|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Product Name: | TC-201 Clarity Platinum | | Cat. No.: | TC-201-CL | | Date: | | «date» |  |
| Serial Number: | «serial\_number» | | Technician: | «tester» | |  | | |  |
| Purpose: | ⮽QC Finished Unit | ⬜ New Revision | | | ⬜ RMA | | ⬜ Other: N/A | |  |

**A. Visual Inspection**

|  |  |  |  |
| --- | --- | --- | --- |
| **Item** | ⬜ **TECO TC-201** | ⮽ **OEM TC-201** | **Note** |
| Box  Appearance | a. Teco Box  b. Barcode sticker on the top of the box | Refer to receiving specifications:  Appendix A | ⮽Pass  ⬜ Fail  ⬜ N/A  Comments: N/A |
| Instrument  Appearance | * 1. Teco Diagnostics logo below the screen   2. TC-201 logo at the left-bottom of the front.   3. Device information sticker at the bottom of the device | Refer to receiving specifications:  Appendix A | ⮽ Pass  ⬜ Fail  ⬜ N/A  Comments: N/A |
| Packaging  Standard | 1. Analyzer in bag and foam holder; 2. Serial Number sticker on the analyzer and the box, 3. Power adapter, paper roll, quick reference guide and manual on top. | 1. Analyzer in bag and foam holder; 2. Serial Number sticker on the analyzer and the box, 3. Power adapter, paper roll, quick reference guide and manual on top. | ⮽ Pass  ⬜ Fail  ⬜ N/A  Comments: N/A |
| Packing  Items | 1x TC-201  1x Power adaptor 9V 4A  1x Paper roll width 2 ¼”  1x Quick Reference Guide  1x Manual | 1x OEM TC-201  1x Power adaptor 9V 4A  1x Paper roll width 2 ¼”  1x Quick Reference Guide  1x Manual | ⮽ Pass  ⬜ Fail  ⬜ N/A  Comments: N/A |

**B. Optical and Operating System Inspection**

|  |  |  |
| --- | --- | --- |
| **Item** | **Specifications** | **Note** |
| Calibrate Optics | LED sensor values should be ≈ 2700 - 3300 | ⮽ Pass ⬜ Fail Comments: N/A |
| Strip Bed Position | The number should be 19800 | ⮽ Pass ⬜ Fail Comments: N/A |
| Serial Number | The number should match the correlated document | ⮽ Pass ⬜ Fail Comments: N/A |
| Software Version | |  | | --- | |  | | ⮽ Pass ⬜ Fail Comments: N/A |
| Interface Version | |  | | --- | | DV22.03.12.0 | | ⮽ Pass ⬜ Fail Comments: N/A |

**C. Configuration Inspection**

|  |  |
| --- | --- |
| **Item** | **Note** |
| Verify the sensitivity setting for each parameter. Refer to APPENDIX B of  QL807-101 | ⮽ Pass ⬜ Fail Comments: N/A |
| Verify the strip type box which is selected for display  ⬜ URS10 ⮽ CLA-10P | ⮽ Pass ⬜ Fail Comments: N/A |
| Verify time & date | ⮽ Pass ⬜ Fail Comments: N/A |
| Perform device self-diagnosis tests | ⮽ Pass ⬜ Fail Comments: N/A |
| Perform and validate device failure alert mechanism | ⮽ Pass ⬜ Fail Comments: N/A |

**D. Performance Tests**

|  |  |
| --- | --- |
| Perform Incorrect Strip type (If applicable) | ⮽ Pass ⬜ Fail Comments: N/A |

1) Using URS-10/ OEM URS-10 strips

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Additional Components: 3 Levels of Urine Control (Kova-Trol) and 2 Lots of URS-10 strips | | | | | | | |
| Level I: | Lot#: K305366 | | Level II: | Lot#: K304781 | | Level III: | Lot#: K304788 |
| Exp. Date: 2023-12-31 | | Exp. Date: 2022-11-30 | | Exp. Date: 2022-12-31 |
| URS-10/  OEM URS-10: | | Lot#: 93467 | | | URS-10/  OEM URS-10: | Lot#: 93468 | |
| Exp. Date: 2024-06-23 | | | Exp. Date: 2024-06-23 | |

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

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Control Range** | **LEU** | **NIT** | **URO** | **PRO** | **pH** | **BLO** | **SG** | **KET** | **BIL** | **GLU** |
| KOVA I | 1+ - 3+ | (+) | 4.0 - ≥8.0 | 100 - ≥300 | 6.5 - 8.0 | 2+ - 3+ | 1.010 - 1.025 | 40 - ≥80 | 2+ - 3+ | 500 - 1000 |
| KOVA II | 1+ - 3+ | (+) | 0.2 - 1.0 | TRA - 30 | 7.0 - 8.5 | 1+ - 2+ | 1.005 - 1.015 | TRA - 40 | (-) - 1+ | 100 - 250 |
| KOVA III | (-) | (-) | 0.2 - 1.0 | (-) | 5.0 - 6.5 | (-) | 1.005 - 1.015 | (-) | (-) | (-) |

**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» |

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Released |  |  |  |  |  |  |  |  |  |  |
| Rejected |  |  |  |  |  |  |  |  |  |  |

|  |  |
| --- | --- |
| **Item** | **Note** |
| Delete all results after passing the QC tests | ⮽ Pass ⬜ Fail Comments: N/A |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Test Performed By: |  | Signature |  | Date: |  |
| Test Reviewed By: |  | Signature: |  | Date: |  |