

# Schedule of Accreditation



|                                               |                                     |
|-----------------------------------------------|-------------------------------------|
| Organisation Name                             | Hermitage Clinic Unlimited          |
| Trading As                                    | Blackrock Health Hermitage Clinic   |
| INAB Reg No                                   | 236MT                               |
| Contact Name                                  | Aileen Coughlan                     |
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| Website                                       |                                     |
| Accreditation Standard                        | EN ISO 15189                        |
| Standard Version                              | 2022                                |
| Date of award of accreditation                | 09/06/2009                          |
| Scope Classification                          | Blood Transfusion Science           |
| Scope Classification                          | Haematology                         |
| Services available to the public <sup>1</sup> | Yes                                 |

<sup>1</sup> 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 | Old Lucan Road, Dublin, D20 |

# 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) and other antigens by manual methods    | Red blood cells and plasma | Grifols DG (Gel card technology) Manual Method                               | CE Based Method                                                | 0 to 4+ reactivity/grading                     | HMC-BB-SOP-091<br>HMC-BB-SOP-102 |
|                                                                                                            |                                                                             |                            | Tube Technique                                                               | CE Based Method                                                | 0 to 4+ reactivity/grading                     | HMC-BB-SOP-091                   |
|                                                                                                            | Blood grouping including ABO, Rh(D) and other antigens by manual methods    |                            | Grifols Eflexis DG Gel Card Automated System, Grifols DG Gel Card Technology | CE Based Method                                                | Positive Grade 1-4/<br>Negative 0/ Mixed Field | HMC-BB-SOP-091                   |
| 1020 Transfusion science - .02 Blood grouping including ABO, Rh(D) and other antigens by automated methods | Blood grouping including ABO, Rh(D) and other antigens by automated methods |                            | Grifols DG (Gel card technology) Erythra Eflexis                             | CE Based Method                                                | 0 to 4+ reactivity/grading                     | HMC-BB-SOP-091<br>HMC-BB-SOP-107 |

|                                                                            |                                                                                                                                 |                            |                                                                                                                 |                 |                                                                         |                                                    |
|----------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------|----------------------------|-----------------------------------------------------------------------------------------------------------------|-----------------|-------------------------------------------------------------------------|----------------------------------------------------|
| 1020 Transfusion science -<br>.03 Blood group antibody screen              | Antibody screening                                                                                                              | Plasma                     | Automated Method using Eflexis Grifols DG Gel card system<br><br>Manual Method using Grifols DG Gel Card System | CE Based Method | 0 to 4+ reactivity/grading                                              | HMC-BB-SOP-093<br>HMC-BB-SOP-102<br>HMC-BB-SOP-107 |
|                                                                            | Blood group antibody screen                                                                                                     |                            | Grifols Eflexis DG Gel Card Automated System, Grifols DG Gel Card Technology                                    | CE Based Method | Positive Grade 1-4/<br>Negative 0                                       | HMC-BB-SOP-093                                     |
| 1020 Transfusion science -<br>.04 Identification of blood group antibodies | Antibody Identification                                                                                                         |                            | Automated Method using Eflexis Grifols DG Gel card system<br><br>Manual Method using Grifols DG Gel Card System | CE Based Method | 0 to 4+ reactivity/grading                                              | HMC-BB-SOP-094<br>HMC-BB-SOP-102<br>HMC-BB-SOP-107 |
|                                                                            |                                                                                                                                 |                            | Grifols Eflexis DG Gel Card Automated System, Grifols DG Gel Card Technology                                    | CE Based Method | Positive Grade 1-4/<br>Negative 0                                       | HMC-BB-SOP-094                                     |
| 1020 Transfusion science -<br>.05 Cross match compatible donor units       | Determination of compatibility of donor units using appropriate techniques including the investigation of transfusion reactions |                            | Grifols DG (Gel card technology)<br>Manual Method                                                               | CE Based Method | 0 to 4+ reactivity/grading                                              | HMC-BB-SOP-095<br>HMC-BB-SOP-102                   |
|                                                                            |                                                                                                                                 | Red Blood Cells and Plasma | Grifols Eflexis DG Gel Card Automated System, Grifols DG Gel Card Technology                                    | CE Based Method | Positive Grade 1-4/<br>Negative 0<br>[Compatible versus Non-Compatible] | HMC-BB-SOP-095                                     |
| 1020 Transfusion science -<br>.06 Red cell phenotyping                     | Antigen Typing                                                                                                                  | Red blood cells            | Automated Method using Eflexis Grifols DG Gel card system<br><br>Manual Method using Grifols DG Gel Card        | CE Based Method | 0 to 4+ reactivity/grading                                              | HMC-BB-SOP-085<br>HMC-BB-SOP-102<br>HMC-BB-SOP-107 |

