Schedule of Accreditation

Organisation Name: Mid Western Regional Hospital Limerick (Serology/Immunology)

INAB Reg No: 303MT

Contact Name: Kathleen Keane

Address: University Hospital Limerick, Dooradoyle, Limerick, Limerick

Contact Phone No: 061 485075

Email: kathleenmartina.keane@hse.ie

Website: http://www.ulh.ie

Accreditation Standard: ISO 15189

Date Initially Awarded: 05/06/2012

Scope Classification:
- Microbiology and virology
- Haematology
- Histopathology and cytopathology

Services available to the public: No

¹ Refer to document on interpreting INAB Scopes of Accreditation

<table>
<thead>
<tr>
<th>Name</th>
<th>Address</th>
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<tbody>
<tr>
<td>1 University Hospital Limerick</td>
<td>St. Nessan's Road, Dooradoyle, Limerick, Limerick, V94 F858</td>
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<tr>
<td>2 Nenagh Hospital-Haematology</td>
<td>Tyone, Nenagh, Tipperary</td>
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<tr>
<td>3 Ennis Hospital - Haematology</td>
<td>Gord Road, Ennis, Clare</td>
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</table>
## Scope of Accreditation

### Ennis Hospital - Haematology

**Haematology**

**Category:** A

<table>
<thead>
<tr>
<th>Medical pathology field - Test</th>
<th>Test/Assay</th>
<th>Specimen Type</th>
<th>Technique</th>
<th>Range of Measurement/Equipment</th>
<th>Method (CE/Non-CE/in house developed/based on standard method)</th>
<th>Std. Ref &amp; SOP</th>
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<tbody>
<tr>
<td>1030 Haematology - .30 Tests for haemoglobin variants and thalassaemia</td>
<td>Sickle screening</td>
<td>Manual method</td>
<td>Qualitative solubility test</td>
<td>CE/based on standard method</td>
<td>LP-E-HAE-SICKLE</td>
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<tr>
<td>1030 Haematology - .41 General haemostasis related tests</td>
<td>APTT</td>
<td>Na Citrate</td>
<td>Automated Coagulometric</td>
<td>IL ACL TOP</td>
<td>CE/based on standard method</td>
<td>LP-E-HAE-EQPACTLTOP LP-E-HAE-APTTAACLTOP</td>
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<td>D-Dimer</td>
<td>Automated immunological</td>
<td>IL ACL TOP</td>
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<td>LP-E-HAE-EQPACTLTOP LP-E-HAE-DDIMERACLTOP</td>
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<td>PT / INR</td>
<td>Automated</td>
<td>IL ACL TOP</td>
<td>CE/based on standard method</td>
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<td>Serum / Plasma</td>
<td>Manual method</td>
<td>Rapid immuno assay</td>
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## Haematology

