



Instrumentation
Laboratory

**Urgent Product Notification
for the Glucose and Lactate Parameters
on the GEM Premier 3000**

December 2005

Dear Valued GEM Premier 3000 Customer:

Our records indicate that your facility may be using one or more GEM Premier 3000 instruments to perform glucose and lactate analysis. Recently, we received one reported occurrence impacting glucose and lactate results when the instrument exhibited a "**Cartridge error 1.08**", an indication of a reference reading outside the electronic limits.

In the majority of instances when this error occurs, the problem will self-correct or the cartridge will be rejected by the instrument. However, in rare cases, the event may result in clinically significant high readings of glucose and lactate results. These results will be flagged on the printout with a "Cartridge error 1.08". Our internal review estimated the probability of this event as approximately one failure in 4,000 cartridges.

If a "Cartridge error 1.08" is flagged on the instrument printout, your laboratory should **immediately** disable the glucose and lactate channels or remove the cartridge. Credit will be issued to you for the cartridge.

NOTE: Refinements to the GEM Premier 3000 software are being finalized to correct this situation with an anticipated release in early 2006.

Instrumentation Laboratory regrets any inconvenience that this issue may cause your laboratory. Please contact your local representative should you have any questions.

Sincerely,

Carol Marble
Regulatory Affairs Director

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