



# GEM Premier Blood Gas Analyzer and iQM System

Product Specialist  
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# 大綱

- Blood Gas品管需求與流程
- 儀器介紹
- iQM 功能與技術
- 採檢注意事項
- 上機操作流程

# 品管需求

- 根據107年醫院評鑑條文2.8.3「醫事檢驗作業具有完備的品質保證措施」中，項目7 (原 2.8.3-優良 4)
  - 檢驗科室以外之檢驗儀器(如：血糖機、血液氣體分析儀(blood gas analyzer)等)有品質管理機制。

**針對Hospital-based POCT進行品質管理機制**

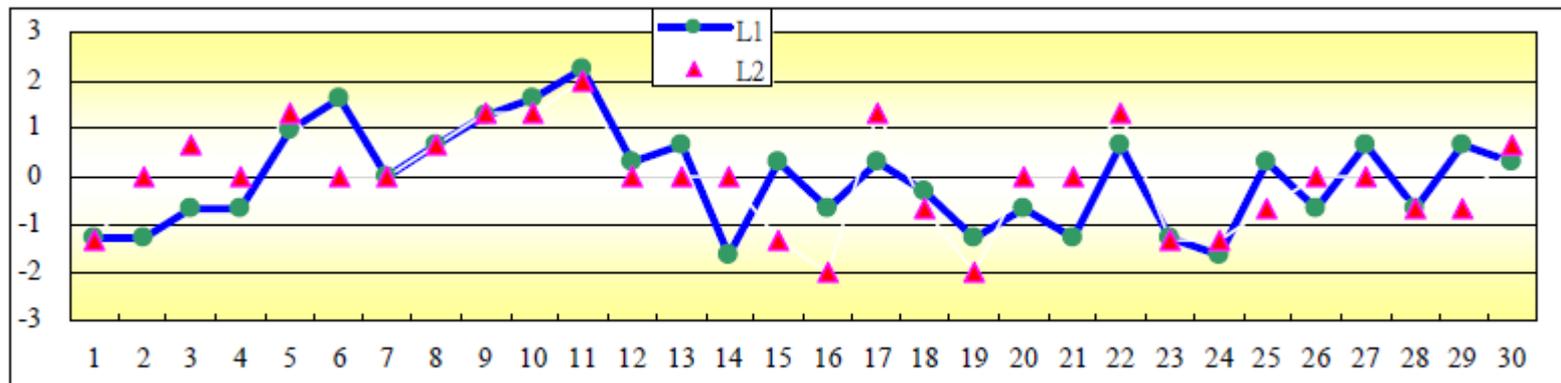
(104與107年版醫院評鑑基準及評量項目)

# Quality Control Guidelines

- CHM.34400 Daily QC - Blood Gas Instruments
  - A minimum of **one level of quality control for pH, pCO<sub>2</sub> and pO<sub>2</sub>** is analyzed at **least every eight hours** of operation when patient specimens are tested, or more frequently if specified in the manufacturer's instructions or laboratory procedure, and when changes occur that may impact patient results.
- CHM.34500 Daily QC - Blood Gas Instruments
  - **The control materials for pH, pCO<sub>2</sub> and pO<sub>2</sub> represent both high and low values on each day of patient testing.**
- CHM.34600 QC - Blood Gas Instruments
  - **At least one level of quality control material for pH, pCO<sub>2</sub> and pO<sub>2</sub> is included each time patient specimens are tested**, except for automated instruments that internally calibrate at least once every 30 minutes of use.
- ISO 15189 section 5.6.1
  - **Design internal quality control systems that verify attainment of the intended quality goals**
- CLSI document EP23 Laboratory QC Based on Risk Management
  - **Establish test method quality requirements based on risk management**

# Blood Gas品管流程

- 以Automated Traditional QC為例：
  - 操作時間：每8小時做一次，3 Level
  - 繪製 L-J Chart
  - 如果超出範圍，則用戶必須進行故障排除，例如重新 Cal，重複QC，或更換組件/試劑等



# 實驗室當前所遇到的問題

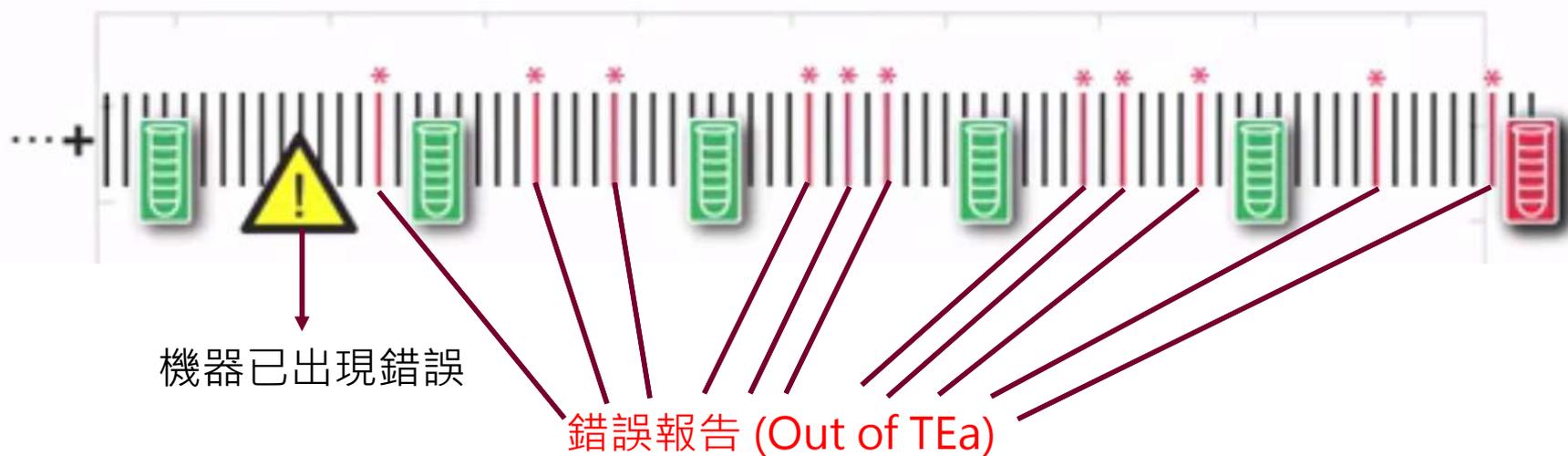
- 儀器設定的頻率不一定符合風險管理的需求
- 仰賴儀器所設定的自動校正與QC
- 試劑卡匣、校正液與品管液的批號效期管理困難
- 傳統QC會因Priming或是試劑Dead Volume所造成的浪費，使品管成本提高
- 檢驗科如何管理POC單位的品管

# 管理POCT潛在的問題

- 19% 的使用者未參與訓練
- 25% 的使用者未遵照製造商操作手冊
- 32% 未落實執行品管計劃
- 32% 沒有品管計劃

([www.cms.hhs.gov/clia/cowppmp.asp](http://www.cms.hhs.gov/clia/cowppmp.asp))

# 一天可能發錯多少筆報告?



## 您的儀器呢?

# 儀器簡介

## Instrument Overview

# GEM Premier重症監護測試系統

1. 模組化設計單一卡匣
2. 完整的檢測項目
3. **智能品質管理系統 iQM**
4. 免傳統保養維護
5. 觸控螢幕

## Measured Analytes

Analyte	Displayed Ranges
pH	6.80 to 7.80
pCO <sub>2</sub>	5 to 115 mmHg
pO <sub>2</sub>	0 to 760 mmHg
Na <sup>+</sup>	100 to 200 mmol/L
K <sup>+</sup>	0.1 to 20.0 mmol/L
Ca <sup>++</sup>	0.10 to 5.00 mmol/L
Glu	20 to 500 mg/dL
Lac	0.3 to 15.0 mmol/L
Hct	15% to 65%

觸控螢幕

一鍵上機



單一卡匣裝載



	<b>GEM 3500</b>	<b>GEM 4000</b>
<b>Dimensions</b>	<b>44.5x33.0x30.0 cm</b>	<b>45.5x30.5x38.1 cm</b>
<b>Weight</b>	<b>14.2 kg / 1.9 kg</b>	<b>20 kg / 3.6 kg</b>
<b>Analyte Menu</b>	<b>BG, Hct</b>	<b>BG, Hct, Hb, tBili</b>
	<b>BG, Lytes, Hct</b>	<b>BG, Lytes(+ Cl<sup>-</sup>), Hct, Hb, tBili</b>
	<b>BG, Lytes, Glu, Lac, Hct</b>	<b>BG, Lytes(+ Cl<sup>-</sup>), Glu, Lac, Hct, Hb, tBili</b>
<b>Sample Volume</b>	<b>BG/Hct: 135 µL</b>	<b>All item: 150 µL</b>
	<b>BG/Hct/Lytes: 135 µL</b>	<b>CO-Ox: 100 µL</b>
	<b>All item (capillary): 145 µL</b>	<b>All item w/o CO-Ox (Capillary): 65 µL</b>
	<b>All item: 150 µL</b>	
<b>Time To Results</b>	<b>85 sec</b>	<b>70 sec (w/o CO-Ox)</b>
		<b>95 sec (w/ CO-Ox)</b>

1. BG = pH, pCO<sub>2</sub>, pO<sub>2</sub>
2. Lytes = Na<sup>+</sup>, K<sup>+</sup> and Ca<sup>++</sup>
3. Hb = tHb, O<sub>2</sub>Hb, HHb, COHb, MetHb, sO<sub>2</sub>
4. tBili = PAKs available with or without tBili.

# 外部能力測試



cap

## AQ

# Critical Care/Aqueous Blood Gas With Chemistry

pO<sub>2</sub> - mm Hg

INSTRUMENT	NO. LABS	MEAN	S.D.	C.V.	MEDIAN	LOW VALUE	HIGH VALUE
IL GEM PREMIER 3000	49	59.1	2.3	3.8	59	55	64
IL GEM PREMIER 3500	150	59.4	2.5	4.2	59	54	66
IL GEM PREMIER 4000	625	59.4	2.8	4.6	59	51	68
IL GEM PREMIER 5000	90	53.8	3.9	7.2	53	45	65

(2019 CAP AQB)

12

# 設計核心

- **簡單性**：便於操作，不需季/年度保養
- **靈活性**：可彈性組合分析項目
- **iQM**：搭載智能品質管理系統
- **GEM web Plus**：數據雲端管理



# 多樣性卡匣選擇

**GEM 3500: 21 days**  
**GEM 4000: 30 days**

說到做到！  
 品管不扣除可用次數

Analyte Menu	Tests/PAK	Onboard Use Life (weeks)
BG,* Hct	75	4
	150	3
	300	3
	450	3
	600	2
BG, Lytes,** Hct	75	4
	150	3
	300	3
	450	3
	600	2
BG, Lytes, Glu, Lac, Hct	75	3
	150	3
	300	3
	450	3
	600	2

MENU	PAK SIZE					Onboard Use-life
	75	150	300	450	600†	
Blood Gas, Hct, tHb, O <sub>2</sub> Hb, HHb, Methb, sO <sub>2</sub> , Total Bili* <b>BG</b>	✓	✓	✓	✓	✓	30 days
Blood Gas, Electrolytes, Hct, tHb, O <sub>2</sub> Hb, HHb, Methb, sO <sub>2</sub> , Total Bili* <b>BG+Lyte</b>	✓	✓	✓	✓	✓	30 days
Blood Gas, Electrolytes, Glu, Lac, Hct, tHb, O <sub>2</sub> Hb, HHb, Methb, sO <sub>2</sub> , Total Bili* <b>BG+Lyte+Glu/Lac</b>	✓	✓	✓	✓	✓	30 days
Menus with: Creat, BUN, measured tCO <sub>2</sub> are in development.						

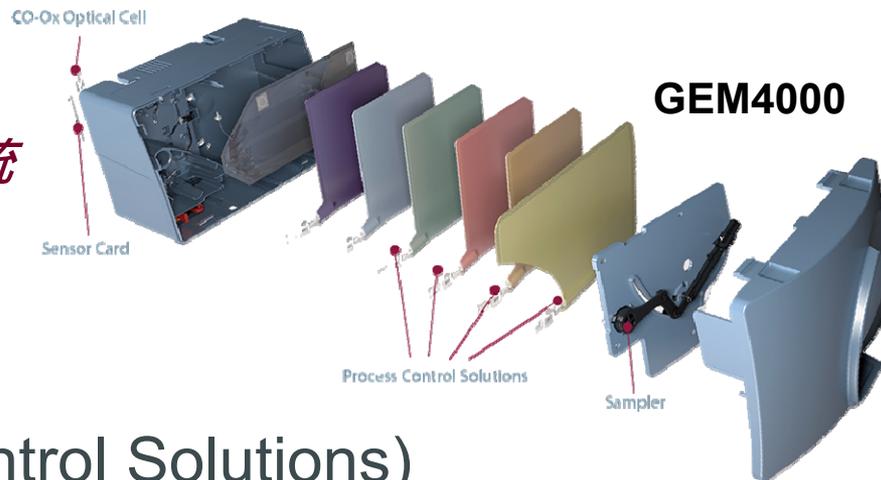
† Onboard use-life is 21 days.

\* Cartridges available with or without Total Bili.