**Category: A**

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<th>Test/Assay</th>
<th>Specimen Type</th>
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<tr>
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<td>Erythrocyte sedimentation rate (ESR)</td>
<td>NaCitrate</td>
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<td>Desaga S2000 ESR Analyser</td>
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<td>ESR</td>
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<td>Malaria film</td>
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<td>Staining / microscopy</td>
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<td>Activated Protein C</td>
<td>Citrated plasma</td>
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<td>Test/assay</td>
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<td>1051 Histopathology - .01 Processing fixed specimens for Histopathological testing</td>
<td>Cut up Tissue processing Embedding Microtomy Automatted and manual Haematoxylin and Eosin staining Coverslapping</td>
<td>Human tissue</td>
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<td>LP-L-HIS-PRISMAG2 LP-L-HIS-SORTING</td>
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<td>Diagnostic interpretation and reporting of human tissue specimens Specialist areas excluded: Medical renal pathology Paediatric pathology Perinatal pathology Neuropathology Breast screening pathology (Breast Check designated laboratories only)</td>
<td>Human tissue (excluding breast and inflammatory skin samples)</td>
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<td>Special stains Alcian Blue/PAS Congo red Diastase PAS Elastic Perls Grocotts methenamine silver (GMS) Gram Massons Trichome PAS Retic Warthin Starry Ziehl Neelsen (ZN)</td>
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<tr>
<td>1011 Macroscopic examination and description</td>
<td>Macroscopic examination and description of: Sputum CSF Fluids</td>
<td>CAPD Fluid CSF Other body fluids Pleural fluid Sputum</td>
<td>N/A / Manual</td>
<td>CE/based on standard method</td>
<td>N/A</td>
<td>LP-L-MIC-CAPD LP-L-MIC-CSF LP-L-MIC-FLUID LP-L-MIC-SPUTA</td>
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<tr>
<td>1012 Preparation of films on glass slides followed by microscopic examination with or without fixation and staining with dyes as required - .01 Microscopic examination for general bacteriology purposes (including enumeration and description of human cells)</td>
<td>Microscopic examination of: General Bacteriology</td>
<td>All swabs Antral washout Blood Bone marrow Bronchial lavage / brushings washings Cannulae and associated swabs CAPD Contact lens cases and cleaning fluid Corneal scrapings CSF Endotracheal tubes Faeces Gastric washing Middle ear effusion Other body fluids Pleural Fluid Post-mortem specimens Pus / Exudates Semen Sinus aspirate / washout Sputum Tissue Urine</td>
<td>Light/fluorescent microscope / Microscopic examination with or without fixation and staining with dyes for enumeration and description of human cells</td>
<td>CE/based on standard method</td>
<td>N/A</td>
<td>LP-L-MIC-TISSUE LP-L-MIC-BC LP-L-MIC-BILE LP-L-MIC-BORD LP-L-MIC-CANUL LP-L-MIC-CAPD LP-L-MIC-CSF LP-L-MIC-EAR LP-L-MIC-EYE LP-L-MIC-FAECES LP-L-MIC-FLUID LP-L-MIC-GENITAL LP-L-MIC-LEG LP-L-MIC-MOUTH LP-L-MIC-NOSE LP-L-MIC-OCP LP-L-MIC-SINUS LP-L-MIC-SPUTA LP-L-MIC-TB LP-L-MIC-THROAT LP-L-MIC-URINE LP-L-MIC-WOUNDS</td>
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<td>1012 Preparation of films on glass slides followed by microscopic examination with or without fixation and staining with dyes as required - .02 Microscopic examination for parasites</td>
<td>Microscopic examination of: Parasites</td>
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<td>Light/fluorescent microscope / Microscopic examination with or without fixation and staining with dyes for enumeration and description of human cells</td>
<td>CE/based on standard method</td>
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<td>Methodology</td>
<td>Notes</td>
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<tr>
<td>1012</td>
<td>Preparation of films on glass slides followed by microscopic examination with or without fixation and staining with dyes as required - .04 Microscopic examination for mycobacteria</td>
<td>Microscopic examination of: Mycobacteria</td>
