



**Bio-Rad**  
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## **Urgent Product Notification**

### **Coombszym-K, Catalog Number 816040, Lot 2949140-00, UDI 07611969952564**

Dear Valued Customer:

Bio-Rad Laboratories would like to inform you that the internal Quality Control product Coombszym-K, Lot 2949140-00 (Catalog Number 816040, UDI 07611969952564) shows a decrease in reactivity. This may result in unexpected weak results.

Patient testing results are not directly impacted as Coombszym-K is used as a control reagent.

#### **Customer Actions**

Bio-Rad's recommendation for management of this lot of Coombszym-K is to stop using the product. Please sign and return the attached confirmation form indicating that lot 2949140-00 has been discarded and the number of vials that require replacement. The affected products will be replaced free of charge by another lot.

If you have distributed this product to any other facility, you are required to provide a copy of this notification to them and/or notify Bio-Rad.

Customers who have any questions regarding this notification should contact their Bio-Rad representative.

We apologize for any inconvenience this may have caused and appreciate your support of Bio-Rad products.

Sincerely,

Bio-Rad Medical Diagnostics GmbH

**Dr. Marc Gorzellik**  
QA Manager

**Barbara Becker**  
International Product Manager Reagents