

As an accredited laboratory, this laboratory is entitled to use the following accreditation symbol.



Valid until 10 September 2012  
Issued on 11 September 2009



ISO 15189  
ML 003-01

## Schedule of Accreditation

Accreditation Scheme for Medical/Clinical Laboratories  
Sri Lanka Accreditation Board for Conformity Assessment

Accreditation Number: ML 003-01

**Vindana Reproductive Health Centre Laboratory**  
**No. 09, Barnes Place,**  
**Colombo 07.**

**Scope of Accreditation:** Performing Medical Tests under the fields of Clinical Biochemistry, Immunology / Endocrinology & Andrology

The laboratory is accredited for the following tests.

| Sl. No. | Field of Testing      | Tests                | Test Method   | Test Instrument | Analytical Range | MU (±) |       |
|---------|-----------------------|----------------------|---|-----------------|------------------|--------|-------|
|         |                       |                      |   |                 |                  | ppu*1  | Pnu*2 |
| 01      | Clinical Biochemistry | Glucose-( Plasma)    | Enzymetic colorimetric assay<br>Manufactures specifications * | Hitachi 704     | 2-450( mg/dL)    | 3.1    | 1.2   |
|         |                       | Creatinine-( Serum)  | Kinetic colorimetric assay<br>Manufactures specifications *   | Hitachi 704     | 0.2-25 ( g/dL )  | 1.1    | 1.6   |
|         |                       | Urea - ( Serum)      | Kinetic UV assay<br>Manufactures specifications *             | Hitachi 704     | 5-400( mg/dL)    | 1.1    | 1.9   |
|         |                       | Bilirubin - ( Serum) | Colorimetric assay<br>Manufactures specifications *           | Hitachi 704     | 0.1-30( mg/dL)   | 1.3    | 5.5   |

\* Roche Diagnostics, Germany – AAALAC, EC, ISO EN 9001-2000 , ISO NIBSC, NCCLS  
PPU\*1 - Precipath V (Roche Diagnostics) PNU\*2 – Preci norms V (Roche Diagnostics)

| Sl. No.                         | Field of Testing  | Tests              | Test Method  | Test Instrument | Analytical Range       | MU (±) |       |
|---------------------------------|---|--------------------|--|-----------------|------------------------|--------|-------|
|                                 |   |                    |  |                 |                        | ppu*1  | Pnu*2 |
| 01                              | Clinical Biochemistry   | SGOT-(Serum )      | IFCC reference method<br>Manufactures specifications*          | Hitachi 704     | 4-800 ( U/l )          | 0.8    | 4     |
|                                 |   | SGPT -( Serum)     | IFCC reference method<br>Manufactures specifications*          | Hitachi 704     | 4-600 ( U/l )          | 3.9    | 3.8   |
|                                 |   | ALP - ( Serum)     | Colorimetric assay<br>Manufactures specifications*             | Hitachi 704     | 5-2000 ( U/l )         | 1.1    | 0.8   |
|                                 |   | TP - ( Serum)      | Colorimetric assay<br>Manufactures specifications*             | Hitachi 704     | 0.2-15 ( g/dL )        | 1.2    | 1.5   |
|                                 |   | Cholestrol-(Serum) | Enzymetic colorimetric assay<br>Manufactures specifications*   | Hitachi 704     | 3-800 (mg/dL)          | 2.4    | 1.3   |
|                                 |   | TG - ( Serum)      | Enzymetic colorimetric assay<br>Manufactures specifications*   | Hitachi 704     | 3-800 (mg/dL)          | 1.9    | 4.6   |
|                                 |   | HDL - ( Serum)     | Enzymetic colorimetric assay<br>Manufactures specifications*   | Hitachi 704     | 3-800 (mg/dL)          | -      | -     |
|                                 |   | LDL - ( Serum)     | Enzymetic colorimetric assay<br>Manufactures specifications*   | Hitachi 704     | 3-800(mg/dL )          | NA     | NA    |
|                                 |   | GGT- ( Serum)      | IFCC recommended method<br>Manufactures specifications*        | Hitachi 704     | 0-40 ( U/L )           | 5.2    | 8     |
|                                 |   | UFR - (Urine)      | Chromatographic<br>Immunoassay<br>Manufactures Specifications* | Manual          | Qualitative estimation | -      | -     |
| Urine Pregnancy Test - ( Urine) | Chromatographic<br>Immuno assay<br>Manufactures specifications* | Manual             | Qualitative estimation   | -               | -                      |        |       |