<td>Light/fluorescent microscope / Microscopic examination with or without fixation and staining with dyes for enumeration and description of human cells</td>
<td>CE/based on standard method</td>
<td>N/A</td>
<td>LP-L-MIC-EAR LP-L-MIC-EYE LP-L-MIC-FAECES LP-L-MIC-FLUID LP-L-MIC-GENITAL LP-L-MIC-LEG LP-L-MIC-MOUTH LP-L-MIC-NOSE LP-L-MIC-OCP LP-L-MIC-SINUS LP-L-MIC-SPUTA LP-L-MIC-TB LP-L-MIC-THROAT LP-L-MIC-URINE LP-L-MIC-WOUNDS</td>
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<tr>
<td>1013</td>
<td>Culture of organisms in liquid or agar based culture media with visual or instrument monitoring for growth - .01 Culture of general</td>
<td>Culture of: General bacteria As per specimen type in classification in 1012</td>
<td>BacTAlert 3D system / BacT Alert/Manual</td>
<td>CE/based on standard method</td>
<td>N/A</td>
<td>LP-L-MIC-CPESCREEN LP-L-MIC-CE LP-L-MIC-GENITAL LP-L-MIC-LEG LP-L-MIC-MOUTH LP-L-MIC-NOSE LP-L-MIC-OCP LP-L-MIC-SINUS LP-L-MIC-SPUTA LP-L-MIC-TB LP-L-MIC-THROAT LP-L-MIC-URINE LP-L-MIC-WOUNDS</td>
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<td>1013 Culture of organisms in liquid or agar based culture media with visual or instrument monitoring for growth - .03</td>
<td>Culture of: Mycobacteria</td>
<td>BacTAlert 3D system / BacT Alert/Manual</td>
<td>CE/based on standard method</td>
<td>N/A</td>
<td>LP-L-MIC-BILE \ LP-L-MIC-BORD \ LP-L-MIC-CANUL \ LP-L-MIC-CAPD \ LP-L-MIC-CSF \ LP-L-MIC-EAR \ LP-L-MIC-ESBL \ LP-L-MIC-EYE \ LP-L-MIC-FAECES \ LP-L-MIC-FLUID \ LP-L-MIC-GENITAL \ LP-L-MIC-LEG \ LP-L-MIC-MOUTH \ LP-L-MIC-MRSA \ LP-L-MIC-NOSE \ LP-L-MIC-SINUS \ LP-L-MIC-SPUTA \ LP-L-MIC-TB \ LP-L-MIC-THROAT \ LP-L-MIC-URINE \ LP-L-MIC-WOUNDS</td>
<td>LI-L-MIC-CPESCREEN \ LI-L-MIC-TISSUE \ LI-L-MIC--VRE \ LP-L-MIC-BC \ LP-L-MIC-BILE \ LP-L-MIC-BORD \ LP-L-MIC-CANUL \ LP-L-MIC-CAPD \ LP-L-MIC-CSF \ LP-L-MIC-EAR \ LP-L-MIC-ESBL \ LP-L-MIC-EYE \ LP-L-MIC-FAECES \ LP-L-MIC-FLUID \ LP-L-MIC-GENITAL \ LP-L-MIC-LEG \ LP-L-MIC-MOUTH \ LP-L-MIC-MRSA \ LP-L-MIC-NOSE \ LP-L-MIC-WOUNDS</td>
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<td>1014</td>
<td><strong>Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques</strong> - .03 Enzyme immunoassay,</td>
<td>Stool Manual method / Enzyme immuno assay (EIA) CE/based on standard method N/A</td>
<td>LP-L-SER-HPA</td>
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<td>1014</td>
<td><strong>Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques</strong> - .04 Immunochromatographic methods,</td>
<td>Faeces Manual method / Immunochromatographic lateral flow CE/based on standard method N/A</td>
<td>LP-L-SER-ROAD</td>
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<td><strong>Detection of:</strong> - Urinary pneumococcal antigen - Legionella urine antigen</td>
<td>Urine Binax now streptococcus pneumoniae antigen card / Immunochromatographic assay CE/based on standard method N/A</td>
<td>LI-L-MIC-LEAGBIN LP-L-MIC-STPNBIN</td>
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<td>1015</td>
<td><strong>Detection and/or identification of bacterial, parasite, fungal and viral nucleic acids</strong> - .03 Nucleic acid amplification tests, CE marked commercial systems</td>
<td>Nasopharyngeal specimens Cepheid GeneXpert Influenza A&amp; Influenza B assay / Nucleic acid amplification test CE/based on standard method N/A</td>
<td>LP-L-SER-XPERTFLU</td>
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<td>Detection of: Norovirus GI and GII</td>
<td>Faeces Serosep EntericBio Norovirus real time PCR CE / Based on Standard Method N/A</td>
<td>LP-L-SER-EBNORO</td>
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<td>Detection of: Chlamydia trachomatis and Neisseria gonorrhoeae</td>
<td>Endocervical swab Vaginal swab Urethral swab Urine M2000sp and M2000rt / PCR (amplification) CE/based on standard method N/A</td>
<td>LP-L-MIC-CHLAMGC</td>
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<td>Detection of: Toxigenic Clostridium difficile Salmonella, Shigella, Campylobacter and Verotoxigenic E.coli</td>
<td>Faeces Illumipro-10 Roche light cycler 480 / PCR (Amplification) CE/based on standard method N/A</td>
<td>LP-L-MIC-CDTOXILLUM LP-L-MIC-ENTBIO LP-L-MIC-CDIFFENTBIO</td>
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<td>1016</td>
<td><strong>Identification of cultured bacteria and fungi using non-nucleic acid based techniques</strong> - .01 Biochemical methods , CE marked commercial systems</td>
