

We have important information regarding Actim CRP test for which we need your immediate assistance.

We have observed that in **occasional Actim CRP dipsticks**, the third test line (>80 mg/L) is lighter than specified. This means that the CRP concentrations >80 mg/L can be interpreted as concentrations between 40 and 80 mg/L. This CRP level is already an indication for further testing or treatment. To ensure that no false patient results are observed, **we have decided to withdraw the kit lots affected by this problem:**

0030416
0030253
0030142
0030015
0029746
0029745
0029435
0029150
0029148

We will revert to you with replacement of the withdrawn kits soonest possible.

In the meanwhile, we kindly ask you to:

1. **Please confirm via email that you have received this information.**
2. Assess the **number of kits in your storage**. Please fill in the information in below table.
3. Assess the **number of kits delivered to your customers**. Please fill the information in below table.
4. **Withdraw the kits of from the customer and please confirm us when the kits have been returned from the customer.**
5. **Please send 1 kit for our investigation in below address and Fedex number**, and the rest of the kits can be discarded.

Kit lot	Kits in your storage	Kits in customers' storage
0030416		
0030253		
0030142		
0030015		
0029746		
0029745		
0029435		
0029150		
0029148		

Return address:

Medix Biochemica, att. Kaisu Rannasmaa
Noljakantie 13
80130 Joensuu
Finland
Fedex number 234537008

Corrective actions:

During the investigation we have seen the phenomena in these particular lots, the previous and following lots tested work according to specifications. We are making thorough investigations to identify the root cause for this phenomenon and **will make respective corrective and preventive actions.**

Please accept our sincere apologies for all the inconvenience that this brings to you. If you have any questions, please let us know.

Hanna Kostia, Feb. 26, 2014

Hanna Kostia
Quality Systems Manager
Medix Biochemica
Asematie 13, 02700 Kauniainen, Finland
Tel. +358 9 547 680, