**Cape Clinic Laboratory**

**Tool 2: Investigation Records 903**

Month/Year \_\_\_June 20XX\_\_\_ **Maintenance Log for XYZ Chemistry Analyzer (Serial Number 12345)**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Daily - Initial Boxes** | **1** | **2** | **3** | **4** | **5** | **6** | **7** | **8** | **9** | **10** | **11** | **12** | **13** | **14** | **15** | **16** | **17** | **18** | **19** | **20** | **21** | **22** | **23** | **24** | **25** | **26** | **27** | **28** | **29** | **30** | **31** |
| Externally Clean All Probes and Mixers | AM | AM | AM | AM | AM | AM | AM | AM | AM | AM | TK | TK | TK | TK | TK | TK | TK | TK | TK | TK | LS | LS | LS | LS | LS | LS | LS | LS | LS | LS |  |
| Clean Tube and Cup Adapters | AM | AM | AM | AM | AM | AM | AM | AM | AM | AM | TK | TK | TK | TK | TK | TK | TK | TK | TK | TK | LS | LS | LS | LS | LS | LS | LS | LS | LS | LS |  |
| Empty Waste | AM | AM | AM | AM | AM | AM | AM | AM | AM | AM | TK | TK | TK | TK | TK | TK | TK | TK | TK | TK | LS | LS | LS | LS | LS | LS | LS | LS | LS | LS |  |
| Check Washing Solutions | AM | AM | AM | AM | AM | AM | AM | AM | AM | AM | TK | TK | TK | TK | TK | TK | TK | TK | TK | TK | LS | LS | LS | LS | LS | LS | LS | LS | LS | LS |  |
| Empty Sample Tip Disposal Box | AM | AM | AM | AM | AM | AM | AM | AM | AM | AM | TK | TK | TK | TK | TK | TK | TK | TK | TK | TK | LS | LS | LS | LS | LS | LS | LS | LS | LS | LS |  |
| Empty Slide Disposal Boxes | AM | AM | AM | AM | AM | AM | AM | AM | AM | AM | TK | TK | TK | TK | TK | TK | TK | TK | TK | TK | LS | LS | LS | LS | LS | LS | LS | LS | LS | LS |  |
| Check Hydropneumatic Gauges | AM | AM | AM | AM | AM | AM | AM | AM | AM | AM | TK | TK | TK | TK | TK | TK | TK | TK | TK | TK | LS | LS | LS | LS | LS | LS | LS | LS | LS | LS |  |
| Check Reference Fluid Electrolyte (ISE Calibrator A) Solution | AM | AM |  | AM | AM | AM | AM | AM | AM | AM |  | AM | TK |  | TK | TK | TK |  | TK | TK | LS | LS | LS | LS | LS | LS | LS | LS | LS | LS |  |
| Change Disposable Tip and Clean Reference Fluid Electrolyte Tip Retainer | AM | AM |  | AM | AM | AM | AM |  | AM | AM |  | AM | TK |  |  |  | TK |  | TK |  | LS |  |  |  | LS |  | LS |  |  | LS |  |
| Clean the Reference Fluid Tip Sleeve | AM |  |  | AM | AM | AM | AM | AM | AM | AM |  | AM | TK |  | TK | TK | TK |  | TK | TK | LS | LS | LS | LS | LS |  | LS | LS |  | LS |  |
| Clean Electrolyte Sample Pickup Probe | AM | AM |  | AM |  | AM | AM | AM | AM | AM |  | AM | TK |  | TK | TK | TK |  | TK | TK | LS | LS | LS | LS | LS |  | LS | LS |  | LS |  |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Weekly – Initial and Date** | **Week 1** | **Week 2** | **Week 3** | **Week 4** | **Week 5** |  | **Monthly- Initial and Date** |  |
| Internally Clean Sample and Reagent Pickup Probes | AM  4/6/20XX | TK  13/6/20XX | TK  21/6/20XX | LS  28/6/20XX |  |  | Replace Air Filter | TK  19/6/20XX |
| Adjust Pinch Value Tubing | AM 4/6/20XX | TK  13/6/20XX | TK  21/6/20XX | LS  4/28/20XX |  |  | Clean the Reagent Bar Code Reader | TK  19/6/20XX |
| Clean Glucose Reaction Cup, Lines, Stirrer | AM  4/6/20XX | TK  13/6/20XX | TK  21/6/20XX | LS  4/28/20XX |  |  | Clean the Sample Bar Code Reader | TK  19/6/20XX |
| Clean Flow Cell with Bleach | AM  4/6/20XX | TK  13/6/20XX | TK  21/6/20XX | LS  4/28/20XX |  |  | Make Backup QC and Configuration Disks | LS  30/6/20XX |