<td>Identification of organisms using: Biochemical methods As per specimen type in classification in 1012 APIs, ARIS, Madli-Tof / Manual, Commercial ID systems, Automated ID systems, Spectroscopy CE/based on standard method N/A</td>
<td>LP-L-MIC-MALDI LP-L-MIC-ARIS EXTMIC-5 EXTMIC-6 EXTMIC-26 EXTMIC-29 EXTMIC-31 EXTMIC-32 EXTMIC-39 EXTMIC-43</td>
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<td>1016</td>
<td>Identification of cultured bacteria and fungi using non-nucleic acid based techniques - .04 Identification using MALDI-TOF Spectroscopy</td>
<td>Identification of organisms using: Maldi-Tof Spectroscopy</td>
<td>APIs, ARIS, Madli-Tof / Manual, Commercial ID systems, Automated ID systems, Spectroscopy</td>
<td>N/A</td>
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<td>1017</td>
<td>Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes) - .01 Anaerobes</td>
<td>Aerobes / Anaerobes</td>
<td>Manual / Disc diffusion/Minimum inhibitory concentration</td>
<td>N/A</td>
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<td>Yeasts</td>
<td>Yeasts</td>
<td>Manual / Disc diffusion/Minimum inhibitory concentration</td>
<td>N/A</td>
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<td></td>
<td>Other categories of organism (as specified)</td>
<td>Aerobes</td>
<td>ARIS sensititre / Breakpoint</td>
<td>N/A</td>
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<tr>
<td>1017</td>
<td>Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes) - .03 Yeasts</td>
<td>Yeasts</td>
<td>Manual / Disc diffusion/Minimum inhibitory concentration</td>
<td>N/A</td>
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<td>Other categories of organism (as specified)</td>
<td>Aerobes</td>
<td>ARIS sensititre / Breakpoint</td>
<td>N/A</td>
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<td>1018</td>
<td>Detection of antibody response to infection using appropriate CE marked commercial techniques - .01 Particle agglutination, using CE marked commercial systems</td>
<td>Omega Immutrep Rapid Plasmin Reagin (RPR)</td>
<td>Manual method / Card test - antigen flocculation</td>
<td>N/A</td>
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<td>Omega Immutrep TPHA</td>
<td>Manual method / Haem-agglutination assay</td>
<td>CE/based on standard method</td>
<td>N/A</td>
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<td>1018</td>
<td>Detection of antibody response to infection using appropriate CE marked commercial techniques - .02 Enzyme immunoassay, using CE marked commercial systems</td>
<td>Anti-Streptolysin 0 (ASO)</td>
<td>Siemens BNII / Laser nephelometry</td>
<td>N/A</td>
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<td>Biorad Genscreen HIV 1 &amp; 2 Ag / Ab</td>
<td>Manual method &amp; automated method, ETL-MAX 3000 / Enzyme Immunoassay (EIA)</td>
<td>CE/based on standard method</td>
<td>N/A</td>
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<td>Biorad Monolisa</td>
<td>Manual method / Enzyme immuno assay (EIA)</td>
<td>CE/based on standard method</td>
<td>N/A</td>
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<td>Test</td>
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<td>CE/Based on Standard Method</td>
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<td>Anti-HBc Plus assay</td>
<td>Enzyme immuno assay (EIA)</td>
<td>Standard method</td>
<td>HBCEIA</td>
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<td>Biorad Monolisa Hepatitis B Surface Antigen (HBsAg) Ultra assay</td>
<td>Manual method / Enzyme immuno assay (EIA)</td>
<td>CE/Based on standard method</td>
<td>N/A</td>
<td>LP-L-SER-HEPBEIA</td>
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<td>Euroimmun EBNA-1 IgG</td>
<td>Manual method &amp; automated method, ETI-MAX 3000 / Enzyme Immunoassay (EIA)</td>
<td>CE/Based on standard method</td>
<td>N/A</td>
<td>LP-L-SER-EBNA-1 IgG</td>
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<td>Euroimmun EBV-CA IgG</td>
<td>Manual method &amp; automated method, ETI-MAX 3000 / Enzyme Immunoassay (EIA)</td>
<td>CE/Based on standard method</td>
<td>N/A</td>
<td>LP-L-SER-EBVCA-IgG</td>
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<td>Euroimmun EBV-CA IgM</td>
<td>Manual method &amp; automated method, ETI-MAX 3000 / Enzyme Immunoassay (EIA)</td>
<td>CE/Based on standard method</td>
<td>N/A</td>
<td>LP-L-SER-EBVCA-IgM</td>
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<td>Euroimmun Measles IgG</td>
<td>Manual method &amp; automated method, ETI-MAX 3000 / Enzyme Immunoassay (EIA)</td>
<td>CE/Based on standard method</td>
<td>N/A</td>
<td>LP-L-SER-MEASG</td>
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<td>Euroimmun Mumps IgG</td>
<td>Manual method &amp; automated method, ETI-MAX 3000 / Enzyme Immunoassay (EIA)</td>
<td>CE/Based on standard method</td>
<td>N/A</td>
<td>LP-L-SER-MUMP SG</td>
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<td>Euroimmun VZV IgG</td>
<td>Manual method &amp; automated method, ETI-MAX 3000 / Enzyme Immunoassay (EIA)</td>
<td>CE/Based on standard method</td>
<td>N/A</td>
<td>LP-L-SER-VZVG</td>
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<td>Immunetics Lyme C6 Blood (serum)</td>
<td>Manual method / Enzyme immuno assay (EIA)</td>
<td>CE/Based on standard method</td>
<td>N/A</td>
<td>LP-L-SER-LYM EC6</td>
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<td>Microimmune Mumps IgM Blood (serum / plasma)</td>
<td>Manual method &amp; automated method, ETI-MAX 3000 / Capture Enzyme Immunoassay (EIA)</td>
<td>CE/Based on standard method</td>
<td>N/A</td>
<td>LP-L-SER-MUMP SM</td>
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<td>Quantitative detection of antibodies to hepatitis B (and HBs) in serum / plasma by Enzyme Immunoassay</td>
<td>Manual method &amp; automated method, ETI-MAX 3000 / Enzyme Immunoassay (EIA)</td>
<td>CE/Based on standard method</td>
<td>N/A</td>
<td>LP-L-SER-DIASORIN-ANTIHB S</td>
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<td>Syphilis IgM</td>
<td>Manual method / ELISA</td>
<td>CE/Based on standard method</td>
<td>N/A</td>
<td>LP-L-SER-SYPH-IGMLAB21</td>
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<td>Abbott Architect Anti-HBc (total)</td>
<td>Manual method / Enzyme immuno assay (EIA)</td>
<td>CE/Based on standard method</td>
<td>N/A</td>
<td>LP-L-SER-ARCH-HBC II</td>
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<td>Abbott Architect Anti-HBc IgM</td>
<td>Abbott Architect i2000SR / Chemiluminescent Microparticle</td>
<td>CE/Based on standard method</td>
<td>N/A</td>
<td>LP-L-SER-ARCH-COREM</td>
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<td>Abbott Architect</td>
<td>Immunoassay (CMIA)</td>
<td>CE/based on standard method</td>
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<td>Anti-HBs</td>
<td>Abbott Architect i2000SR / Cemiluminescent Microparticle Immunoassay (CMIA)</td>
<td>N/A</td>
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<td>Anti-HCV</td>
<td>Abbott Architect i2000SR / Cemiluminescent Microparticle Immunoassay (CMIA)</td>
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<td>Anti-Hepatitis B e antigen</td>
<td>Abbott Architect i2000SR / Cemiluminescent Microparticle Immunoassay (CMIA)</td>
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<td>CMV IgG</td>
<td>Abbott Architect i2000SR / Cemiluminescent Microparticle Immunoassay (CMIA)</td>
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<td>CMV IgM</td>
<td>Abbott Architect i2000SR / Cemiluminescent Microparticle Immunoassay (CMIA)</td>
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<td>HCV Ag</td>
<td>Abbott Architect i2000SR / Cemiluminescent Microparticle Immunoassay (CMIA)</td>
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<td>Hepatitis A IgG</td>
<td>Abbott Architect i2000SR / Cemiluminescent Microparticle Immunoassay (CMIA)</td>
<td>N/A</td>
<td>LP-L-SER-ARCH-HAVABM</td>
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<td>Hepatitis A IgM</td>
<td>Abbott Architect i2000SR / Cemiluminescent Microparticle Immunoassay (CMIA)</td>
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<td>Hepatitis B e Antigen</td>
<td>Abbott Architect i2000SR / Cemiluminescent Microparticle Immunoassay (CMIA)</td>
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<td>Hepatitis B Surface Antigen (HBsAG) Qualitative</td>
<td>Abbott Architect i2000SR / Cemiluminescent Microparticle Immunoassay (CMIA)</td>
<td>N/A</td>
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<td>HIV 1&amp;2 Ag / Ab</td>
<td>Abbott Architect i2000SR / Cemiluminescent Microparticle Immunoassay (CMIA)</td>
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<td>Rubella IgG</td>
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<td>1029 Miscellaneous - .99 Miscellaneous tests</td>
<td>Pregnancy testing Urine</td>
<td>Alere hCG cassette / Chromatographic immunoassay</td>
<td>N/A</td>
<td>LP-L-MIC-PREGALERE</td>
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