## 表單編號: SPOCT12-001 版次:2.2

## 附件一、Siemens RAPIDLab500 blood gas analyzer品管檢閱記錄表

## Siemens RAPIDLab500 blood gas analyzer品管圖表檢閱記錄

|  |  |  |  |
| --- | --- | --- | --- |
| 項目：全項(機台故障/品管異常/領用新批號試劑,請務必在問題欄位註明清楚)年： 月 | | | |
| 日期 | 檢閱人員簽名 | 檢閱結果(正常 / 異常) | 問 題 內 容 簡 述 (需 註 明 項 目) |
| 1 |  | □ / □ |  |
| 2 |  | □ / □ |  |
| 3 |  | □ / □ |  |
| 4 |  | □ / □ |  |
| 5 |  | □ / □ |  |
| 6 |  | □ / □ |  |
| 7 |  | □ / □ |  |
| 8 |  | □ / □ |  |
| 9 |  | □ / □ |  |
| 10 |  | □ / □ |  |
| 11 |  | □ / □ |  |
| 12 |  | □ / □ |  |
| 13 |  | □ / □ |  |
| 14 |  | □ / □ |  |
| 15 |  | □ / □ |  |
| 16 |  | □ / □ |  |
| 17 |  | □ / □ |  |
| 18 |  | □ / □ |  |
| 19 |  | □ / □ |  |
| 20 |  | □ / □ |  |
| 21 |  | □ / □ |  |
| 主管月檢閱: | | |  |

## 表單編號：SPOCT12-002 版次:2.2

## 附件二、Blood gas RAPIDPoint500試劑換批號平行測試記錄

## Blood gas RAPIDPoint500試劑換批號平行測試記錄

## 科別：麻醉科機台

## 試劑名稱：\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ 供應廠商：\_\_\_\_\_\_\_\_\_\_\_\_\_\_ 貨號：\_\_\_\_\_\_\_\_\_\_\_

## 檢驗項目：Blood Gas

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 開封日期(年/月/日) | 項目名稱 | 新試藥批號/有效期限 | 測試結果(新批號) | 舊試藥批號/有效期限 | 測試結果(舊批號) | 差異(新-舊) | \*可接受範圍(±2SD) | 通過/失敗 |
|  | PH |  | L1:L2:L3: |  | L1:L2:L3: | L1:L2:L3: | L1:L2:L3: | 🞏通過🞏失敗🞏通過🞏失敗🞏通過🞏失敗 |
|  | PCO2 |  | L1:L2:L3: |  | L1:L2:L3: | L1:L2:L3: | L1:L2:L3: | 🞏通過🞏失敗🞏通過🞏失敗🞏通過🞏失敗 |
|  | PO2 |  | L1:L2:L3: |  | L1:L2:L3: | L1:L2:L3: | L1:L2:L3: | 🞏通過🞏失敗🞏通過🞏失敗🞏通過🞏失敗 |
|  | tHb |  | L1:L2:L3: |  | L1:L2:L3: | L1:L2:L3: | L1:L2:L3: | 🞏通過🞏失敗🞏通過🞏失敗🞏通過🞏失敗 |
|  | Na+ |  | L1:L2:L3: |  | L1:L2:L3: | L1:L2:L3: | L1:L2:L3: | 🞏通過🞏失敗🞏通過🞏失敗🞏通過🞏失敗 |
|  | K+ |  | L1:L2:L3: |  | L1:L2:L3: | L1:L2:L3: | L1:L2:L3: | 🞏通過🞏失敗🞏通過🞏失敗🞏通過🞏失敗 |
|  | CL- |  | L1:L2:L3: |  | L1:L2:L3: | L1:L2:L3: | L1:L2:L3: | 🞏通過🞏失敗🞏通過🞏失敗🞏通過🞏失敗 |
|  | Ca++ |  | L1:L2:L3: |  | L1:L2:L3: | L1:L2:L3: | L1:L2:L3: | 🞏通過🞏失敗🞏通過🞏失敗🞏通過🞏失敗 |
|  | Glu |  | L1:L2:L3: |  | L1:L2:L3: | L1:L2:L3: | L1:L2:L3: | 🞏通過🞏失敗🞏通過🞏失敗🞏通過🞏失敗 |

