

## Urgent Recall for Product Correction - GEM Premier 4000 Cartridge - K+ Reporting

**Note:** The Therapeutic Goods Association has been advised of this action.  
**TGA Reference #:** RC-2011-RN-00599-3

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June 2011

Dear Valued GEM Premier 4000 Customer,

This notification is intended to alert your facility regarding a serious issue identified with the K+ sensor on the GEM Premier 4000 cartridge. Instrumentation Laboratory Co. fully understands the implications and is working to expedite the release of an effective mitigation to prevent this occurrence in the near future. Until available, we require that you follow the Mandatory Customer Actions described below.

**NOTE:** The GEM 4000 Blood Gas/CO-Ox only cartridges are unaffected by this notification.

- **Issue Description:**

We recently confirmed rare occurrences of **falsely lowered K+ results** (potential negative bias of 0.6 to 1.2 mmol/L) can occur during cartridge life on patient blood analysis, leading to erroneous results with potentially severe impact to patient treatment.

**Frequency:** The event is considered rare based on an internal investigation that identified an incidence rate of 0.0013% (1 out of 77,000 samples) from an estimated 1.7 million sample results.

- **Mandatory Customer Actions:**

Please use whichever of the following options that works best for your institution. Both options will have the same effect to eliminate the impact of a potential erroneous K+ result from being reported.

- **Option No. 1**

- **Verify K+ results prior to reporting as follows:**

- Verify all K+ results from the GEM Premier 4000 using an alternative analyser (e.g. GEM Premier 3000/3500 or other chemistry analyser) prior to reporting.

**NOTE:** Ensure that the GEM Premier 4000 K+ results are not transmitted to your LIS system prior to verification.

- If the bias between the GEM Premier 4000 and the alternative analyser is  $\geq \pm 0.6$  mmol/L **do not report the result and proceed as follows:**
  - Either discontinue use and replace the cartridge immediately
  - Or,
  - Disable the K+ parameter as detailed under Option No. 2 and continue to use the cartridge for all other parameters.

- **Option No. 2**
  - **Disable the K+ (Potassium) Parameter as follows:**
    - Go to MENU and perform the following steps.
      - Management
      - Log-in
      - Configuration
      - Tab 3
      - Parameters Setup
    - Deselect Potassium by pressing the check mark (✓) on the K+ button.
    - Press OK to save change.
    - After disabling, K+ results will no longer be reported, either on the screen or on printouts. All other measured parameters will be reported as currently configured.


NOTE: If the analyser is connected to the GEMweb Plus server and you require support, please contact Abacus ALS.

Please share this information with your staff and retain a copy of this letter in your files as a record of the notification.

A representative of Abacus ALS will be in contact to discuss the most appropriate solution for your facility.

If you have not already done so, please verify your receipt of this notification by completing the response form below and returning it to Abacus ALS by:

**Fax:** 1800 287 222 **ATTN: Anthy Hatzilias** or scan and email to: [a.hatzilias@abacus-als.com](mailto:a.hatzilias@abacus-als.com)

	<input type="checkbox"/> I verify that our facility is aware of the Urgent Recall for Product Correction of the GEM Premier 4000 Cartridge dated June 2011
<b>Date:</b>	
<b>Name:</b>	
<b>Position:</b>	
<b>Facility/Institution:</b>	
<b>City/State:</b>	
<b>Telephone:</b>	
<b>Fax Number:</b>	

We apologise for any inconvenience that the above required actions may cause your facility and appreciate your prompt attention to the matter.

Please do not hesitate to contact Abacus ALS at [@abacus-als.com](mailto:@abacus-als.com) with any questions or Free Call 1800 222 287

Best Regards,

Anthy Hatzilias  
Product Specialist  
Abacus ALS