reviewer / date MNT 1/7/20XX

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|  |  |  |  | **Cape Clinic Laboratory** | | | |  |  | |  |
| **MONTH / YEAR** | June, 20XX |  | **Reagent Tracking Log for XYZ Chemistry Analyzer (SN 12345)** | | | | | | | |  |
|  | **ALT** | **AST** | **Bili - Total** | **Calcium** | **CK** | **Creat** | **Gluc** | | | **TP** | **Cal A**  **Sol’n** |
| Serial Number | AL123 | AS123 | BT123 | CA123 | CK124 | CR123 | GL123 | | | TP123 | REF123 |
| Manufacturer Expiry Date | 17/5/20XX | 4/3/20XX | 17/5/20XX | 17/5/20XX | 1/5/20XX | 4/3/20XX | 2/3/20XX | | | 1/5/20XX | 8/11/20XX |
| On-board stability (days) | **30** | **30** | **20** | **12** | **15** | **7** | **15** | | | **30** | **30** |
| **DAY 1** | AM | AM |  |  |  |  |  | | | AM |  |
| **2** |  |  |  |  |  | AM |  | | |  |  |
| **3** |  |  |  |  |  |  | AM | | |  |  |
| **4** |  |  |  |  | AM |  |  | | |  |  |
| **5** |  |  |  |  |  |  |  | | |  |  |
| **6** |  |  | AM |  |  |  |  | | |  |  |
| **7** |  |  |  |  |  |  |  | | |  |  |
| **8** |  |  |  | AM |  | AM |  | | |  |  |
| **9** |  |  |  |  |  |  |  | | |  |  |
| **10** |  |  |  |  |  |  |  | | |  |  |
| **11** |  |  |  |  |  |  |  | | |  |  |
| **12** |  |  |  |  |  |  |  | | |  |  |
| **13** |  |  |  |  |  |  |  | | |  |  |
| **14** |  |  |  |  |  | TK |  | | |  |  |
| **15** |  |  |  |  |  |  | TK New Lot # GL678 / 24/12/20XX | | |  |  |
| **16** |  |  |  |  | TK |  |  | | |  |  |
| **17** |  |  |  |  |  |  |  | | |  | TK |
| **18** |  |  |  |  |  |  |  | | |  |  |
| **19** |  |  |  |  |  |  |  | | |  |  |
| **20** |  |  | TK |  |  | TK |  | | |  | TK |
| **21** |  |  |  |  |  |  |  | | |  |  |
| **22** |  |  |  |  |  |  |  | | |  |  |
| **23** |  |  |  |  |  |  |  | | |  |  |
| **24** |  |  |  |  |  |  |  | | |  |  |
| **25** | LS | LS |  |  |  |  |  | | |  | LS |
| **26** |  |  |  |  |  | LS |  | | |  |  |
| **27** |  |  |  |  |  |  |  | | | LS |  |
| **28** |  |  |  |  | LS |  | LS (GL678 / 24/12/20XX) | | |  |  |
| **29** |  |  |  |  |  |  |  | | |  |  |
| **30** |  |  |  |  |  |  |  | | |  | LS |
| **31** |  |  |  |  |  |  |  | | |  |  |