# GEM 專用卡匣

單一卡匣、All-in-one包裝、封閉系統

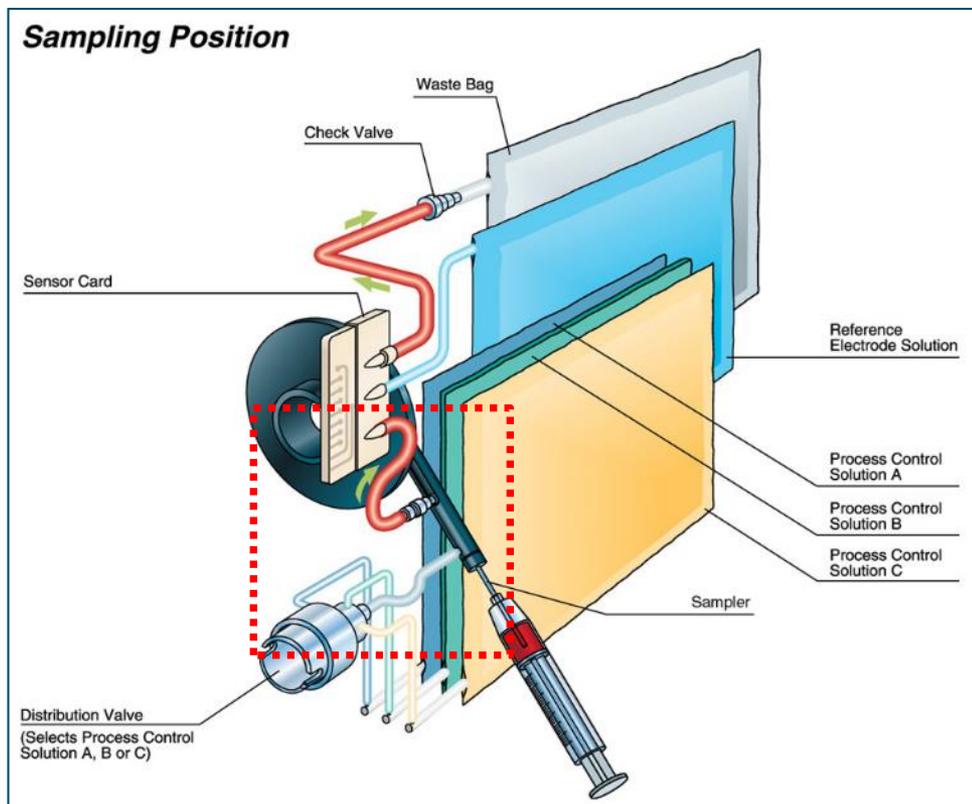
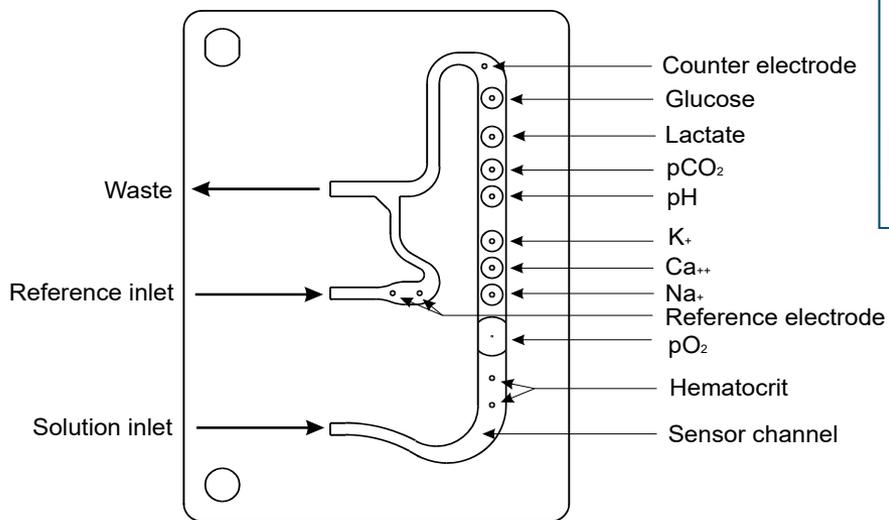
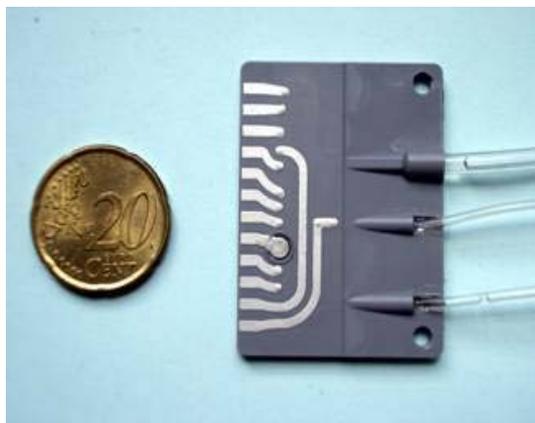
- 卡匣內包含：
  - 電極感應卡片 (Sensors)
  - 流程控制液 (Process Control Solutions)
  - 進樣器 (Sampler)
  - 管路 (Tubing)
  - 廢液袋 (Waste Bag)



全分析路徑於封閉卡匣內  
機台免保養



# 電極感應卡片

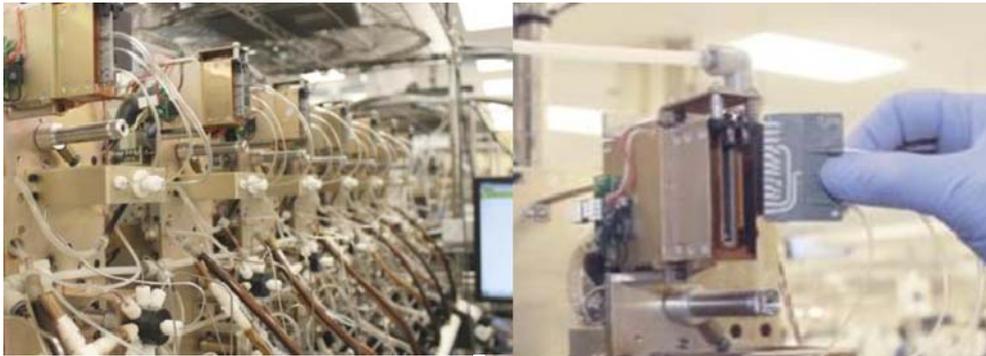


- 簡單簡短的檢體路徑
- 降低Clot的機率

# 產品品質保證與追溯性



- 感應卡與試劑的出廠檢驗
- 卡匣的追溯性 → NIST (National Institute of Standards and Technology)



## Certificate of Traceability and Uncertainty

**Product:** GEM® Premier 4000 Cartridge

**Approach:** per ISO 17511 with uncertainty expressed with K = 2 (95% confidence)

Analytes	Methods and Materials
General approach	Analytes are assigned against working calibrators using validated standing measurement procedures. Working calibrators are assigned using validated selected measurement procedures which are based on the following reference methods:
pH & Ca <sup>++</sup>	per CLSI no. C46-A for pH and CLSI no. C39-A for iCa, i.e., direct potentiometry versus secondary standards prepared from: • phosphate salts for pH, NIST #1861 & 186II, and • calcium carbonate for Ca <sup>++</sup> , NIST #915.
pCO <sub>2</sub> & pO <sub>2</sub>	per CLSI nos. C21-A & C46-A, i.e., tonometry at 37°C using gas mixtures assured to ±.01% versus NIST
Na <sup>+</sup> & K <sup>+</sup>	per NIST pub. no. 260-60 (Aug.'78) and 260-63 (May'79), i.e., flame photometry versus secondary standards prepared from NaCl & KCl, NIST #919 & NIST #918.
Cl <sup>-</sup>	per NIST pub. no. 260-67 (nov.'79) and CLSI no. RS10-P, i.e., coulometric-amperometric titration with silver ion versus secondary standards prepared from NIST #919.
Glucose & Lactate	by automated spectrophotometry: • glucose: hexokinase method per CDC no. 77-8330 and CLSI no. RS1-A using secondary standard prepared from NIST #917 • lactate: no reference method established for lactate. Lactate oxidase is used with secondary standard prepared from USP cat. no. 1614308
tBili	by automated, modified Jendrassik-Grof using standards prepared from NIST #916
Hct	by centrifugation using whole blood per CLSI H7-A3 for establishing correlation. Maintained from lot to lot by controlling conductivity by controlling sodium concentration.
tHb	per CLSI H15-A3 (2000), Hemoglobincyanide by Colorimetry using CyanMetHb standards per CLSI specifications.

### Uncertainty of Measurement at Normal Concentrations

analyte	pH	pCO <sub>2</sub>	pO <sub>2</sub>	Na <sup>+</sup>	K <sup>+</sup>	Ca <sup>++</sup>	Cl <sup>-</sup>	Glucose	Lactate	tHb	tBili	Hct
Units	(eq/kg)	mmHg	mmHg	mmol/L	mmol/L	mmol/L	mmol/L	mg/dL	mmol/L	g/dL	mg/dL	%
U	.005	0.9	1.6	0.8	.06	.011	0.7	1.9	.02	0.2	+0.5	0.5

*P. D'Orazio* 7/13/11  
Paul D'Orazio, PhD, R&D Director

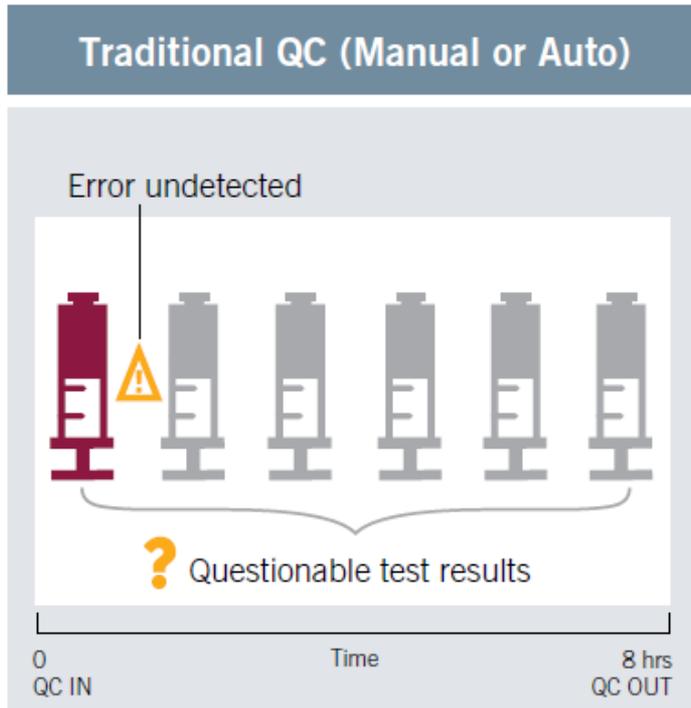
*Stan Wharton* 13-Jul-11  
Stan Wharton, VP of WW QA & RA

Rev. 03/2011

# 智能品質管理系統的功能與技術

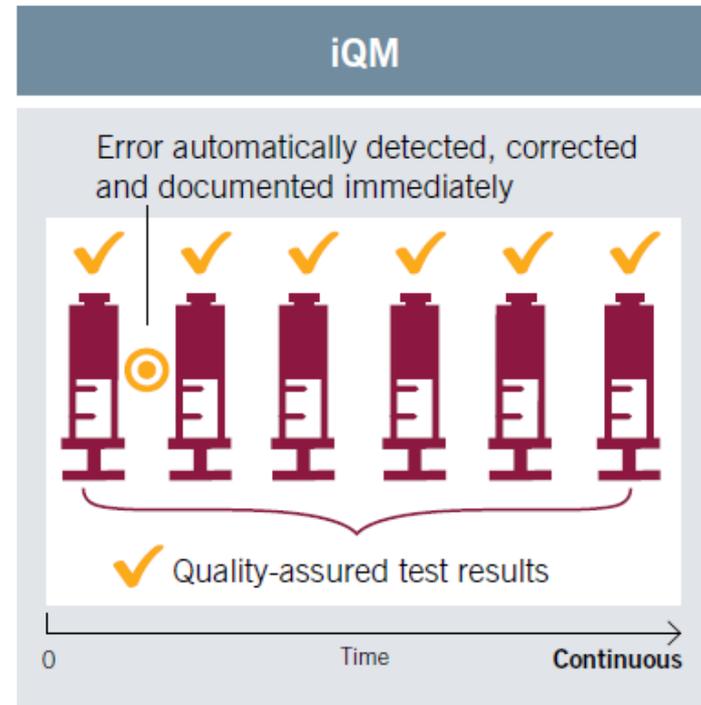
## iQM Features and Technical Description

# 連續性的品質管理



All results from 8-hour period require review

VS.



iQM assures quality continuously

iQM reduces error detection time from hours to minutes.<sup>1,2</sup>

	pH	pO <sub>2</sub>	pCO <sub>2</sub>	Na <sup>+</sup>	K <sup>+</sup>	Ca <sup>++</sup>	Glu	Lac	Hct
<b>iQM</b>	<b>3 mins</b>	<b>3 mins</b>	<b>3 mins</b>	<b>17 mins</b>	<b>3 mins</b>	<b>3 mins</b>	<b>11 mins</b>	<b>6 mins</b>	<b>3 mins</b>
Traditional QC (Manual or Auto)	≥ 8 hrs	≥ 8 hrs	≥ 8 hrs	≥ 8 hrs	≥ 8 hrs	≥ 8 hrs	≥ 8 hrs	≥ 8 hrs	≥ 8 hrs

# Dr. Westgard提出的新品管概念

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HOME ▶ ESSAYS ▶ TRENDS ▶ A MOMENTOUS HAPPENING - A NEW WAY TO DO QC!

## A MOMENTOUS HAPPENING - A NEW WAY TO DO QC!



Written by James O. Westgard

A new QC technology has been cleared that replaces the use of traditional external quality controls. This happened because a manufacturer submitted a claim for this new QC technology and provided the documentation to defend that claim. Read all about it!

***Replaces the use of traditional external QC.***

- The CLIA standard for QC
- A momentous happening!
- What is iQM?
- How does iQM work?
- How does a manufacturer validate QC performance?
- What performance is expected for iQM?
- How does iQM performance compare with traditional QC?
- References

AdChoices ▶

### Espresso ELN

Electronic Lab  
Notebook for  
R&D. Download  
your \*free\* copy  
now!

[www.chembytes.com](http://www.chembytes.com)

(<http://www.westgard.com/essay47.htm>)

20

# 何謂iQM?

*FDA-cleared Intended Use Statement\**

“iQM is an **active** quality process control program designed to provide **continuous monitoring** of the analytical process with **real-time, automatic error detection, automatic correction** of the system and **automatic documentation** of all corrective actions, **replacing the use of traditional external quality controls.**”\*\*

\* Approved in 2002 for GEM Premier 3000 and again in 2006 for GEM Premier 4000.

\*\* Facilities should follow local, state and federal regulatory guidelines to ensure that a total quality management system is followed.

