



**URGENT FIELD SAFETY NOTICE**  
**GEM PAKs (Cartridges) for GEM Premier 5000 with iQM2®**

June 22, 2026

Dear Valued GEM Premier 5000 with iQM2 Customer:

This Urgent Field Safety Notice informs you of an issue identified with specific lots of GEM Premier 5000 PAKs (cartridges) distributed to your facility.

A list of affected lots is provided below:

| System           | PAK Description                          | UDI            | Part No.    | Lot No.  | Expiration Date (YYYY-MM-DD) |
|------------------|------------------------------------------|----------------|-------------|----------|------------------------------|
| GEM Premier 5000 | 5K BG/ISE/GL/COOX/TBILI 300 Test Pak 31d | 08426950807766 | 00055430011 | 260505K  | 2026-10-03                   |
|                  | 5K BG/ISE/GL/COOX 450 Test Pak 31d       | 08426950807810 | 00055445010 | 260505K  | 2026-10-03                   |
|                  | 5K BG/ISE/GL/COOX 600 Test Pak 21d       | 08426950807599 | 00055360010 | 260505K  | 2026-10-03                   |
|                  | 5K BG/ISE/GL/COOX 300 Test Pak 31d       | 08426950807759 | 00055430010 | 260505K  | 2026-10-03                   |
|                  | 5K BG/ISE/GL/COOX 150 Pak 31d            | 08426950807698 | 00055415010 | 260505K  | 2026-10-03                   |
|                  | 5K BG/ISE/GL/COOX 600 Test Pak 21d       | 08426950807599 | 00055360010 | 260504AG | 2026-10-03                   |
|                  | 5K BG/ISE/GL/COOX 600 Test Pak 21d       | 08426950807599 | 00055360010 | 260505F  | 2026-10-03                   |
|                  | 5K BG/ISE/GL/COOX/TBILI 600 Test Pak 21d | 08426950807605 | 00055360011 | 260505F  | 2026-10-03                   |
|                  | 5K BG/ISE/GL/COOX/TBILI 600 Test Pak 21d | 08426950807605 | 00055360011 | 260505J  | 2026-10-03                   |
|                  | 5K BG/ISE/GL/COOX 300 Test Pak 31d       | 08426950807759 | 00055430010 | 260505F  | 2026-10-03                   |
|                  | 5K BG/ISE/GL/COOX/TBILI 450 Test Pak 31d | 08426950807827 | 00055445011 | 260505F  | 2026-10-03                   |

| System           | PAK Description                          | UDI            | Part No.    | Lot No. | Expiration Date (YYYY-MM-DD) |
|------------------|------------------------------------------|----------------|-------------|---------|------------------------------|
| GEM Premier 5000 | 5K BG/ISE/GL/COOX/TBILI 450 Test Pak 31d | 08426950807827 | 00055445011 | 260505J | 2026-10-03                   |

### Issue Description and Result Impact

Internal testing identified that the active ingredient concentration in the lysing bag solution of specific GEM Premier 5000 and GEM Premier 7000 PAK lots did not meet established manufacturing specifications. Accordingly, the affected PAK lots are being removed from the field.

As the lysing solution is used in CO-Oximetry (CO-Ox) and total bilirubin (tBili) measurements, affected PAKs listed above may experience an increased rate of total hemoglobin (tHb) failures during Auto PAK Validation (APV), resulting in automatic disabling of the CO-Ox/tBili parameters on the GEM Premier 5000 and GEM Premier 7000 systems. APV is an instrument quality safeguard designed to detect PAK performance issues before patient results are reported.

If the CO-Ox/tBili parameters are disabled, these results will not be reported until the PAK is replaced. This may cause a temporary interruption in result availability and a potential delay in patient diagnosis and treatment. Non-CO-Ox/tBili analyte results are unaffected by this issue.

### Mandatory Customer Actions

Please take the following actions **immediately**:

- **Check** your inventory for the affected PAK lot numbers listed above.
- **Discontinue use and destroy** per local procedures any inventory of the affected PAK lots listed above.
- **Document** the destruction on the Mandatory Response Tracking Form.
- **Forward** this notification to all affected locations within your facility.
- **Retain** a copy of this notification for your records.
- **Complete and return** the Mandatory Response Tracking Form **within 10 days of receipt**.

Werfen sincerely apologizes for any disruption this issue may cause to your laboratory operations. We are committed to the quality and reliability of our products and are taking immediate action to prioritize replacement of affected PAKs to minimize impact on testing.

We appreciate your prompt attention to this Urgent Field Safety Notice and will monitor the effectiveness of this field action in accordance with applicable regulatory requirements.



Senior Regulatory Affairs Manager

Instrumentation Laboratory Co.

A Werfen Company