

Market withdrawal: QuikRead go® wrCRP and QuikRead go® wrCRP+Hb

Dear Partner,

Orion Diagnostica has received complaints on QuikRead go wrCRP (146521, 146522) and QuikRead go wrCRP+Hb (146255) products. Our investigations have shown that in rare cases the tests of the below mentioned lots may give either erroneous CRP results or the measurement flow is interrupted by the error message "Faulty Reagent Addition". We are investigating possible effects of improper use and storage of product and manufacturing process.

As with any diagnostic test, result should always be evaluated in the light of all clinical findings before making treatment decisions. Too low CRP results, in general, may provide misleading information for the diagnosis, therapy and monitoring of inflammatory disorders. However, due to the non-specific nature of CRP, even low values <10 mg/l do not exclude infections or exacerbations of inflammations.

Orion Diagnostica has concluded that there is no risk for serious incident.

The following QuikRead go wrCRP and QuikRead go wrCRP+Hb production lots are withdrawn:

Product name	Cat. No.	Production lots
QuikRead go wrCRP	146521	HV91, HX65, HX78, HY57, HY79
QuikRead go wrCRP+Hb	146255	HV86, HX85, HY65
QuikRead go wrCRP, 500 tests	146522	HX79, HY56

We kindly ask you to take the following measures:

Phase I - Immediate Customer Information

Immediately discontinue shipping the above mentioned QuikRead go wrCRP and QuikRead go wrCRP+Hb lots to your customers.

Inform your customers who are using the above mentioned products and ask them to stop the use of kits from the lots in question. This information should be documented.

Collect all kits of the above mentioned lots back from your customers. After you have received the kits we ask you to prepare for returning them to us.

Inform us that you have received this information and that you have informed your customers by signing the Immediate Customer Information Form attached.

Phase II - Inventories

Inform us about both the number of kits you have in your stock and the number of kits you have collected from your customers by filling in the attached Distributor Inventory Form. Our customer service will be in contact with you regarding the return, replacement and timetable.

We deeply regret the inconvenience this withdrawal may cause to you and your customers.

Best regards,



Paula Luokola
Product Manager