**主動的程序監控，透過連續監測，它可以達到即時的自動偵錯、自動矯正，並且自動記錄矯正措施。來取代傳統的外部品管。**

## Validation of iQM Active Process Control Technology

\*James O. Westgard, PhD, †Kevin D. Fallon, PhD, and †Sohrab Mansouri, PhD

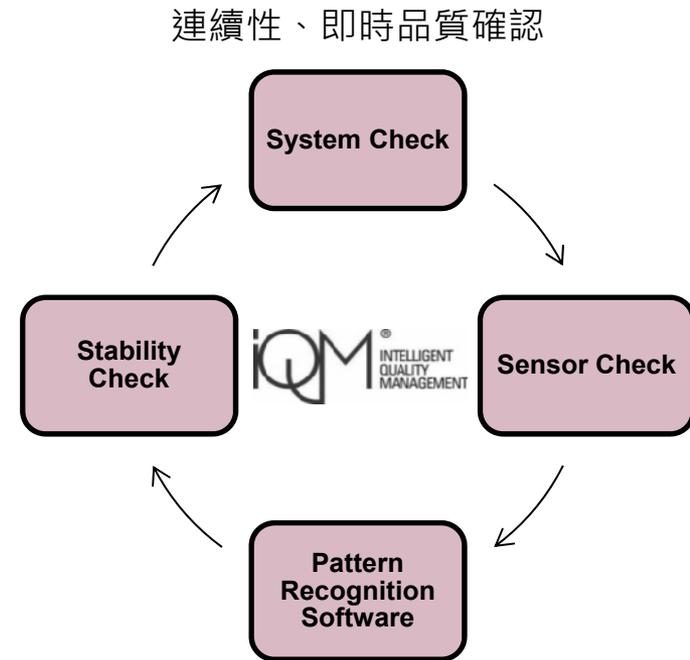
### 結論：

- GEM iQM平均偵錯時間3-10分鐘 / 傳統 QC 8小時
- Sigma值也證實GEM的確是一套控制良好的系統

Statistic	Measurement (units)								
	pH unit	pCO <sub>2</sub> mmHg	pO <sub>2</sub> mmHg	Na <sup>+</sup> mmol/L	K <sup>+</sup> mmol/L	Ca <sup>++</sup> mmol/L	Glucose mg/dL	Lactate mmol/L	Hct %
Mean	7.40	32	176	144	3.6	1.16	0	0.0	11
SD	0.002	0.41	1.37	0.90	0.011	0.009	1.4	0.05	0.09
CV		1.26%	0.78%	0.62%	0.30%	0.77%	2.28%		0.79
Method Sigma*	20.0s	12.2s	12.9s	4.47s	45.9s	11.3s	8.78s	9.66s	20.8s
Quality TEa	0.04	5.0	17.62	4.0	0.50	0.10	0.667	0.45	1.80
Drift Limit**	0.03	3.0	10.0	3.0	0.30	0.06	0.555	0.3	1.0
Average Detection Time (min)	3	3	3	10	3	3	7	3	3

# iQM都在做些甚麼？

- 系統確認 **System Checks**
  - 確認系統流路、機械、電子訊號
- 電極確認 **Sensor Checks**
  - 監控分析誤差
- 模式確認 **Pattern Checks**
  - 識別電位變化圖型，辨別特定錯誤
- 試劑穩定性確認 **Process Control Solution Stability Checks**
  - 監控流程控制液的穩定度



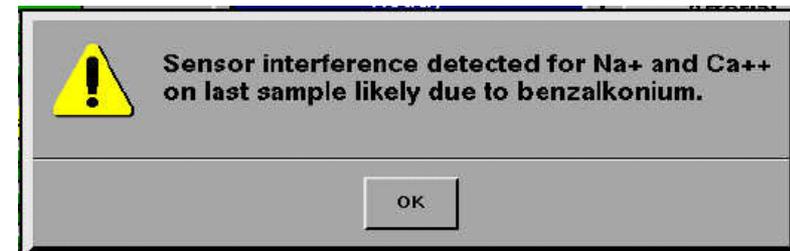
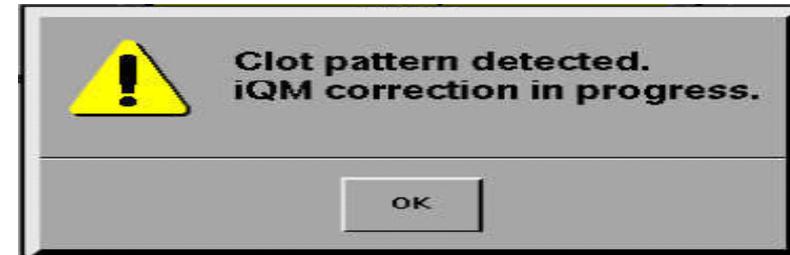
# 電極感應器確認

- 監控整個分析途徑
  - 3 PCSs (A-C, D) 在卡匣效期內連續執行
  - PCS評估感應器與卡匣效能
  - iQM同時會監控PCS穩定度
- 流程控制液
  - Solution A : 每 4 hrs或20隻檢體。 2 point 品管、以及 $pO_2$  穩定度確認。
  - Solution B : 每 30 minutes或每隻檢體。 1 point 品管。 每30 sec偵測電極狀況。
  - Solution C : 每24 hours低氧品管。 確認pH &  $pCO_2$  功能、及clot 清除。
  - Solution D : 每12 hours。 確認sensor靈敏度。

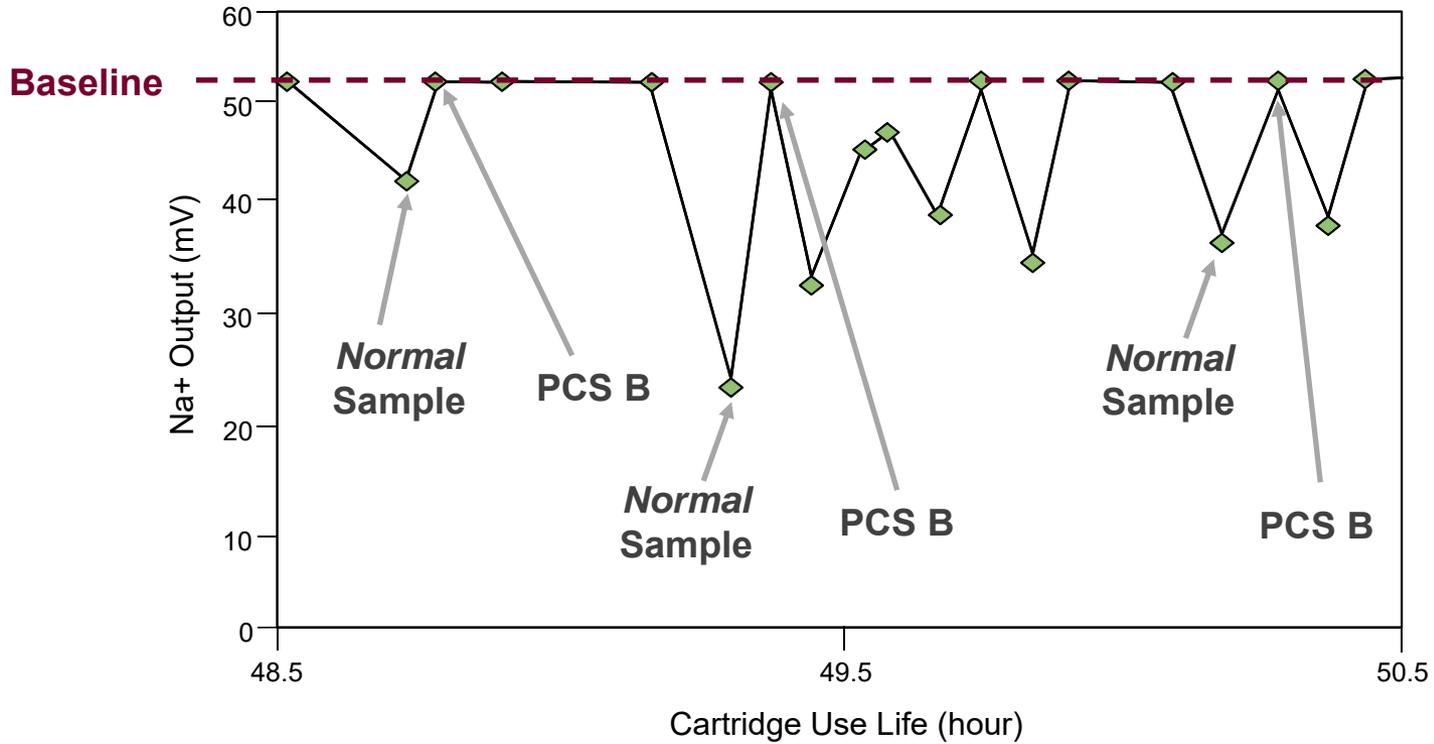
PC Solution	Measurement Assessment	Frequency
A	<ul style="list-style-type: none"> <li>• Used for sensitivity check on all sensors</li> </ul>	Every 4 hours
B	<ul style="list-style-type: none"> <li>• Used to assess sensor sensitivity and performance</li> <li>• Used as corrective actions in high frequency after interference</li> <li>• All sensor outputs are checked every 30 seconds</li> </ul>	After every sample or every 30 minutes
C	<ul style="list-style-type: none"> <li>• Low level of <math>pO_2</math>, pH and <math>pCO_2</math> sensors</li> <li>• Used for conditioning the interference rejection membrane for glucose/lactate sensors</li> </ul>	24 hours
D	<ul style="list-style-type: none"> <li>• Used to assess sensor sensitivity</li> </ul>	12 hours

# 模式確認

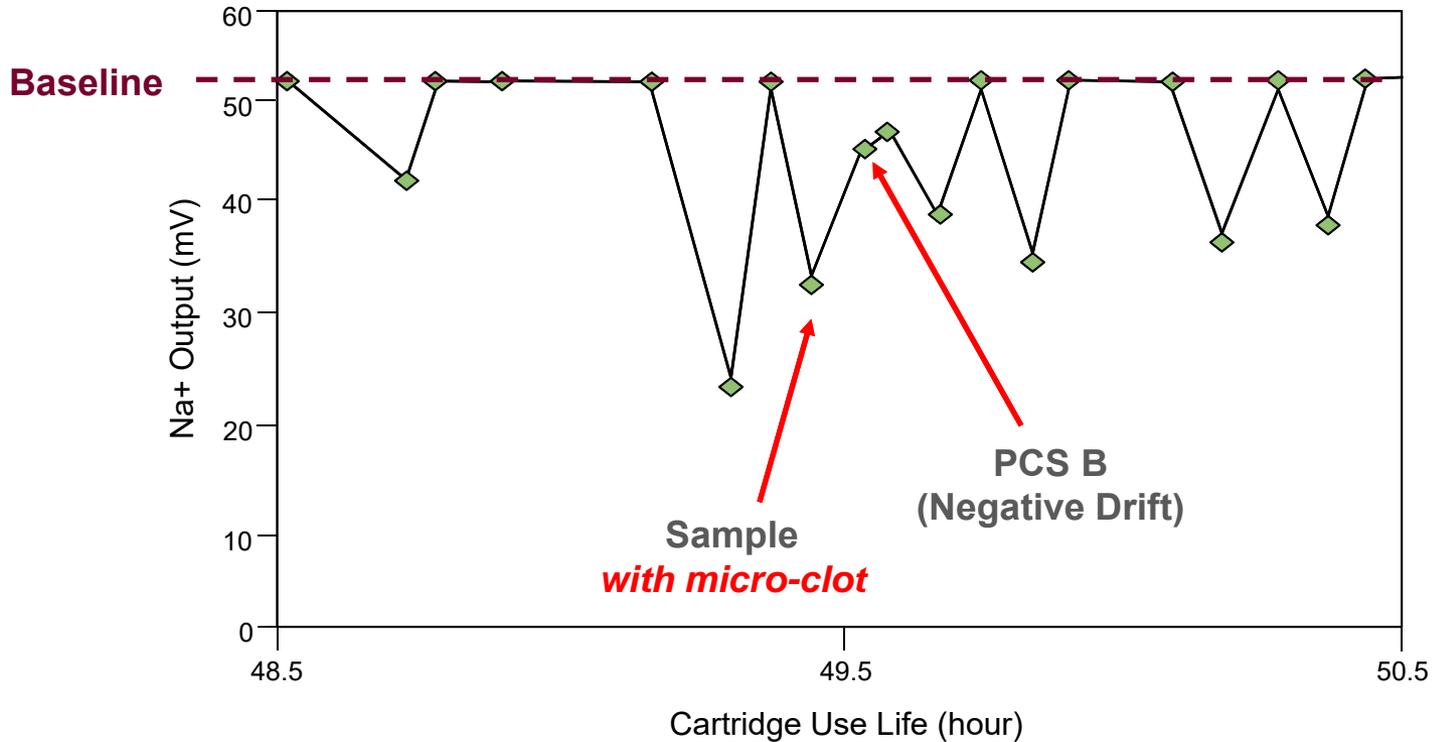
- 以電位演算法進行錯誤識別，包含：
  - 微凝塊
  - 干擾物
  - pH、 $p\text{CO}_2$ 、 $p\text{O}_2$  電極穩定性
  
- 啟動矯正措施
  - 確認特定錯誤模式
  - 啟動對應的矯正措施以排除錯誤
  - 停用無法修正的電極



# 模式確認 *正常檢體的Sensor變化*



# 模式確認 *偵測到微凝塊*



感應器模式檢查表示可能有微凝塊  
 →在樣本測量後，PCS B發生負漂移 (Negative PCS B drift)

# 模式確認 偵測到微凝塊

my/PP 03 11/18/2013 10:49 IQM® On 445 Tests 3 Days

**Processing 01:24** Disconnected

Start New Sample Enter Information View Results

JUSTINE, THYME Age: 8 years Mixed Venous, Not Validated

**Micro clot detected for:**  
**Na<sup>+</sup>.**  
**iQM correction in progress.**

OK

**Clot pattern detected.**  
**iQM correction in progress.**

OK

09/05/2002 15:13:24

DATABASE CONFIGURATION CARTRIDGE DIAGNOSTICS SHUTDOWN

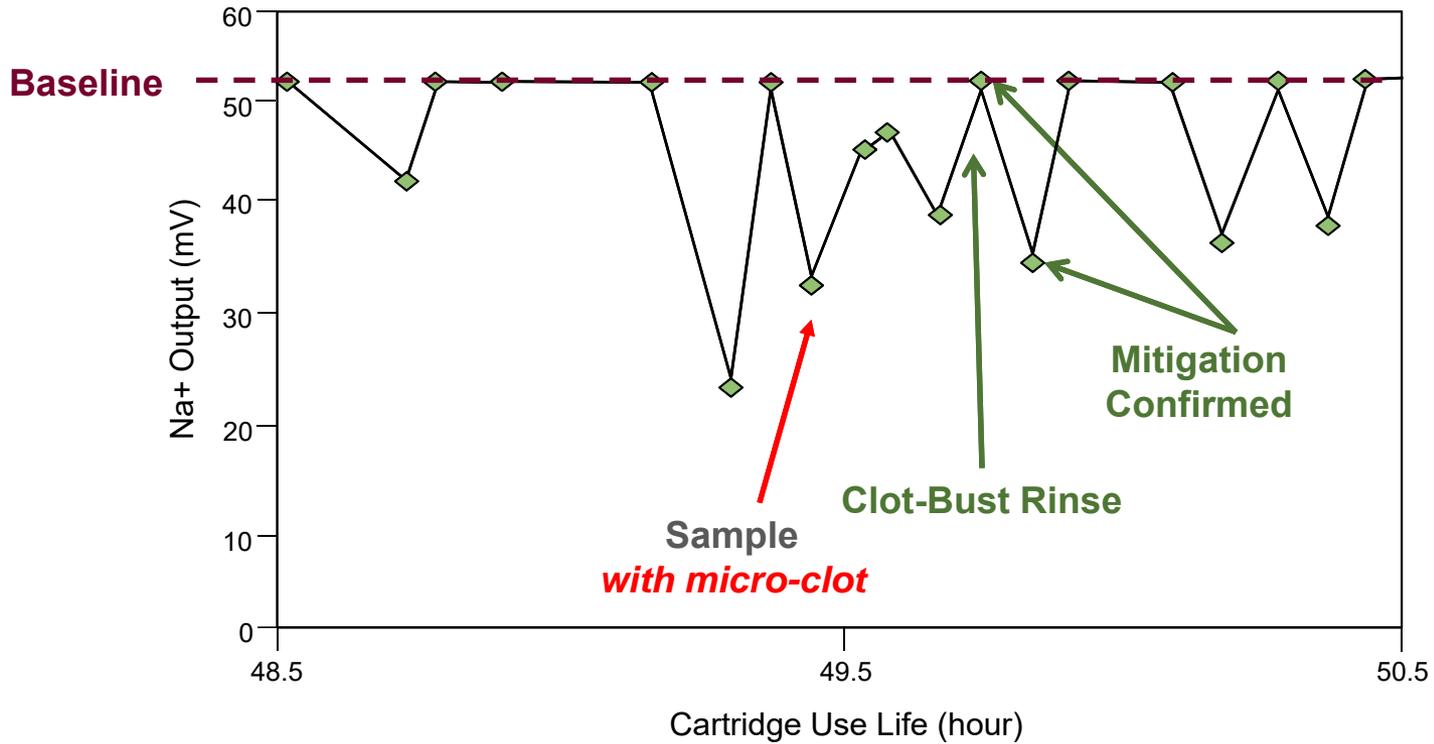
pH OK Busy Arterial  
pCO2 OK iQM: On

**Checking for presence of interference and micro clots.**  
**Please wait for results.**

Glucose OK QC  
Lac OK CVP  
Hct OK  
CO-ox OK

00:02:09 TRAINING Next QC Messages

# 模式確認 *偵測到微凝塊*



iQM根據錯誤模式啟動矯正措施：  
 沖洗微凝塊→確認微凝塊已被清除

# 模式確認 *偵測到微凝塊*



確認已經排除錯誤才能開放檢測下一支檢體

# 模式確認 *偵測到微凝塊*

Date/Cart.Lot #	Event	Corrective Action	Result
11/18/2013 11:16:11 0123456789A	Interference Detected After Sample # . Operator:	Operator Notified. Sensor Output Adjusted	Cleared
11/18/2013 11:14:37 0123456789A	Solution A Error for Na <sup>+</sup>	Sensor Output Adjusted	Corrected
11/18/2013 11:14:36 0123456789A	Micro Clot Detected	Sensors Rinsed and Checked	Cleared

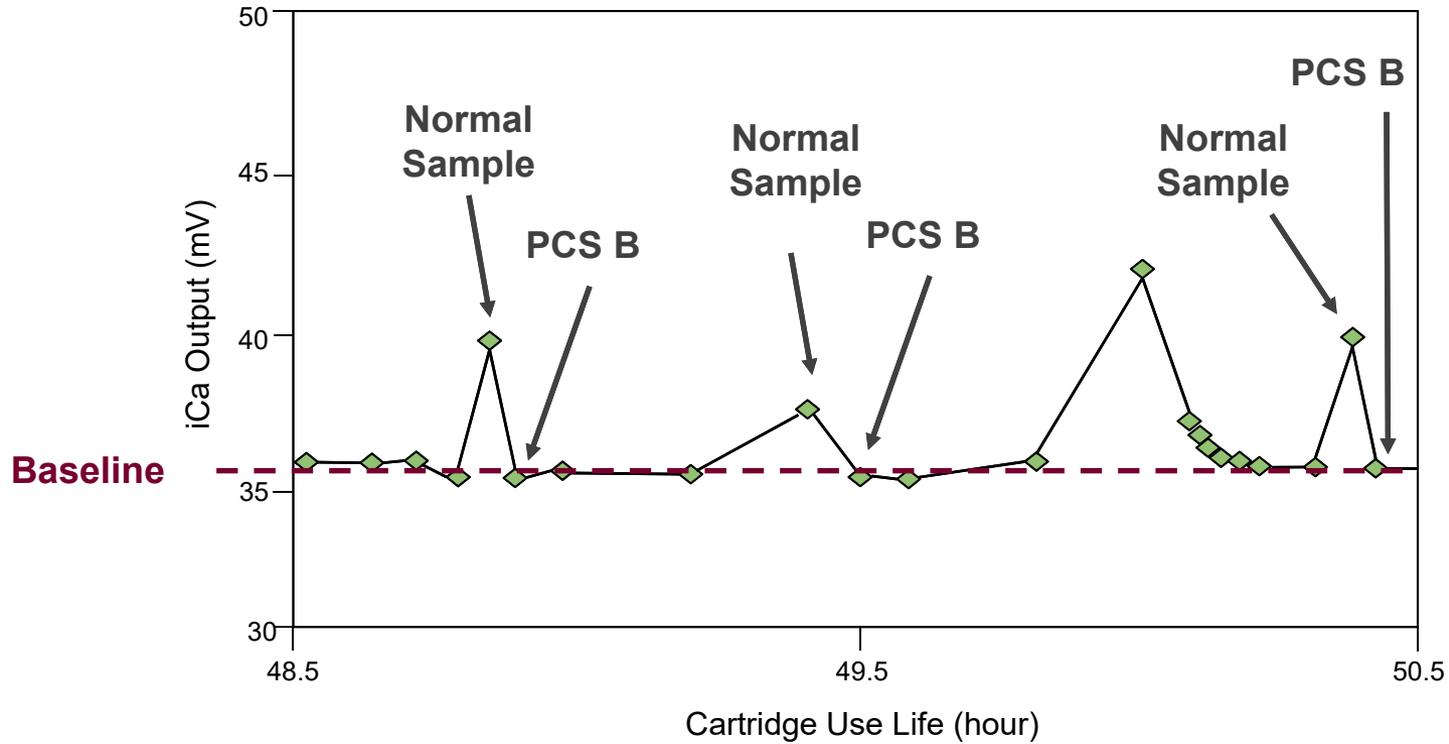
錯誤偵測與矯正措施的過程皆紀錄於矯正行動報告(CAR)

# 模式確認 *偵測到干擾物*

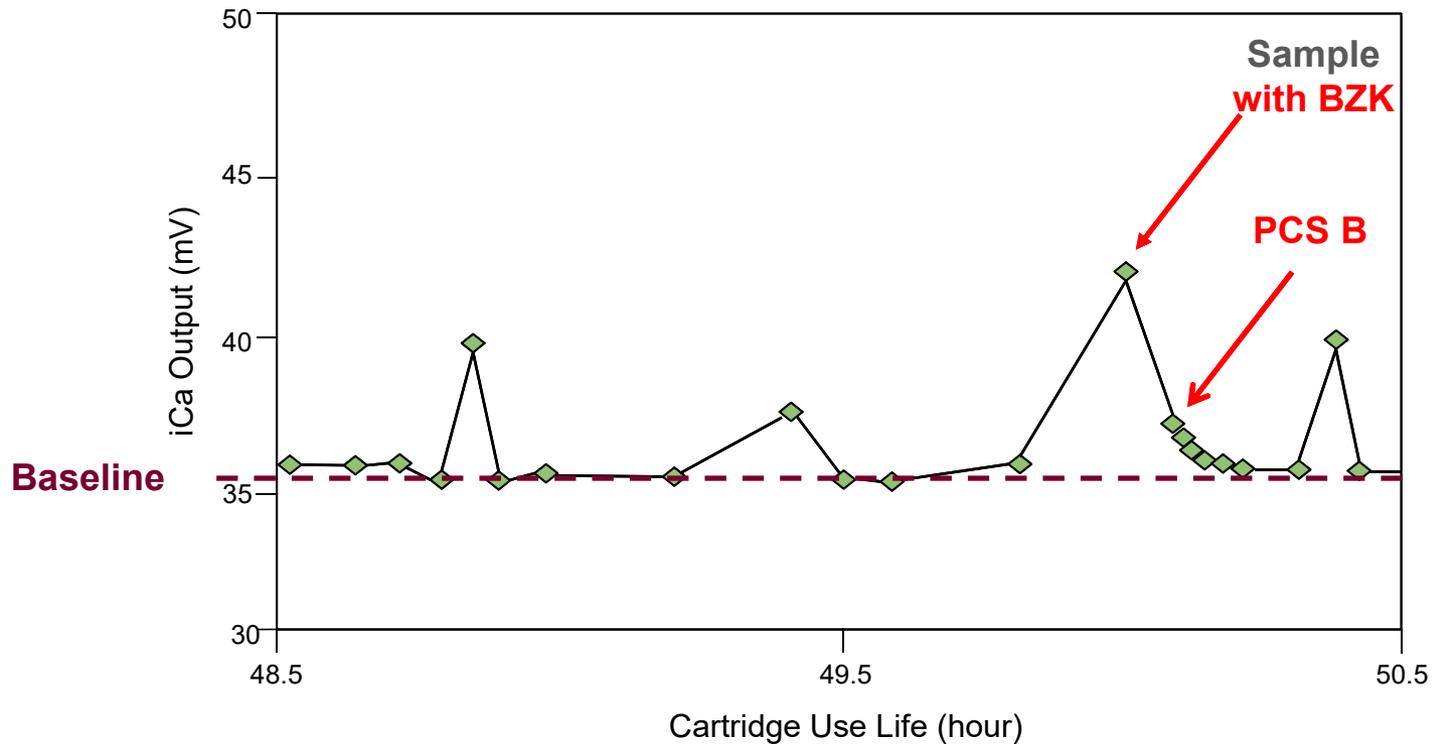
- 檢體內含干擾物會殘留於sensor上，導致當前以及未來檢體讀數錯誤。
  - **Benzalkonium (抑菌劑)** 陽離子會導致 $\text{Na}^+$ 與  $\text{iCa}$  讀數上升。
  - **Thiopental (麻醉劑)** 陰離子會干擾 $\text{Na}^+$ ,  $\text{K}^+$ ,  $\text{pCO}_2$ , 及  $\text{iCa}$  的讀數。



# 模式確認 *正常檢體的Sensor變化*

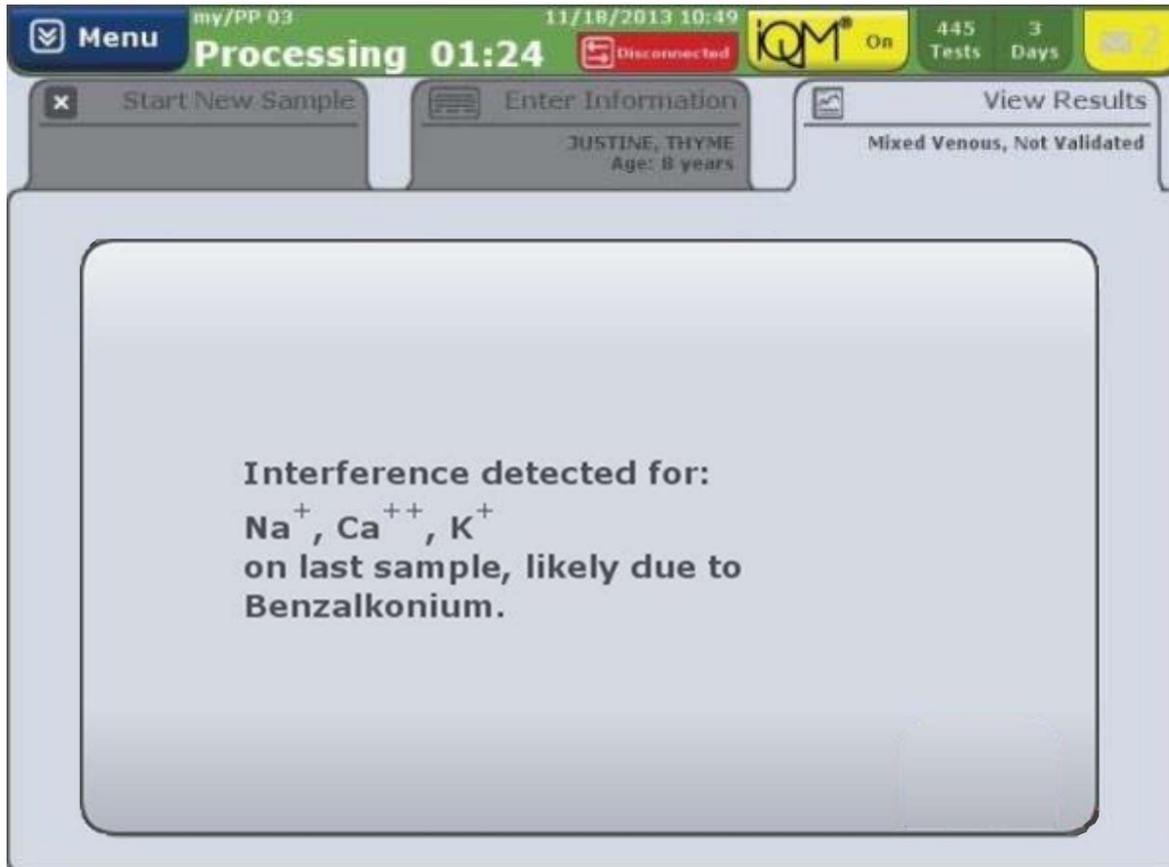


# 模式確認 *偵測到干擾物*



感應器模式檢查表示可能有干擾物  
 →在樣本測量後，PCS B發生正漂移 (Positive PCS B drift)