reviewer / date MNT 1/7/20XX

**Cape Clinic Laboratory**

**Calibration Log for XYZ Chemistry Analyzer (Serial Number 12345)**

reviewer / date MNT 1/7/20XX

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Initial Boxes if Pass \*** | **1** | **2** | **3** | **4** | **5** | **6** | **7** | **8** | **9** | **10** | **11** | **12** | **13** | **14** | **15** | **16** | **17** | **18** | **19** | **20** | **21** | **22** | **23** | **24** | **25** | **26** | **27** | **28** | **29** | **30** | **31** |
| Water Blank (daily) | AM | AM | AM | AM | AM | AM | AM | AM | AM | AM | TK | TK | TK | TK | TK | TK | TK | TK | TK | TK | LS | LS | LS | LS | LS | LS | LS | LS | LS | LS |  |
| Reagent Blank (daily) | AM | AM | AM | AM | AM | AM | AM | AM | AM | AM | TK | TK | TK | TK | TK | TK | TK | TK | TK | TK | LS | LS | LS | LS | LS | LS | LS | LS | LS | LS |  |
| ISE Electrolyte (daily) | AM | AM | AM | AM | AM | AM | AM | AM | AM | AM | TK | TK | TK | TK | TK | TK | TK/TK | TK | TK | TK | LS | LS | LS |  | LS/LS | LS | LS | LS |  | LS |  |
| AST  (weekly) |  |  |  |  |  | AM |  |  |  |  |  |  | TK |  |  |  |  |  |  |  | LS |  |  |  |  |  |  | LS |  |  |  |
| ALT  (weekly) |  |  |  |  |  | AM |  |  |  |  |  |  | TK |  |  |  |  |  |  |  | LS |  |  |  |  |  |  | LS |  |  |  |
| Bilirubin – Total (weekly) |  |  |  |  |  | AM |  |  |  |  |  |  | TK |  |  |  |  |  |  |  | LS |  |  |  |  |  |  | LS |  |  |  |
| Calcium  (weekly) |  |  |  |  |  | AM |  |  |  |  |  |  | TK |  |  |  |  |  |  |  | LS |  |  |  |  |  |  | LS | LS | LS |  |
| CK  (weekly) |  |  |  |  |  | AM |  |  |  |  |  |  | TK |  |  |  |  |  |  |  | LS |  |  |  |  |  |  | LS |  |  |  |
| Creatinine (weekly) |  |  |  |  |  | AM |  |  |  |  |  |  | TK |  |  |  |  |  |  |  | LS |  |  |  |  |  |  | LS |  |  |  |
| Glucose  (weekly) |  |  |  |  |  | AM |  |  |  |  |  |  | TK |  | TK |  |  |  |  |  | LS |  |  |  |  |  |  | LS |  | LS |  |
| Total Protein (weekly) |  |  |  |  |  | AM |  |  |  |  |  |  | TK |  |  |  |  |  |  |  | LS |  |  |  |  |  |  | LS |  |  |  |

\* If calibration event is unsuccessful, then complete an entry on the Corrective Action Log

As-Needed Calibration

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Date** | **Initials** | **Analyte** | **Reason for Calibration** | **Interpretation** |
| 15/6/20XX | TK | glucose | New lot number of reagent (lot # GL678 expiry date 24/12/20XX) | pass |
| 17/6/20XX | TK | NA+ / K+ | Issues with daily electrolyte calibration, put new bottle of Calibrator A on instrument, repeated calibration two more times | pass |
| 25/6/20XX | LS | NA+ / K+ | Issues with daily electrolyte calibration, put new bottle of Calibrator A on instrument, repeated calibration several times | pass |
| 28/6/20XX | LS | calcium | Weekly calibration was unsuccessful, repeated calibration |  |
| 29/6 & 30/6 | LS | calcium | QC was out even reran QC several times | pass |
| 30/6 | LS | glucose | QC was out even reran QC several times | pass |

