parasites | Examination of malarial parasites | | Manual Method & Automated | SP-10 Hematek, Field Stain Microscopy | CE | LP-HAEM-MALARIA, LP-HAEM-SP10, LP- HAEM-HEMATEK |
| | | | Staining microscopy | SP-50 Stainer and RAL | CE | LP-HAEM-SP50, LP- HAEM-RAL |
| 1030 Haematology - .30 Tests for haemoglobin variants and thalassaemia | Sickle Cell Screening | | Manual Method | Clintech Kit | CE | LP-HAEM-SICKLE |
| 1030 Haematology - .41 General haemostasis related tests | Activated Partial Prothrombin Time (A.P.T.T.) | Sodium Citrate Plasma | Automated and Semi Automated | CS-2500 | CE | LP-HAEM- CS25OPER |
| | | | Coagulation | CN-3000 | CE | LP-HAEM-CNOPER, LP-HAEM-CNMAINT, LP-HAEM- CNQCCAL |
| | D-Dimer | | Automated and Semi Automated | CS-2500 | CE | LP-HAEM- CS25OPER |
| | | | Turbidity | CN-3000 | CE | LP-HAEM-CNOPER, LP-HAEM-CNMAINT, LP-HAEM- CNQCCAL |
| | Fibrinogen | | Automated and Semi Automated | CS-2500 | CE | LP-HAEM- CS25OPER |
| | | | Coagulation | CN-3000 | CE | LP-HAEM-CNOPER, LP-HAEM-CNMAINT, LP-HAEM- CNQCCAL |
| | International Normalised Ratio (INR) | | Calculation | CN-3000 Calculated from PT | CE | LP-HAEM-CNOPER, LP-HAEM-CNMAINT, LP-HAEM- CNQCCAL |

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| | Prothrombin Time (P.T.) | | Coagulation | CN-3000 | CE | LP-HAEM-CNOPER, LP-HAEM-CNMAINT, LP-HAEM-CNQCCAL |
| | Prothrombin Time (P.T.)/INR | | Automated and Semi Automated | CS-2500 | CE | LP-HAEM-CS25OPER |
| 1030 Haematology - .57 Screening test for infectious mononucleosis | Screening test for infectious mononucleosis | Serum or Sodium Citrate Plasma or EDTA Whole Blood | Manual Method | Clear View IM II | CE | LP-HAEM-IMSCREN |