主任： 品管醫檢師： 組長： 測試者：

注意事項:

1.新批號試劑應在尚未用於病人檢體前先行測試，測試時最好是與現用試劑作平行測試。

2.定量平行測試檢驗原則：品管合格及3個Level品管液差異結果應落在現況品管值±2SD的範圍內。

## \*可接受範圍：新批號與舊批號的品管值差異不可超過品管液濃度的±2SD

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 項目 | PH | | PO2 | | PCO2 | | tHb | | Na | | K | | CL | | Ca | | Glu | |
|  | mean | ±1SD | mean | ±1SD | mean | ±1SD | mean | ±1SD | mean | ±1SD | mean | ±1SD | mean | ±1SD | mean | ±1SD | mean | ±1SD |
| L1 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| L2 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| L3 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

## (1SD計算方法:(舊批號品管高值-低值)÷6 )

## 表單編號：SPOCT12-003 版次:2.2

附件三、

Blood gas analyzer品管不符合事項處理表

表單編號：

|  |  |  |
| --- | --- | --- |
| 單位: | 發現人員： | 發現時間：年月日 |
| 檢驗項目：機台：RAPIDPoint 500  檢體類別：全血  違反品管規則：🞎13SD  試藥批號：\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_開始使用日期\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  品管液批號：\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_是否改變**🞏**是**🞏**否  懷疑異常種類：🞎 Random error 🞎 Systemic error  此情形最近一週是否發生過🞎是🞎否  通知🞎品管負責人 | | |
| 異常情況說明：  發現人：填寫時間： | | |
| 處理過程及討論：   |  |  | | --- | --- | | Step 1. | Step 2. | | 手動執行□2點□全點校正 | □通知當班Leader | | □進行1次AQC | □通知組長 | | □其他: | □聯絡儀器課維修人員 | |  |  |   發現人：填寫時間： | | |
| 改進措施：  品管負責人： 填寫時間： | | |
| 主管評語  主管： 填寫時間： | | |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 附件四、麻醉科Siemens RAPIDPoint 500 blood gas analyzer保養表 表單編號：SPOCT12-004 版次:2.2 **麻醉科Siemens RAPIDPoint 500 blood gas analyzer保養表 年 月**   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | 項次 | **保養項目/日期** | 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 | | 1 | 清潔儀器外觀 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | | 2 | 機台環境溫度  (合格範圍15-30°C) |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | | 3 | 清潔Sample Port |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | | 4 | 更換 Sample Port |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | | 5 | 更換Wash/Waste Cartridge |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | | 6 | Wash/Waste Cartridge批號 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | | 7 | 更換Measurement Cartridg |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | | 8 | Measurement Cartridge批號 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | | 9 | 更換AQC Cartridge |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | | 10 | 執行人員簽名 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | | 11 | 組長簽名(每週檢閱1次) |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | | 12 | 備註 | 執行請填「V」，不須(未)執行請填「-」 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |   主管簽章: |