**Cape Clinic Laboratory**

Month/Year \_\_\_June 20XX\_\_\_ **Patient Comparison Log for XYZ Chemistry Analyzer (Serial Number 12345)**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Date** | **Initials** | **Analyte** | **Reason for Comparison** | **Before Change** | **After Change** | **% Difference** | **Interpretation** |
| 1/6/20XX | AM | ALT | Reagent change | 24.0 | 24.5 | 2.1 | pass |
| 1/6/20XX | AM | AST | Reagent change | 40.8 | 39.8 | -2.5 | pass |
| 1/6/20XX | AM | TP | Reagent change | 54.0 | 56.0 | 3.7 | pass |
| 2/6/20XX | AM | Creatinine | Reagent change | 49.8 | 48.1 | -3.4 | pass |
| 3/6/20XX | AM | Glucose | Reagent change | 6.19 | 6.09 | -1.6 | pass |
| 4/6/20XX | AM | CK | Reagent change | 645 | 659 | 2.2 | pass |
| 6/6/20XX | AM | Bilirubin Total | Reagent change | 7.79 | 7.70 | -1.2 | pass |
| 8/6/20XX | AM | Calcium | Reagent change | 1.43 | 1.46 | 2.1 | pass |
| 8/6/20XX | AM | Creatinine | Reagent change | 57.5 | 58.9 | 2.4 | pass |
| 14/6/20XX | TK | Creatinine | Reagent change | 168 | 175 | 4.2 | pass |
| 15/6/20XX | TK | Glucose | Reagent change, new lot number GL678 | 3.52  6.84  19.6 | 3.35  6.51  18.7 | -4.8  -4.8  -4.6 | pass |
| 16/6/20XX | TK | CK | Reagent change | 271 | 279 | 3.0 | pass |
| 17/6/20XX | TK | Calibrator A | New bottle | Na 155  K 5.89 | Na 162  K 6.18 | Na 4.5  K 4.9 | pass  pass |
| 20/6/20XX | TK | Creatinine | Reagent change | 63.8 | 63.0 | -1.3 | pass |
| 20/6/20XX | TK | Bilirubin Total | Reagent change | 9.5 | 9.5 | 0 | pass |
| 20/6/20XX | TK | Calibrator A | New bottle | Na 136  K 3.76 | Na 142  K 3.94 | Na 4.4  K 4.8 | pass  pass |
| 25/6/20XX | LS | Calibrator A | New bottle; issues with QC | Na 142  K 2.44 | Na 136  K 2.74 | Na -4.2  K 12.3 | pass  fail |
| 25/6/20XX | LS | ALT | Reagent change | 159 | 163 | 2.5 | pass |
| 25/6/20XX | LS | AST | Reagent change | 106 | 106 | 0 | pass |
| 26/6/20XX | LS | Creatinine | Reagent change | 54.4 | 52.3 | -3.9 | pass |
| 27/6/20XX | LS | TP | Reagent change | 40.3 | 42.0 | 4.2 | pass |
| 28/6/20XX | LS | CK | Reagent change | 86.3 | 89.1 | 3.2 | pass |
| 28/6/20XX | LS | Calcium | Weekly calibration is not passing | 1.42 | 1.42 | 0 | pass |
| 28/6/20XX | LS | Glucose | Reagent change | 3.24 | 3.29 | 1.5 | pass |
| 29/6/20XX | LS | Calcium | QC continues to be unacceptable | 1.48 | 1.49 | 0.7 | pass |
| 30/6/20XX | LS | Calcium | QC continues to be unacceptable | 1.40 | 1.40 | 0 | pass |
| 30/6/20XX | LS | Calibrator A | New bottle; issues with QC | Na 134  K 3.82 | Na 126  K 3.52 | Na -6.0  K -7.9 | fail  fail |
| 30.6 | LS | Glucose | Problems with QC | 18.3 | 18.3 | 0 | Pass |