# 模式確認 *偵測到干擾物*



my/PP 03 11/18/2013 10:49 IQM<sup>®</sup> On 445 Tests 3 Days

Menu Processing 01:24 Disconnected

Start New Sample Enter Information View Results

JUSTINE, THYME Age: 8 years Mixed Venous, Not Validated

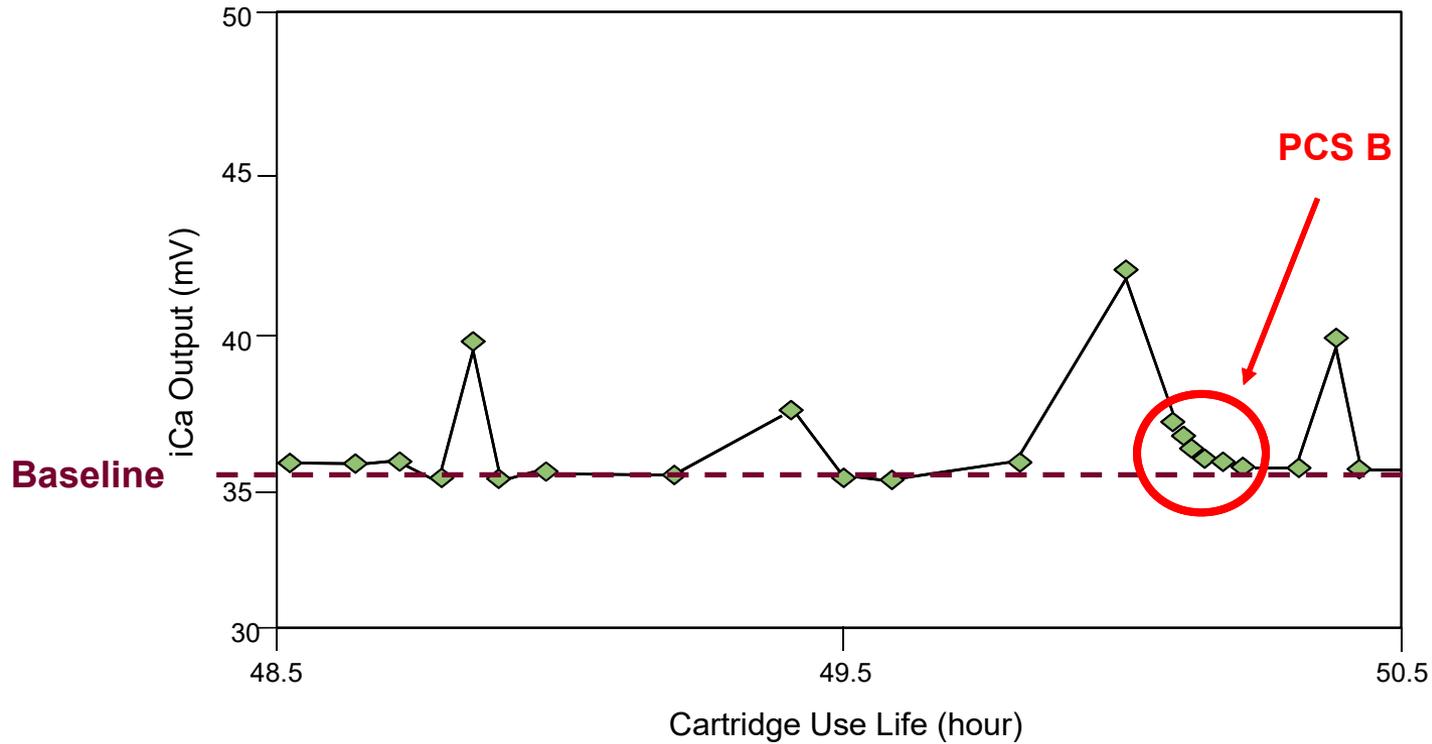
**Interference detected for:  
Na<sup>+</sup>, Ca<sup>++</sup>, K<sup>+</sup>  
on last sample, likely due to  
Benzalkonium.**



**! Sensor interference detected for Na+ on last sample.**

OK

# 模式確認 *偵測到干擾物*



iQM根據錯誤模式啟動矯正措施  
 →增加PCS B執行頻率直到電位恢復正常

# 模式確認 *偵測到干擾物*



確認已經排除錯誤才能開放檢測下一支檢體

# 模式確認 *偵測到干擾物*



Date/Cart.Lot #	Event	Corrective Action	Result
11/18/2013 11:34:15 0123456789A	Temporary sensor error for Lac during post-sample iQM process.	Operator notified.	Operator acknowledged.
11/18/2013 11:25:26 0123456789A	Interference Detected After Sample # . Operator:	Operator Notified. Sensor Output Adjusted	Cleared
11/18/2013 11:18:31 0123456789A	Solution A Error for Cl	Sensor Output Adjusted	Corrected

錯誤偵測與矯正措施的過程皆紀錄於矯正行動報告(CAR)

# 流程控制液穩定度確認

- 頻率
  - 每四小時執行
- 目的
  - 確認在卡匣效期內PCS的穩定度
  - 若PCS穩定度超出允收範圍，則會停用該卡匣
- 如何檢測
  - O<sub>2</sub>是監測試劑品質的最敏感分析目標
  - 檢測PCS A的pO<sub>2</sub>

# 自動記錄

## *iQM Delta Charts*

- 每日僅顯示最大、最小及平均值
- **Delta**值表示量測值減去預期值
- 圖表上繪製**Delta**值以及 **TEa**限制，表示不精確性與偏差 (imprecision and bias)

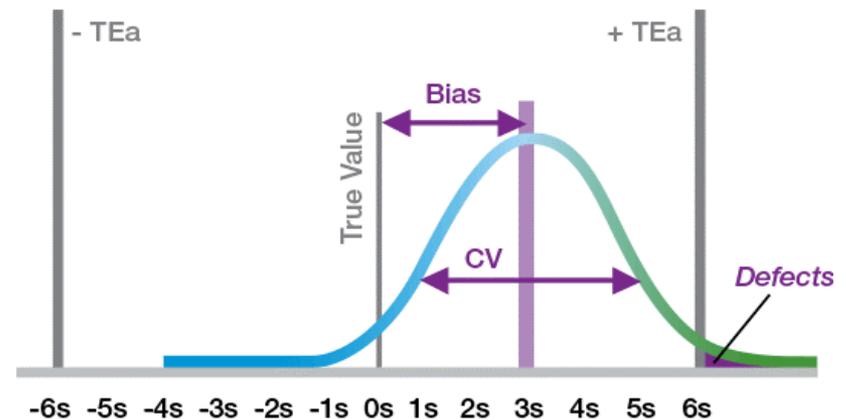
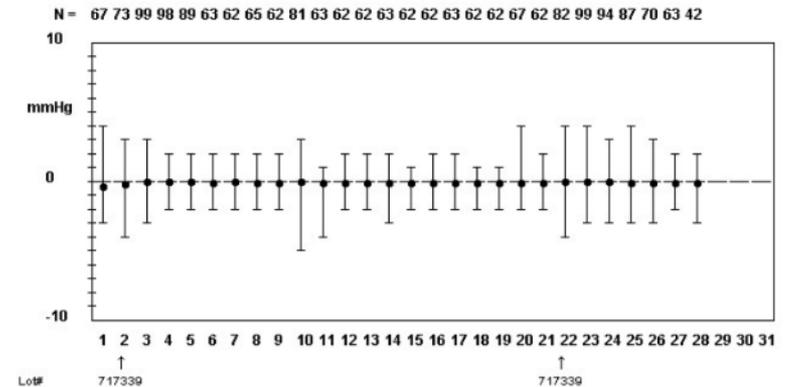
iQM Delta Chart

09/12/2017 13:29:56

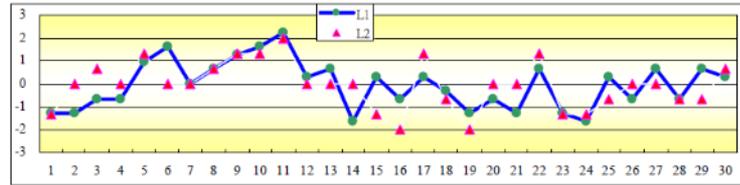
Analyzer: GEM 3000  
Analyte: pO2

S/N: 23889, Name:  
Nominal Target: 175 mmHg

Month: Aug 2017  
PC Solution: B



# Delta Chart



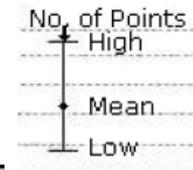
在即時大量的品管監控下，繪製 L-J Chart 缺乏實質意義  
 Delta value = 量測結果 - 預期值

**iQM Delta Chart** **pO2 PC Solution: B** 09/12/2017 13:29:56

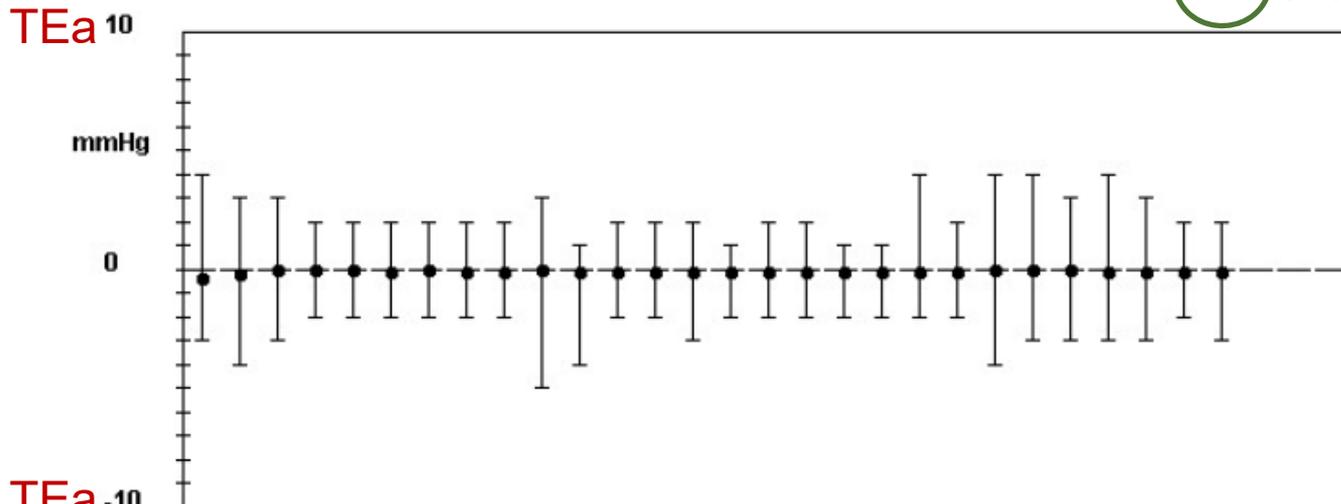
Analyzer: GEM 3000  
 Analyte: pO2

S/N: 23889, Name:  
 Nominal Target: 175 mmHg

Month: Aug 2017  
 PC Solution: B



N = 67 73 99 98 89 63 62 65 62 81 63 62 62 63 62 62 63 62 62 67 62 82 99 94 87 70 63 42 執行次數/天