## 附件五、blood gas analyzer不符合事項處理

## 表單編號：SPOCT12-005 版次:2.2

## Blood gas analyzer不符合事項處理表

|  |  |  |
| --- | --- | --- |
| 科別:麻醉科 | 發現人員： | 發現時間： 年 月 日 時 |
| 檢驗項目：機台： RAPIDPoint 500   * + 1. 機台方面異常:   🞏機械方面故障 🞏校正方面 🞏儀器/電腦連線  🞏其它\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_   * + 1. 試藥異常:   🞏原廠試藥發生異常(填此項需有原廠檢附的異常說明)🞏試藥中斷   * + 1. 其他異常: | | |
| 異常情況說明：   |  |  |  | | --- | --- | --- | | Step 1. | Step 2. | Step 3. | | 儀器顯示錯誤訊息  □校正失敗 | □執行2點校正 | □通知當班Leader | | □D2 Excessive Drift： | □重上品管液 | □通知組長 | | □D3 Slope Error： | □其它 | □聯絡儀器課維修人員 | | □D4 Offset Error： |  | □回溯這一次校正失敗到上一次校正之間報告的正確性 | | □D39 Obstruction |  |  | | □清潔SamplePort □更換SamplePort |  |  | | □Bubble in the Sample  □清潔SamplePort □更換SamplePort  □排除檢體氣泡 |  |  | | □.Insufficient Sample Volume  □清潔SamplePort □更換SamplePort  □檢體重新上機 |  |  | | □D23 Reagent Error  □更換新試藥  □D40 Wash Not Detect  □更換新WASH Cartridge |  |  |   異常發現人員：填寫日期： | | |
| 處理過程：時效影響🞏無影響🞏影響\_\_\_\_\_\_\_\_(時間)  🞏檢體改送檢驗科  處理人：填寫日期：\_\_\_\_\_\_\_\_ | | |
| 實驗室負責人評語: 🞏無需追蹤🞏需追蹤處理, \_\_\_月\_\_\_日提報  實驗室負責人：\_\_\_\_\_\_\_\_\_簽閱日期：\_\_\_\_\_\_\_\_ | | |

## 附件六、Siemens RAPIDPoint 500blood gas analyzer能力評估表

## 表單編號：SPOCT12-006 版次:2.2

## SiemensRAPIDPoint 500blood gas analyzer能力評估表

## 人員姓名: 職稱: 評估日期: 年 月 日

## 操作觀察記錄表:

|  |  |  |
| --- | --- | --- |
| 操作內容 | 未達標準 | 達到標準 |
| 1.檢體先檢查是否有氣泡，若有，應以手指輕彈方式趕至針筒頂端後排除 |  |  |
| 2.先將檢體以兩手掌以滾動方式mix至少10秒 |  |  |
| 3.再上下方式mix至少10秒 |  |  |
| 4.將前端的檢體先打一點到紗布上，觀察是否有clot，若有則退件 |  |  |
| 5.儀器在ready狀態下，選擇左側檢體類別，將syringe放到sample port中，按右下方的Start，等待30秒取出檢體在按右下方箭頭符號。 |  |  |
| 6.手動輸入檢體ID或是條碼輸入，再按右下方箭頭符號。  註: 若有需要註明病人之溫度、Hb或FIO2時，需在此畫面同時輸入 |  |  |
| 7.查詢及列印檢驗報告 |  |  |
| 8.結果判讀(了解危險值需告知醫師並記錄) |  |  |
| 9.儀器外表及Sample port清潔 |  |  |
| 10.儀器保養表填寫正確性 |  |  |
| 11.執行校正，點選右上方system按鍵，選擇calibration一點、兩點校正或全點校正，儀器會自動執行。 |  |  |
| 12.人員執行AQC，執行螢幕左側的AQC圖案，按右下方的Start選擇要執行的level，再按一次Start，螢幕上會顯示報告 |  |  |
| 13.了解如何查詢QC DATA |  |  |
| 14.更換Wash / Waste Cartridg，按下replace輸入密碼儀器門自動打開進行更換。 |  |  |
| 15.更換Measurement Cartridge，按下replace輸入密碼後再按Connector，儀器門自動打開進行更換。 |  |  |

盲樣檢體測試結果:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 結果判讀 | 測量項目 | 測試結果 | 正確結果 | 判定標準(CAP) | 合格與否 |
| pH |  |  | ±0.04 |  |
| PCO2 |  |  | ±5 mm Hg or 8%, |  |
| PO2 |  |  | ±10% |  |
| Na |  |  | ±4 |  |
| K |  |  | ±0.5 |  |
| iCa |  |  | ±0.03 |  |
| Hct |  |  | ±6% |  |

訓練結果 : □ 通過 □ 需再訓練 再訓練日期:

評核(訓練)人員:

組長: