

## Appendix (B): Verification of Reportable Range / Calibration

**Materials to use:**

1. FREN<sup>TM</sup> Linearity Kit from Nova-One Diagnostics (Nova-One.org)
2. FREN<sup>TM</sup> Cartridges (Testosterone Reagents), FREN<sup>TM</sup> System and Auto Processor (AP)
3. Pipette and tips: 70 µl placed in Pretreatment Tube, place Testosterone cartridge and Pretreatment tube in AP. When completed, place cartridge from AP into FREN. Use LIN mode.

| Assay Name          | Cartridge LOT# | Exp. Date<br>(MM/DD/YR) |
|---------------------|----------------|-------------------------|
| <b>Testosterone</b> |                | / /                     |

### Verification of Reportable Range

Nova-One Lot #: \_\_\_\_\_

Date of testing (MM/DD/YR): \_\_\_\_\_

### Calibration Verification Results

|               | Range               | Range                     |
|---------------|---------------------|---------------------------|
|               | Vial - 1            | Vial - 5                  |
| <b>ng/mL</b>  | <20 – 44.37 – 110.9 | 866.2 – <b>1158</b> -1449 |
| <b>Run #1</b> |                     |                           |
| <b>Run #2</b> |                     |                           |
| <b>Run #3</b> |                     |                           |

Run Vial 1 – 5 in Triplicate on same day

|               | Vial - 2                     | Vial - 3                     | Vial - 4                    |
|---------------|------------------------------|------------------------------|-----------------------------|
|               | Range                        | Range                        | Range                       |
| <b>ng/mL</b>  | 95.77 – <b>210.1</b> – 324.5 | 286.3 – <b>426.9</b> – 567.5 | 474.8 – <b>774.5</b> - 1074 |
| <b>Run #1</b> |                              |                              |                             |
| <b>Run #2</b> |                              |                              |                             |
| <b>Run #3</b> |                              |                              |                             |

Run Vial 1 – 4 in Triplicate on same day

\* Repeat if the result is out of range.

\* Copy additional pages as needed in case for more items or if you have another FREN<sup>TM</sup> System.

\* Please, scan this file as PDF or Image and send to [support@nanoentek.com](mailto:support@nanoentek.com) or fax this document to **(781) 790-5649**