



**Bio-Rad  
Laboratories**

Clinical Diagnostics Group  
9500 Jeronimo Road  
Irvine, California 92618-2017  
Tel: (949) 598-1200  
[www.bio-rad.com/qualitycontrol](http://www.bio-rad.com/qualitycontrol)

## **Important Product Quality Notice Notice of Correction**

**Bio-Rad Laboratories**  
**Liquichek Urine Chemistry Control, Level 2**  
**Catalog Numbers 398 and 395X**  
**Lot Nos. 68512 (Level 2), 68510 (MiniPak)**

*This Notice is intended for the end-users of this product.  
If you are not the end-user, please forward this Notice to the appropriate laboratory personnel.*

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|-------------------------|--|
| <b>Date</b>             | May 3, 2018  |
| <b>To</b>               | Clinical Laboratory Supervisor, Manager or Director<br>Cc Chairman Medical Board and relevant Head of Departments  |
| <b>Product</b>          | Liquichek Urine Chemistry Control  |
| <b>Lot Numbers</b>      | 68512 (Level 2), 68510 (MiniPak)   |
| <b>Catalog Nos.</b>     | 398 and 395X   |
| <b>Issue</b>            | <p>We have received multiple customer complaints indicating some analyte values in certain vials of Liquichek Urine Chemistry Control Level 2, Lot 68512, are recovering outside the package insert ranges with high CVs. This could potentially be indicative of microbial contamination in some vials. Due to this issue we recommend that you immediately discontinue use of Lot 68512.</p> <p>The performance of Level 1, Lot 68511 is not impacted.</p> <p>All currently scheduled shipments will now be for the new Lot 65820 of Liquichek Urine Chemistry Control.</p>  |
| <b>Actions Required</b> | <ul style="list-style-type: none"><li>• Discard all remaining inventory of Liquichek Urine Chemistry Control Lot 68512 that you have at your location in accordance with the requirements of your local waste management authorities.</li><li>• Please contact Bio-Rad Laboratories Customer Service at 1-800-2-BIO-RAD (1-800-224-6723) or your local Bio-Rad Laboratories Sales Office to make arrangements for any credit requests or to alter any pending orders or shipments.</li><li>• Have the appropriate laboratory personnel complete the enclosed acknowledgment form to document that you have received this notice and are aware of this product quality notification. Please send the completed form back via email to <a href="mailto:IRV_RA@Bio-Rad.com">IRV_RA@Bio-Rad.com</a> or by fax to 949-598-1557 (Attention: Regulatory Affairs).</li><li>• Contact Bio-Rad Laboratories Technical Support Department in USA at 1-800-854-6737 or by email at <a href="mailto:qsd.techservice@bio-rad.com">qsd.techservice@bio-rad.com</a> if you have technical questions regarding this notice.</li></ul> |

We appreciate your patience and apologize for any inconvenience this may have caused.



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