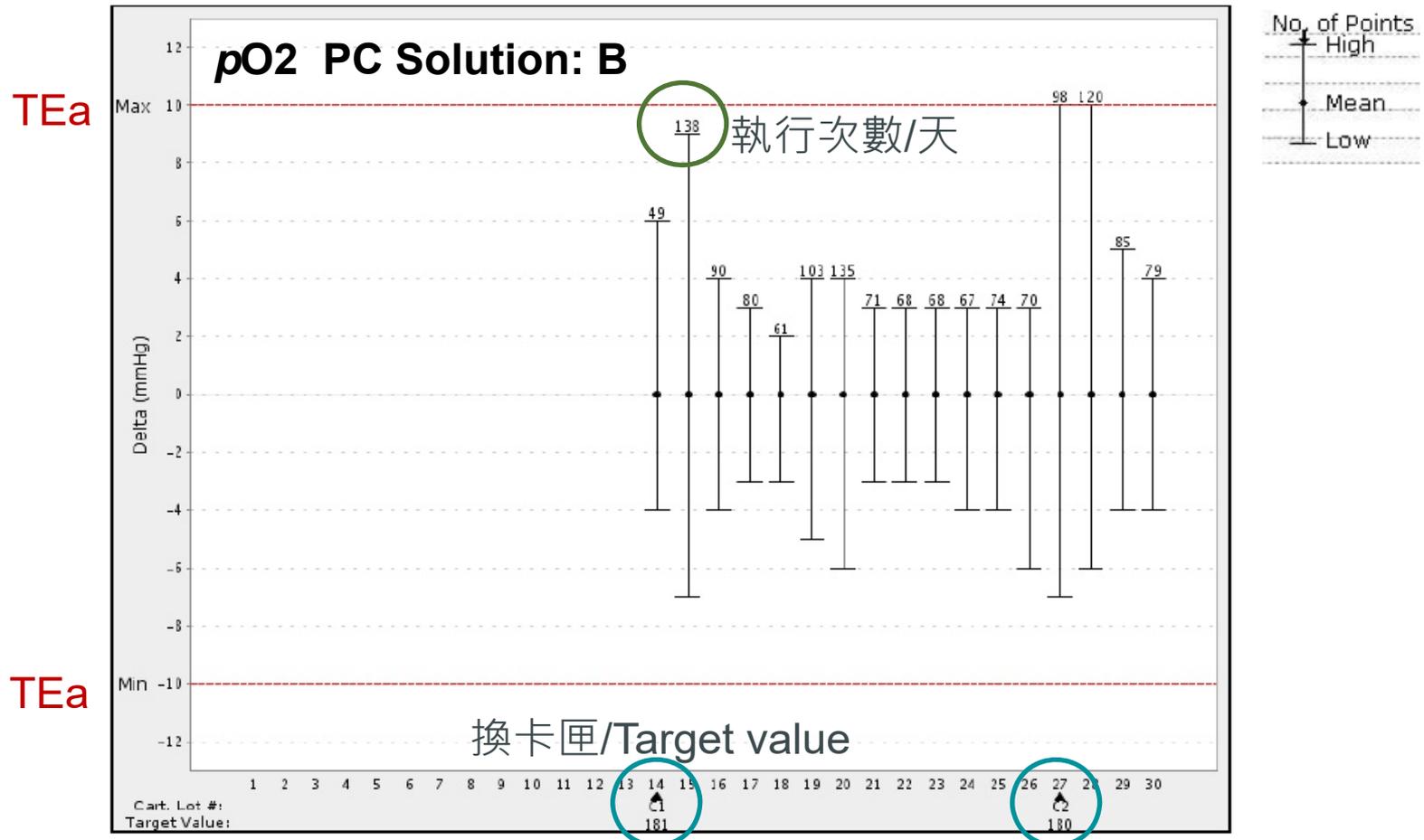
Lot# 717339

717339 換卡匣

# Delta Chart (GEM 4000)

在即時大量的品管監控下，繪製 L-J Chart 缺乏實質意義

Delta value = 量測結果 - 預期值



# 自動記錄

## *iQM Corrective Action Reports*

- 列出重大錯誤，採取的矯正措施和矯正措施的結果
  - 當數值超出可允收範圍
  - 查看矯正行動報告 (Corrective Action Report)

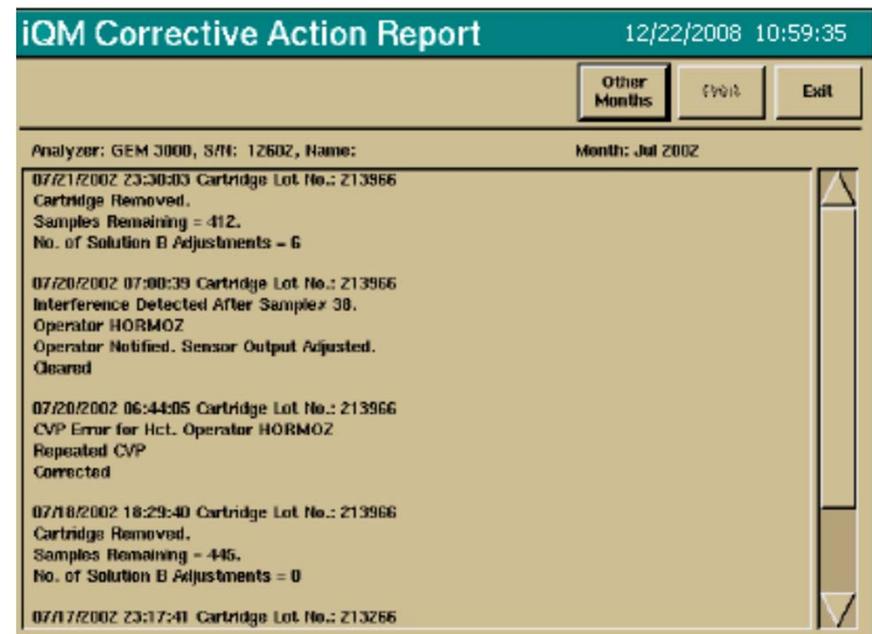


November 2013      GEM Premier 4000/my/PP 03/888003218

Date/Cart.Lot #	Event	Corrective Action	Result
11/18/2013 11:34:15 0123456789A	Temporary sensor error for Lac during post-sample iQM process.	Operator notified.	Operator acknowledged.
11/18/2013 11:25:26 0123456789A	Interference Detected After Sample # . Operator:	Operator Notified. Sensor Output Adjusted	Cleared
11/18/2013 11:18:31 0123456789A	Solution A Error for Cl <sup>-</sup>	Sensor Output Adjusted	Corrected

page 1 of 7

Print      Close



iQM Corrective Action Report      12/22/2008 10:59:35

Other Months      Print      Exit

Analyzer: GEM 3000, S/N: 12602, Name:      Month: Jul 2002

07/21/2002 23:30:03 Cartridge Lot No.: 213966  
Cartridge Removed.  
Samples Remaining = 412.  
No. of Solution B Adjustments = 6

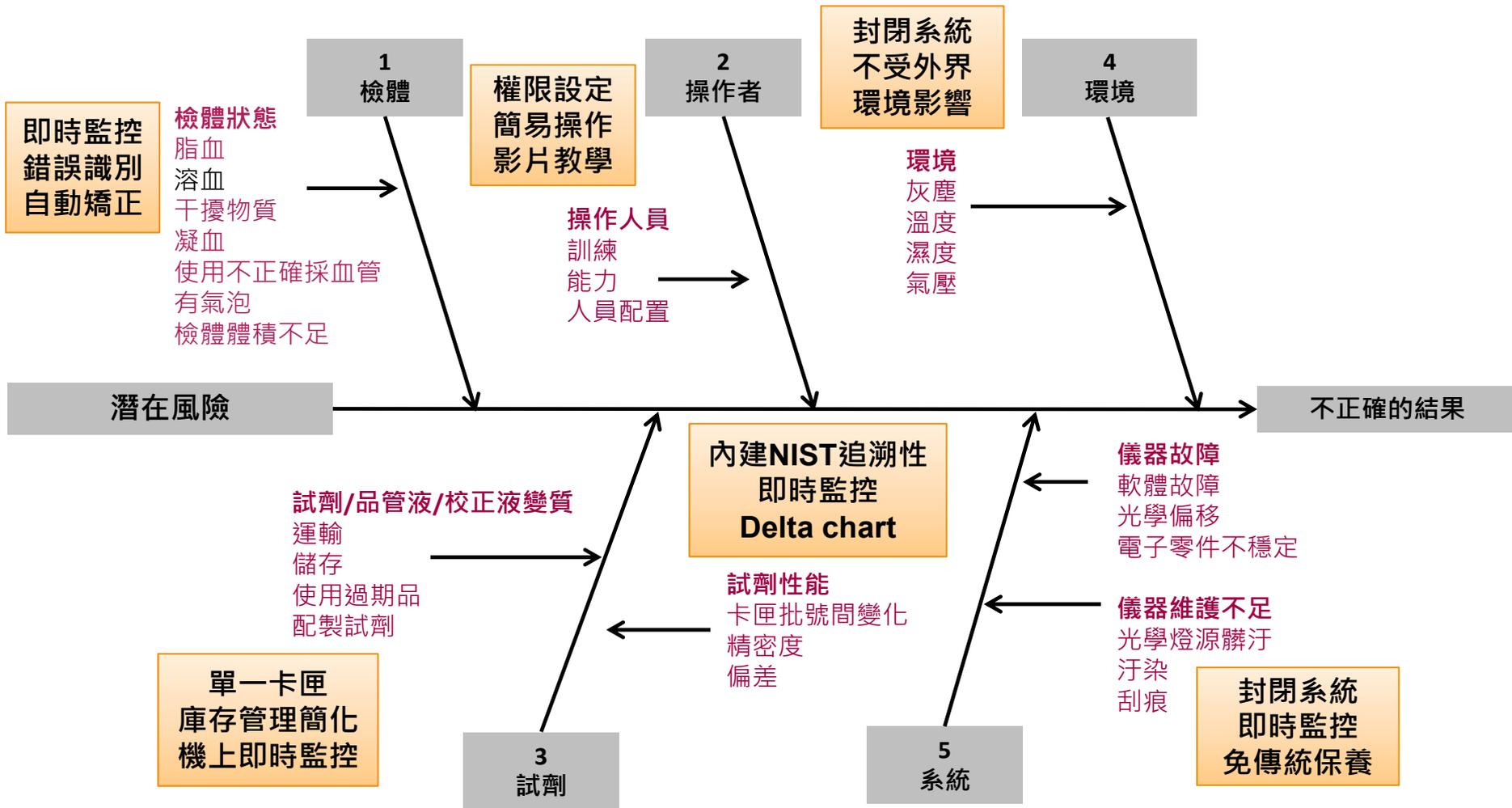
07/20/2002 07:00:39 Cartridge Lot No.: 213966  
Interference Detected After Sample 38.  
Operator HORMOZ  
Operator Notified. Sensor Output Adjusted.  
Cleared

07/20/2002 06:44:05 Cartridge Lot No.: 213966  
CVP Error for Hct. Operator HORMOZ  
Repeated CVP  
Corrected

07/18/2002 18:29:40 Cartridge Lot No.: 213966  
Cartridge Removed.  
Samples Remaining = 445.  
No. of Solution B Adjustments = 0

07/17/2002 23:17:41 Cartridge Lot No.: 213266

# GEM Premier System 分析流程



**Red = IQM可解決的錯誤**

Adapted from:  
EP23-A Workbook. [www.clsi.org](http://www.clsi.org)

# 採檢注意事項 Samples Handling

# 分析前會影響血氣檢測準確性的因素

- 空氣污染，檢體中存在氣泡
  - 檢體與Heparin混合不當
  - Heparin類型和濃度
  - 採檢後代謝速率與高白血球數
  - 儲存/運輸條件
  - 導管沖洗不足
- 
- 血氣分析當中有75%的錯誤與分析前因素有關<sup>1</sup>

1. Bonini P, et al. Errors in laboratory medicine. *Clin Chem.* 2002;48(5):691-8.

# 儀器操作

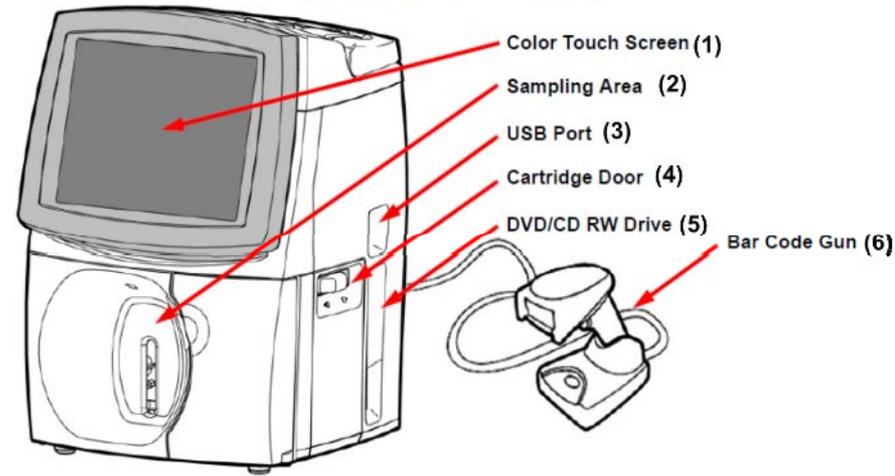
## Instrument Operation

# System Components

正面結構：

- (1) 彩色觸控式螢幕
- (2) 檢體區
- (3) USB孔
- (4) 試藥卡匣門
- (5) 光碟機
- (6) 條碼掃描器

Figure 1-1 GEM Premier 3500 Analyzer



內部結構：

- (1) 螢幕角度調整器
- (2) 印表機
- (3) 儀器提把
- (4) 串列介面(RS232)三組
- (5) 網路連接埠
- (6) 9vdc電源輸出
- (7) USB孔三組
- (8) 電源開關
- (9) 接地片
- (10) 外接電源孔
- (11) 無線網路天線
- (12) 鍵盤連接埠
- (13) 並列埠
- (14) 儀器序號