***After change* must agree within ±5% of *before change*** reviewer / date MNT 1/7/20XX

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **CHEMISTRY DAILY TEMPERATURE / MAINTENANCE LOG** | | | | |
|  |  |  |  |  |
| month/year | JUNE 20XX |  | reviewer / date | MNT 30/6/20XX |
|  |  |  |  |  |
|  | **ROOM TEMPERATURE** | **REAGENT/CALIBRATOR REFRIGERATOR** | **FREEZER** |  |
| **DAY** | acceptable range: (15 - 30'C) *(daily*) | acceptable range: (2 - 8 'C)  *(daily)* | acceptable range: (< - 20 'C)  *(daily)* | **INITIALS** |
| 1 | 25 | 6 | -23 | AM |
| 2 | 23 | 5 | -21 | AM |
| 3 | 23 | 5 | -21 | AM |
| 4 | 26 | 7 | -22 | AM |
| 5 | 25 | 6 | -21 | AM |
| 6 | 25 | 6 | -21 | AM |
| 7 | 23 | 5 | -23 | AM |
| 8 | 25 | 6 | -21 | AM |
| 9 | 25 | 6 | -21 | AM |
| 10 | 24 | 5 | -22 | AM |
| 11 | 27 | 7 | -21 | TK |
| 12 | 26 | 7 | -21 | TK |
| 13 | 25 | 6 | -23 | TK |
| 14 | 25 | 6 | -21 | TK |
| 15 | 24 | 5 | -22 | TK |
| 16 | 23 | 5 | -23 | TK |
| 17 | 23 | 5 | -23 | TK |
| 18 | 25 | 6 | -21 | TK |
| 19 | 25 | 6 | -23 | TK |
| 20 | 24 | 5 | -21 | TK |
| 21 | 25 | 6 | -21 | LS |
| 22 | 25 | 6 | -22 | LS |
| 23 | 23 | 5 | -21 | LS |
| 24 | 25 | 6 | -21 | LS |
| 25 | 25 | 6 | -22 | LS |
| 26 | 25 | 6 | -21 | LS |
| 27 | 25 | 6 | -21 | LS |
| 28 | 28 | 7 | -21 | LS |
| 29 | 25 | 6 | -23 | LS |
| 30 | 25 | 6 | -21 | LS |
| 31 |  |  |  |  |
|  |  |  |  |  |
| **MAINTENANCE SCHEDULE** | |  |  |  |
| **Daily:** verify temperatures are within range & document / initial | | | | |
| **As Needed and Documented Under Action:** defrosting /internal cleaning of freezer/ refrigerator | | | | |
| **Annually:** verify thermometer accuracy/acceptability | | | | |
|  |  |  |  |  |
| **Date:** |  | **Action** |  | **Initials** |
|  |  |  |  |  |
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|  | **Cape Clinic Laboratory** | | | | | | | | | |  |
|  |  |  | **Chemistry Analyzer Corrective Action Log** | | | | | |  | reviewer / date | MNT 1/7/20XX |
| Model # XYZ SN# 12345 | | | |  |  |  |  |  |  |  |  |
| **Date:** | **Action Performed:** | | | | | | | | | | **Initials:** |
| 3/6/20XX | Too busy to complete electrolyte daily maintenance, QC is acceptable | | | | | | | | | | AM |
| 7/6/20XX | Located last box of reference fluid disposable tips for electrolytes, will change tips sparingly, an order has been placed for the tips | | | | | | | | | | AM |
| 11/6/20XX | Too busy to complete electrolyte daily maintenance, QC is acceptable | | | | | | | | |  | TK |
| 14/6/20XX | Too busy to complete electrolyte daily maintenance, QC is acceptable | | | | | | | | |  | TK |
| 15/6/20XX | Changed to a new lot number of glucose reagent in afternoon, reran QC several times to ensure QC is acceptable | | | | | | | | |  | TK |
| 16/6/20XX | Sodium QC is unacceptable (> 2SD on Level 1 and > -2SD on Level 2) reran QC, all is acceptable | | | | | | | | |  | TK |
| 17/6/20XX | QC issues with electrolytes (Na+ Level 1 > 2SD, K+ Level 3 > -2SD) recalibrated but was unsuccessful; replaced disposable reference tip and recalibrated; Na+ QC acceptable but K+ was not; placed a new bottle of Cal A Solution on instrument; K+ QC is now acceptable | | | | | | | | |  | TK |
| 19/6/20XX | Glucose QC is unacceptable; cleaned glucose reaction cup and stirrer, reran QC and now is acceptable | | | | | | | | | | TK |
| 20/6/20XX | QC issues with K+ (>2SD); put a new bottle of Cal A Solution on but did not replace disposable tip since we are running low on tips; reran K+ QC and it is now acceptable | | | | | | | | | | TK |
| 24/6/20XX | Glucose QC is unacceptable; cleaned glucose reaction cup and stirrer, | | | | | | | | | | LS |
| 25/6/20XX | Many issues with electrolyte QC; repeated calibration twice, replaced disposable tip and Cal A Solution; reran QC and it is now acceptable | | | | | | | | |  | LS |
| 26/6/20XX | Too busy to complete electrolyte daily maintenance, QC is acceptable | | | | | | | | | | LS |
| 28/6/20XX | Glucose QC is unacceptable; cleaned glucose reaction cup, lines, and stirrer; reran QC and now is acceptable  Calcium QC is unacceptable, reran two more times after calibration and is now acceptable | | | | | | | | | | LS |
| 29/6/20XX | Calcium QC is unacceptable, calibration was unsuccessful; troubleshooting procedure to clean calcium cup and stirrer performed, reran QC and it is acceptable;  too busy to perform daily electrolyte maintenance, but QC is acceptable | | | | | | | | | | LS |
| 30/6/20XX | Calcium QC is unacceptable, calibration was unsuccessful; troubleshooting procedure to clean calcium cup and stirrer performed, reran QC and it is acceptable  Glucose QC was unacceptable; cleaned glucose reaction cup, lines, and stirrer; recalibrated glucose and reran QC; QC is now acceptable  Na+/K+ electrolyte QC is unacceptable, replace tip and Cal A Solution, QC is now acceptable | | | | | | | | | | LS |

**Calcium –Level 1**



**Calcium –Level 3**



**Glucose – Level 1**



**Glucose – Level 3**



**Potassium – Level 1**



**Potassium – Level 3**



**Sodium – Level 1**



**Sodium – Level 3**