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 PPU\*1 - Precipath V (Roche Diagnostics) PNU\*2 – Preci norms V (Roche Diagnostics)

| Sl. No.                    | Field of Testing           | Tests   | Test Method  | Test Instrument          | Analytical Range                     | MU (±)      |        |
|----------------------------|----------------------------|---|--------------|--------------------------|--------------------------------------|-------------|--------|
|                            |                            |   |              |                          |                                      | PCU *1      | PCU *2 |
| Immunology / Endocrinology | FSH - (Serum)              | Electrochemiluminescence Immuno assay Manufactures specifications *       | ELECSYS 1010 | 0.100 - 200 ( m IU/ml )  | 1.2                                  | 2.2         |        |
|                            | LH - (Serum )              | Electrochemiluminescence Immuno assay Manufactures Specifications *       | ELECSYS 1010 | 0.100-200 (m IU/ml       | 5.6                                  | 2.2         |        |
|                            | Prolactin- ( Serum )       | Electrochemiluminescence Immuno assay Manufactures specifications *       | ELECSYS 1010 | 0.0470-470 ( ng/ml )     | 2                                    | 2           |        |
|                            | Insulin - ( Serum )        | Electrochemiluminescence Immuno assay Manufactures specifications *       | ELECSYS 1010 | 0.200-1000 ( m IU/ml )   | 2.5                                  | 2.1         |        |
|                            | CA-125 - ( Serum )         | Electrochemiluminescence Immuno assay Manufactures specifications *       | ELECSYS 1010 | 0.600-5000 ( U/ml )      | TM 1<br>2.5                          | TM 2<br>2.7 |        |
|                            | β-HCG (Total) - ( Serum )  | Electrochemiluminescence Immuno assay Manufactures specifications *       | ELECSYS 1010 | 0.100- 10000 ( m IU/ml ) | TM 1<br>3.2                          | TM 2<br>2.7 |        |
|                            | Rubella IgG - ( Serum )    | Microparticle Enzyme Immuno- sorbant Aaasy Manufactures specifications *  | IMX          | 0-500 (IU/ml )           | (- ve ) N/A<br>( + ve ) 6.1          |             |        |
|                            | β-HCG (Total) - ( Serum )  | Microparticle Enzyme Immuno- sorbant Aaasy Manufactures specifications *  | IMX          | 0-1000 ( m IU/ml )       | Low ≤ 7.2<br>Med ≤ 5.6<br>High ≤ 6.6 |             |        |
| Andrology                  | Sperm processing- (Semen ) | WHO 1999  | -            | Not applicable           | NA                                   |             |        |
|                            | Sperm freezing - (Semen)   | Manufacturers specifications (Fertipro NV Belgium), ISO 13485 ISO 9001 CE | -            | Not applicable           | NA                                   |             |        |

\* Roche Diagnostics, Germany - AAALAC, EC, ISO EN 9001-2000 , ISO NIBSC, NCCLS  
PCU\* 1 & 2 - Precicontrol universal 1 & 2 (Roche Diagnostics)  
TM 1- Tumeor Marker 1 (Roche Diagnostics)  
TM 2- Tuma Marker 2 (Roche Diagnostics)

| SI. No. | Field of Testing                                    | Tests            | Test Method | Test Instrument | Analytical Range               | MU ( $\pm$ ) |
|---------|---|------------------|-------------|-----------------|--------------------------------|--------------|
|         | Andrology<br>( Seminal<br>Flid Analysis<br>– Semen) | Appearance       | WHO 1999    | Manual          | Qualitative Estimation         | -            |
|         |   | Liquefaction     |             | Manual          | -                              | -            |
|         |   | Viscosity        |             | Manual          | -                              | -            |
|         |   | pH               |             | Manual          | -                              | -            |
|         |   | Volume           |             | Manual          | 0 - 10 ( ml )                  | 0.02         |
|         |   | Concentration    |             | Manual          | 0 - 400 (10 <sup>6</sup> /ml ) | 3.69         |
|         |   | Motility         |             | Manual          | 0 - 100 ( % )                  | 3.3          |
|         |   | Morphology       |             | Manual          | 0 - 100 ( % )                  | 0.93         |
|         |   | Viability        |             | Manual          | 0 - 100 ( % )                  | 0.90         |
|         |   | Other cell types |             | Manual          | Qualitative Estimation         | -            |

Director /CEO  
Sri Lanka Accreditation Board for Conformity Assessment