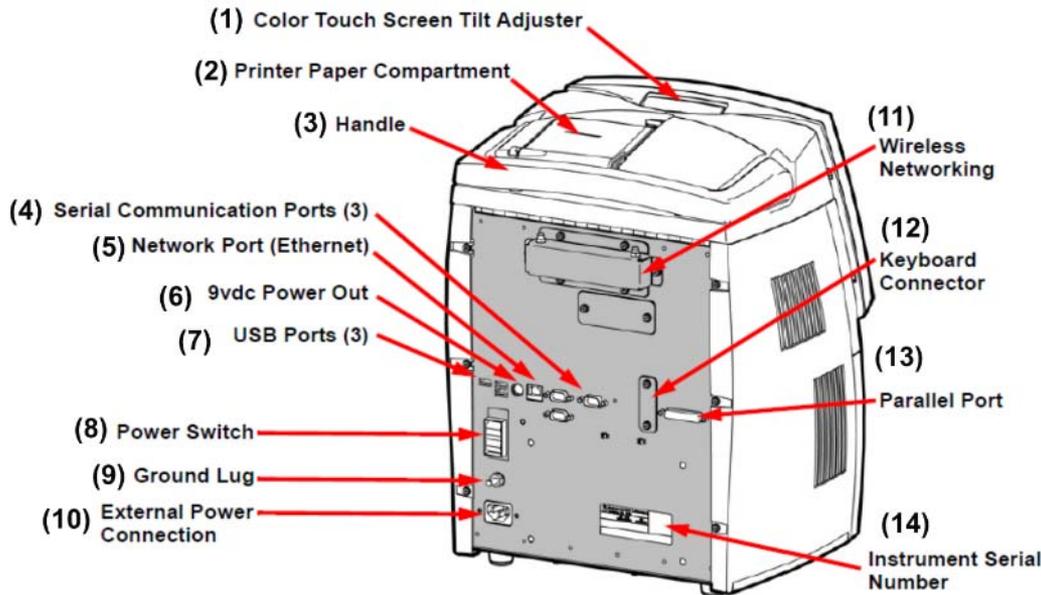
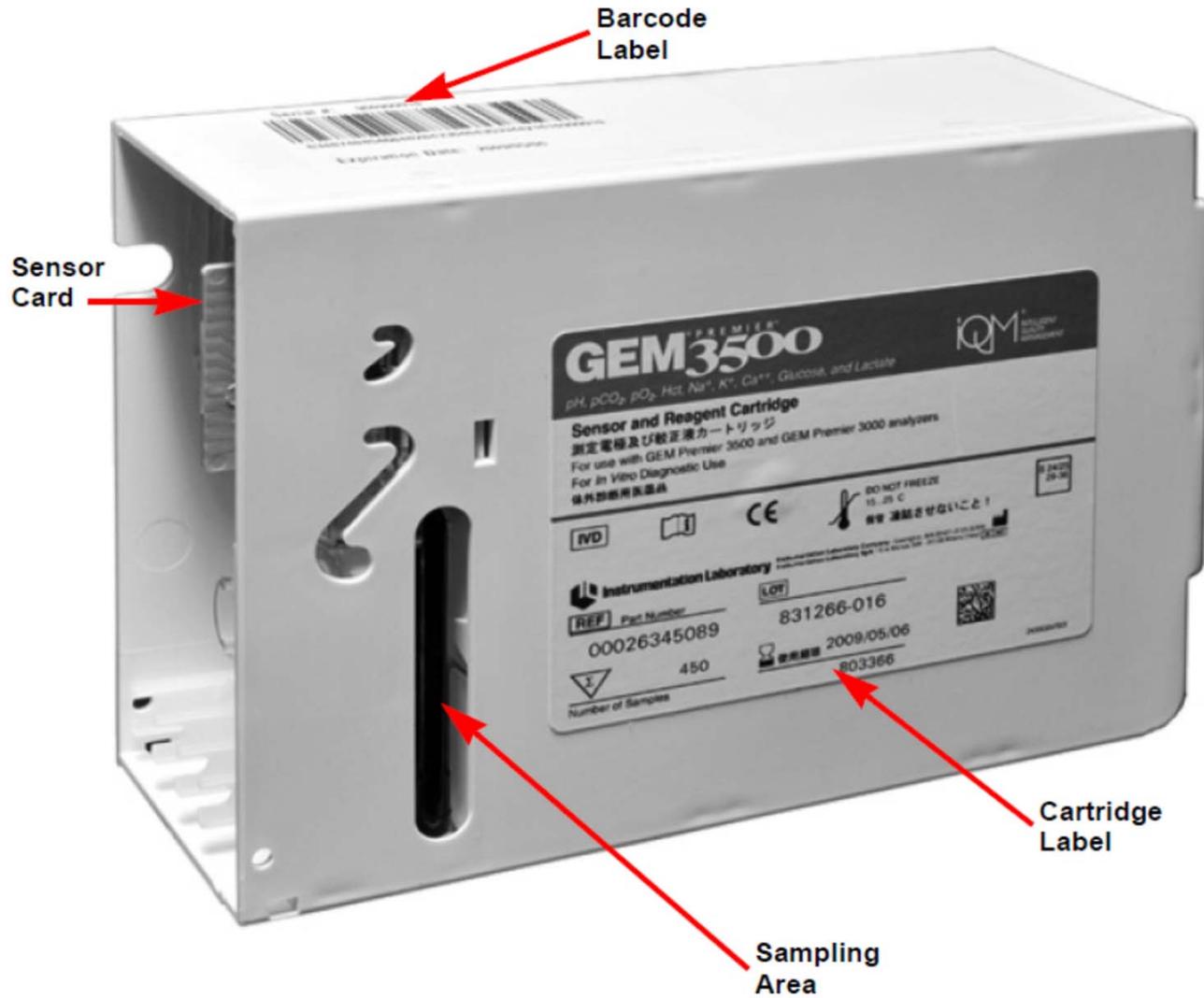
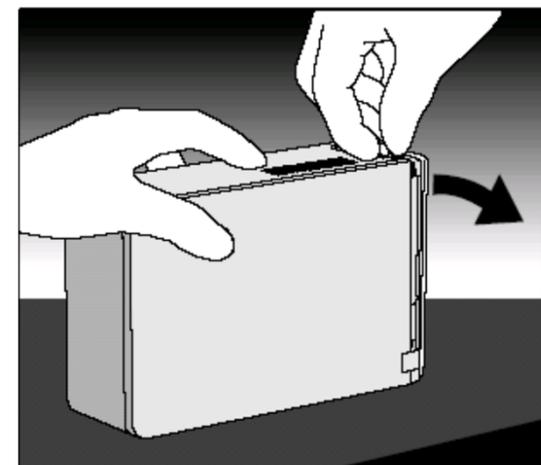
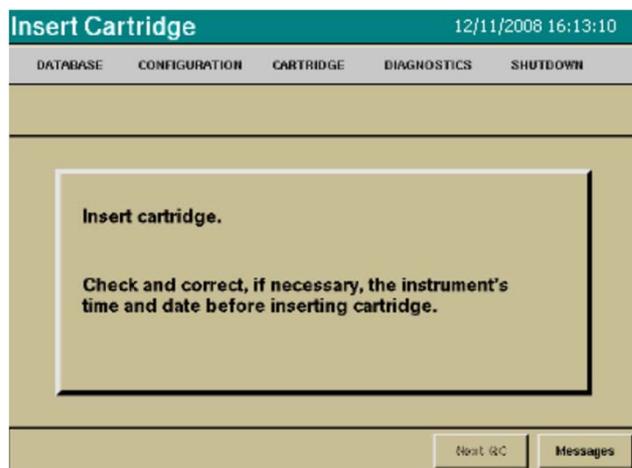


Figure 1-2 GEM Premier 3500 PAK Cartridge



# 安裝卡匣

側蓋拉開後一分鐘內上機



# 執行CVP

Busy **iQM<sup>®</sup> On** 03/04/2015 17:01:57

DATABASE CONFIGURATION CARTRIDGE DIAGNOSTICS SHUTDOWN

1. Select Analytes 2. Type 3. Go

**i** You must run all required levels of CVP material.

OK

pH  pCO<sub>2</sub>  pO<sub>2</sub>  H<sub>2</sub>O<sub>2</sub>  K<sup>+</sup> Pending CVP

Crea  Hct  Glu  Lac Pending CVP

**CVP**

iQM Process in progress 00:03:12 **Messages**

Busy **iQM<sup>®</sup> On** 03/04/2015 17:02:28

DATABASE CONFIGURATION CARTRIDGE DIAGNOSTICS SHUTDOWN

1. Select Analytes 2. Type 3. Go

pH  Crea  iQM Error

pCO<sub>2</sub>  iQM Error  Hct Pending CVP

pO<sub>2</sub> Pending CVP  Glu Pending CVP

H<sub>2</sub>O<sub>2</sub> Pending CVP  Lac Pending CVP

K<sup>+</sup> Pending CVP

Arterial

Venous

Capillary

Other

OC

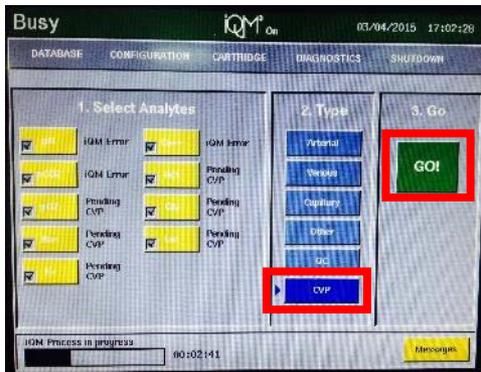
**CVP**

**GO!**

iQM Process in progress 00:02:41 **Messages**

# 執行CVP

- CVP 可保存於2~8°C至效期，或室溫12個月，不能照光
  - CVP 上機前先於25°C回溫最少8小時
1. 以手指夾住CVP瓶“頂端”，快速用力搖晃 混合10秒
  2. 手指輕彈“頂端”使品管液集中於瓶身
  3. 選取畫面類別 [CVP] [GO]
  4. 選取CVP名稱(以及Lot)
  5. 打開CVP置於吸針處，以吸針碰到瓶底後拉起1~3mm
  6. 按下畫面 [OK] 開始吸取CVP
  7. “**嗶嗶嗶嗶**”後移開CVP
  8. 選擇 是否接受品管 [ACCEPT] [Discard]
  9. 選擇 列印 [Print]
  10. 每次新卡匣需 [ACCEPT] CVP 1 & 2 各一次



Lot No.	Description
1802	GEN CVP 1
2602	GEN CVP 2

# 檢體上機

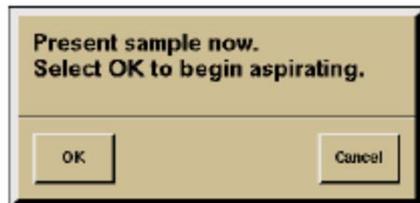
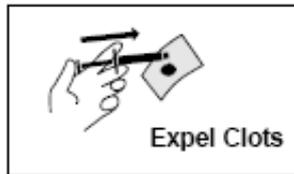
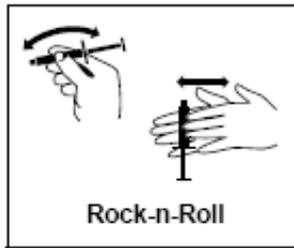
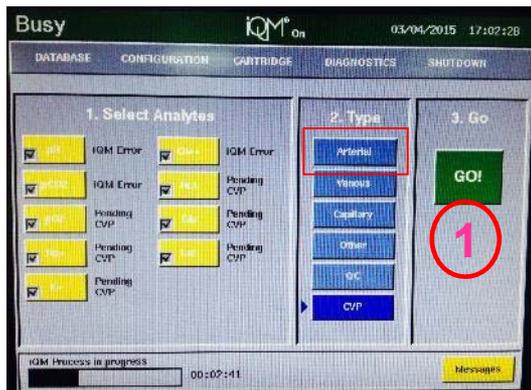


Figure 4.15: Aspiration Prompts

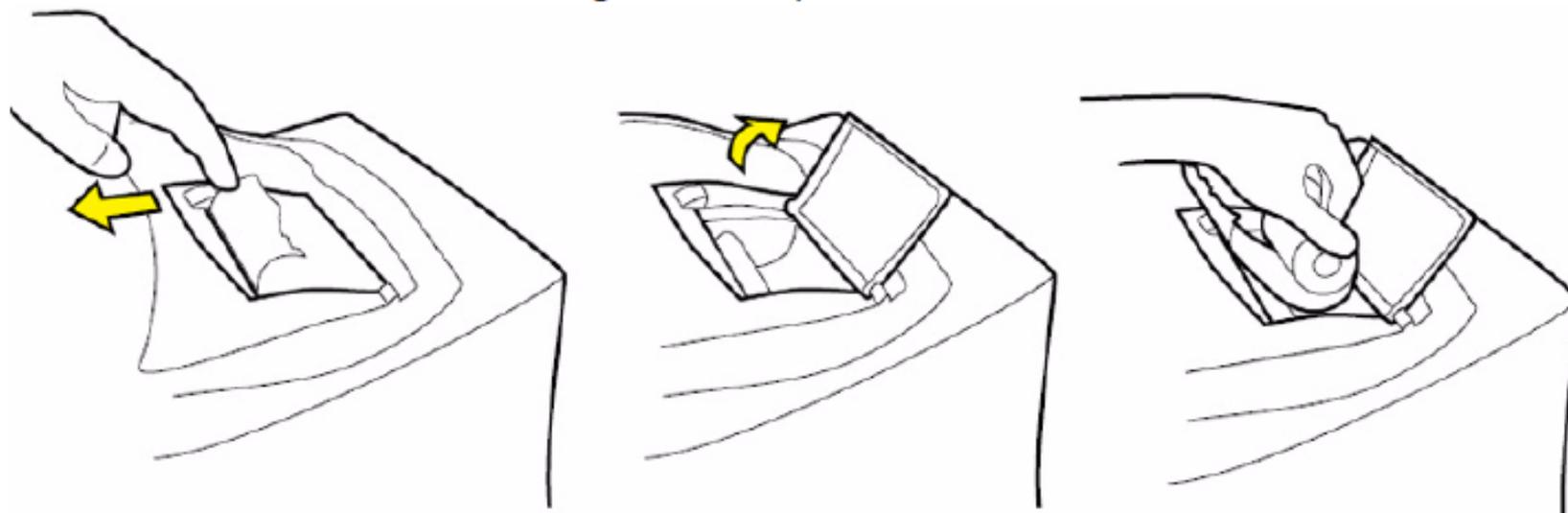
1. 選擇檢體類型，按 GO
2. 混勻檢體，排出一滴
3. 檢體上機
4. 按下OK (等待儀器吸取檢體)
5. 聽到“ 嗶嗶嗶嗶” 移走檢體
6. 輸入ID

## 注意事項

- 一分鐘內上機
- 針接近但不接觸瓶底

# 裝載熱感紙

Figure 2-1 Paper Installation



1. 按鈕開蓋

2. 拿出舊紙捲

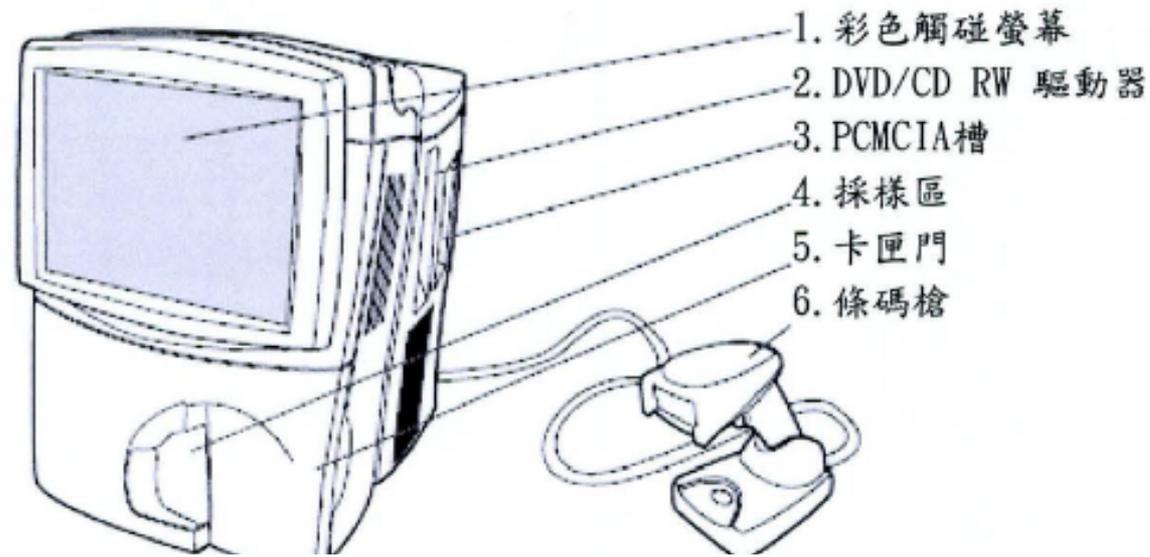
3. 放入新紙捲  
(注意方向)  
蓋上蓋子

# 簡易故障排除

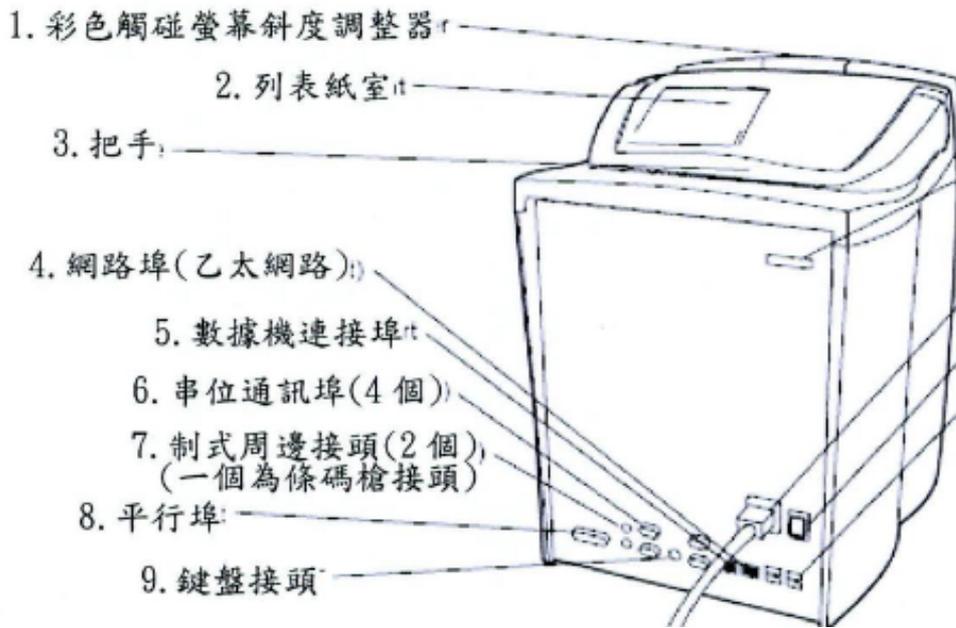
- 常見錯誤代碼
  - ✓ 0.01/0.05 : 無熱感紙 → 請補充紙捲
  - ✓ 1.05 : 檢體量不足 → 重新上機
  - ✓ 1.06 : 吸無檢體 → 重新上機
  - ✓ 1.07 : 檢體前無空氣 → 重新上機
  - ✓ 其它代碼請聯絡工程師
- 檢體有偵測到Clot或某檢測項目顯示 **iQM Error**
  - ✓ 執行 **DIAGNOSTICS** → **Run iQM/PCS Process**

# System Components:

- GEM 4000**



1. 彩色觸碰螢幕
2. DVD/CD RW 驅動器
3. PCMCIA槽
4. 採樣區
5. 卡匣門
6. 條碼槍



10. 儀器序號
11. 電力外接頭
12. 電源開關
13. 通用序列匯流排埠(4個)

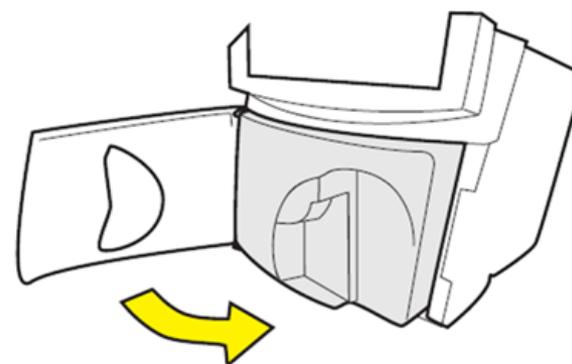
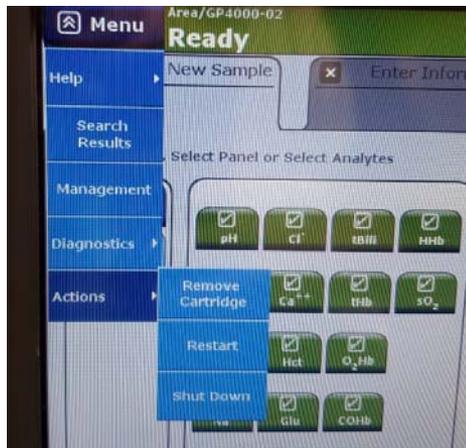
1. 彩色觸碰螢幕斜度調整器
2. 列表紙室
3. 把手
4. 網路埠(乙太網路)
5. 數據機連接埠
6. 串位通訊埠(4個)
7. 制式周邊接頭(2個)  
(一個為條碼槍接頭)
8. 平行埠
9. 鍵盤接頭

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- ( 1 ) 選單(查詢報告、進階設定、移除卡匣、關機等)。
- ( 2 ) 儀器狀態。
- ( 3 ) 卡匣機上效期與剩餘檢測次數
- ( 4 ) 選擇Panels。
- ( 5 ) 選擇測試項目與項目狀態。
- ( 6 ) 選擇檢體類型。
- ( 7 ) 執行檢測。
- ( 8 ) 輸入檢體資訊分頁
- ( 9 ) 查看最後一筆結果分頁

# 安裝卡匣



等待暖機40分鐘

# 執行CVP

### All results within range

CVP Results	CVP Range	Low	High	
pH	7.35	7.14	7.57	
pCO <sub>2</sub>	24	mmHg	68	52
pO <sub>2</sub>	28	mmHg	20	30
Na <sup>+</sup>	125	mmol/L	123	129
K <sup>+</sup>	3.4	mmol/L	3.0	3.6
Ca <sup>++</sup>	1.02	mmol/L	1.57	1.73

### Results out-of-range

CVP Results	CVP Range	Low	High	
pH	7.42	7.33	7.59	
pCO <sub>2</sub>	22	mmHg	13	17
pO <sub>2</sub>	179	mmHg	114	158



**Accept button**



**Menu CVP Due**

1. Analytes: pH, CT, SIB, pO<sub>2</sub>, pCO<sub>2</sub>, Ca<sup>++</sup>, O<sub>2</sub>Hb, pO<sub>2</sub>, Hct, C/Hb, Na<sup>+</sup>, K<sup>+</sup>, Hct, Hct, K<sup>+</sup>, Lac, TBil

2. Type: CVP /  STAT

3. Go: **GO!**

**Menu CVP Due**

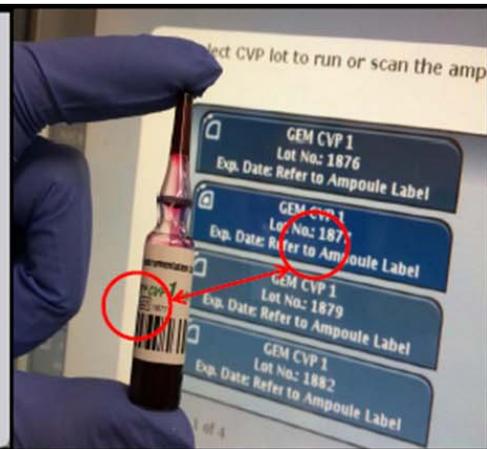
3. Go: **GO!**

Select CVP lot to run or scan the ampoule barcode.

Accepted

- GEM CVP 1 Lot No: 1861 Exp. Date: Refer to Ampoule Label
- GEM CVP 2 Lot No: 2460 Exp. Date: Refer to Ampoule Label
- GEM CVP 3 Lot No: 3854 Exp. Date: Refer to Ampoule Label
- GEM CVP 4 Lot No: 4854 Exp. Date: Refer to Ampoule Label
- GEM CVP 5 Lot No: 5850 Exp. Date: Refer to Ampoule Label

Cancel OK



# 簡易故障排除

- 常見錯誤代碼
  - ✓ 204：未偵測到檢體 → 重新上機
  - ✓ 222：吸取時有空氣 → 重新上機
  - ✓ 201：未能偵測流程控制液 → 更換卡匣
  - ✓ 其它代碼請聯絡工程師
- 檢體有偵測到Clot或某檢測項目顯示 **iQM Error**
  - ✓ 執行 **MENU → DIAGNOSTICS → Run iQM/PCS Process**

# GEMweb Plus 500

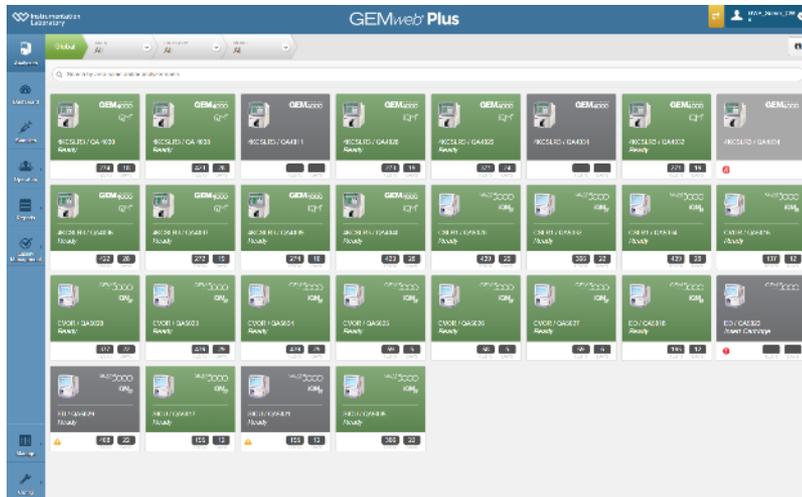
# GEMweb Plus

以單一介面集中管理臨床端的儀器  
監督操作人員並監控患者數據



# 儀器管理

- 分散設備的簡化管理
- 明確的操作訊息
- 所有功能簡單及自動化



The dashboard displays a grid of analyzer cards. Each card shows the analyzer model, location, status, and test/days counts. A search bar is at the top, and a sidebar on the left contains navigation icons for Analyzers, Dashboard, Samples, Operators, Reports, Manage, and Config.

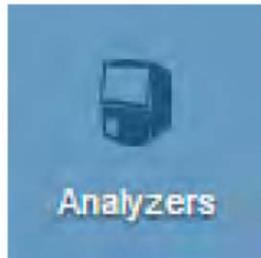
Analyzer Model	Location	Status	Tests	Days
GEM4000 IQM	ICU / G4K-60	Ready	448	13
GEM5000 IQM <sub>12</sub>	ICU3 / G5K-v59	Ready	449	27
NovaNet	Nova / Novanet	Ready	-	-
GEM5000 IQM <sub>12</sub>	East / GEM1	Ready	449	27
GEM5000 IQM <sub>12</sub>	East / GEM2	Ready	448	13
GEM5000 IQM <sub>12</sub>	East / GEM3	Ready	449	27
GEM4000 IQM	Med / G4K	Ready	448	13
GEM5000 IQM <sub>12</sub>	Med G5k	Ready	449	27
GEM4000 IQM	ICU 2 / GEM1	Ready	448	13
GEM5000 IQM <sub>12</sub>	ICU 2 / GEM2	Ready	449	27
GEM5000 IQM <sub>12</sub>	ICU 2 / GEM3	Ready	449	27
GEM4000 IQM	OR1 / GEM 4000	Ready	448	13
GEM5000 IQM <sub>12</sub>	OR2 / GEM 5000	Ready	449	27
GEM4000 IQM	G4KNEW / G4K-60	CVP Due	450	19
GEM5000 IQM <sub>12</sub>	G5K / G5K-62old	-	450	20
GEM5000 IQM <sub>12</sub>	ICU / G5K	Locked	450	20

- Cartridge Status
- Ongoing operations
- Warnings and Errors

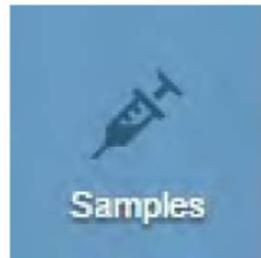
**GEM5000 IQM<sub>12</sub>**  
**OR2 / GEM 5000**  
**Ready**  
**449 TESTS** **27 DAYS**

儀器有警報/ 儀器斷線/ 儀器鎖機

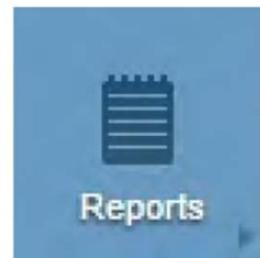
分析儀



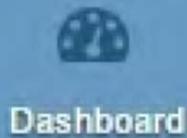
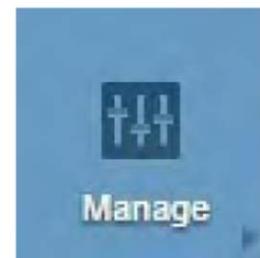
檢體查詢



匯出報告



設定



顯示面板



操作者管理



品管



儀器配置

Our Passion.  
Your Results.