|                                                            |                          |                 |                                                                                                                             |                 |                                   |                                                    |
|------------------------------------------------------------|--------------------------|-----------------|-----------------------------------------------------------------------------------------------------------------------------|-----------------|-----------------------------------|----------------------------------------------------|
|                                                            |                          |                 | System<br>Tube                                                                                                              |                 |                                   |                                                    |
| 1020 Transfusion science -<br>.09 Direct antiglobulin test | Direct antiglobulin test | Red blood cells | Automated Method<br>using Eflexis Grifols<br>DG Gel card system<br><br>Manual Method using<br>Grifols DG Gel Card<br>System | CE Based Method | 0 to 4+<br>reactivity/grading     | HMC-BB-SOP-010<br>HMC-BB-SOP-102<br>HMC-BB-SOP-107 |
| 1020 Transfusion science -<br>.99 Miscellaneous tests      |                          |                 | Grifols Eflexis DG Gel<br>Card Automated<br>System, Grifols DG Gel<br>Card Technology                                       | CE Based Method | Positive Grade 1-4/<br>Negative 0 | HMC-BB-SOP-010                                     |

*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). It also provides Haemovigilance and Traceability services to another site, further details available in the SLA between the accredited medical testing laboratory and the relevant site.*

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<br>Blood counts                            | Blood Counts                                 | EDTA Blood Sample           | Blood Counts                            | Sysmex XN2000                  | CE Based                                                       | HMC-HAE-SOP-063                    |
| 1030 Haematology - .02<br>Visual examination of blood films       | Visual examination of blood films            |                             | Visual examination of blood films       | Manual                         | CE Based                                                       | HMC-HAE-SOP-017                    |
| 1030 Haematology - .03<br>Erthrocyte sedimentation rate           | Erthrocyte sedimentation rate                |                             | Erthrocyte sedimentation rate           | Desaga S2000                   | CE Based                                                       | HMC-HAE-SOP-027                    |
| 1030 Haematology - .05<br>Automated differential leucocyte counts | Automated differential leucocyte counts      |                             | Automated differential leucocyte counts | Sysmex XN200                   | CE Based                                                       | HMC/HAE/SOP/061<br>HMC/HAE/SOP/063 |
| 1030 Haematology - .41<br>General haemostasis related tests       | Activated Partial Thrombin Time (APTT)       | Sodium Citrate Blood Sample | Photo optical                           | ACL Top 350                    | CE Based                                                       | HMC-HAE-SOP-068<br>HMC-HAE-SOP-069 |
|                                                                   | Activated Partial Thrombin Time Ratio (APTR) |                             | Photo optical                           | ACL Top 350                    | CE Based                                                       | HMC-HAE-SOP-068<br>HMC-HAE-SOP-069 |
|                                                                   | D-Dimer                                      |                             | fluoresence                             | ACL Top 350                    | CE Based                                                       | HMC-HAE-SOP-068<br>HMC-HAE-SOP-069 |
|                                                                   | Fibrinogen                                   |                             | Photo optical                           | ACL Top 350                    | CE Based                                                       | HMC-HAE-SOP-068<br>HMC-HAE-SOP-069 |
|                                                                   | International Normalised Ratio (INR)         |                             | Photo optical                           | ACL Top 350                    | CE Based                                                       | HMC-HAE-SOP-068<br>HMC-HAE-SOP-069 |
|                                                                   | Prothrombin Time                             |                             | Photo optical                           | ACL Top 350                    | CE Based                                                       | HMC-HAE-SOP-068<br>HMC-HAE-SOP-069 |

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| 1030 Haematology - .57<br>Screening test for<br>infectious mononucleosis | Screening test for<br>infectious<br>mononucleosis | EDTA Blood Sample | Screening test for<br>infectious<br>mononucleosis | Clearview IM II | CE Based | HMC-HAE-SOP-020 |
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