**CERTIFICATE OF ANALYSIS**

|  |  |  |  |
| --- | --- | --- | --- |
| PRODUCT NAME: | **Clarity Platinum Urine Analyzer** | DATE OF TESTING: | «date» |
| STOCK CODE: | TC-201-CL |  |  |
| SERIAL NO. | «serial\_number» |  |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Packing Check** | **Quantity** | **Remarks** | **Checked** | **Checked by** |
| 1 | Urine Chemistry Analyzer | 1 | Reader | ✓ | «tester» |
| 2 | Printer Paper | 1 Roll | Thermal Paper | ✓ | «tester» |
| 3 | Power Cord | 1 | US/9V | ✓ | «tester» |
| 4 | Operator’s Manual | N/A | N/A | N/A | N/A |

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Mechanical Check** | **PASSED/FAILED** | **Checked by** |
| 1 | Power on, LCD Screen on, Strip Bed moves out/in | **PASSED** | «tester» |
| 2 | Press ‘Test’, Strip bed moves out (ready to test) | **PASSED** | «tester» |
| 3 | Date/Time Setting | **PASSED** | «tester» |
| 4 | Function of Feeding Paper | **PASSED** | «tester» |

**TOLERANCE LEVELS OF CONTROLS FOR TC-201-CL TEST**

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Controls** | **LEU** | **NIT** | **URO** | **PRO** | **pH** | **BLO** | **SG** | **KET** | **BIL** | **GLU** |
| KOVA I  LOT#: K305366  EXP: 2023-12-31 | 1+ to 3+ | POS (+) | 4.0 to ≥8.0 EU/dL | 100 to ≥300 mg/dL | 6.5 to 8.0 | 2+ to 3+ | 1.010 to 1.025 | 40 to ≥80 mg/dL | 2+ to 3+ | 500 to ≥1000 mg/dL |
| KOVA II  LOT#: K304781  EXP: 2022-11-30 | 1+ to 3+ | POS (+) | 0.2 to 1.0 EU/dL | Trace to 30 mg/dL | 7.0 to 8.5 | 1+ to 2+ | 1.005 to 1.015 | Trace to 40 mg/dL | NEG (-) to 1+ | 100 to 250 mg/dL |
| KOVA III  LOT#: K304788  EXP: 2022-12-31 | NEG (-) | NEG (-) | 0.2 to 1.0 EU/dL | NEG (-) | 5.0 to 6.5 | NEG (-) | 1.005 to 1.015 | NEG (-) | NEG (-) | NEG (-) |

**TC-201-CL TEST RESULTS**

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Controls** | **LEU** | **NIT** | **URO** | **PRO** | **pH** | **BLO** | **SG** | **KET** | **BIL** | **GLU** |
| KOVA I | «KOVA-I\_LEU» | «KOVA-I\_NIT» | «KOVA-I\_URO» | «KOVA-I\_PRO» | «KOVA-I\_pH» | «KOVA-I\_BLO» | «KOVA-I\_SG» | «KOVA-I\_KET» | «KOVA-I\_BIL» | «KOVA-I\_GLU» |
| KOVA II | «KOVA-II\_LEU» | «KOVA-II\_NIT» | «KOVA-II\_URO» | «KOVA-II\_PRO» | «KOVA-II\_pH» | «KOVA-II\_BLO» | «KOVA-II\_SG» | «KOVA-II\_KET» | «KOVA-II\_BIL» | «KOVA-II\_GLU» |
| KOVA III | «KOVA-III\_LEU» | «KOVA-III\_NIT» | «KOVA-III\_URO» | «KOVA-III\_PRO» | «KOVA-III\_pH» | «KOVA-III\_BLO» | «KOVA-III\_SG» | «KOVA-III\_KET» | «KOVA-III\_BIL» | «KOVA-III\_GLU» |

QC 🗹 PASSED 🞎 FAILED

|  |  |  |  |
| --- | --- | --- | --- |
| APPROVED BY: | **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | DATE: | \_\_\_\_\_\_\_\_\_ |
|  | Toscany Gonzalez | | |
|  | Quality Control | | |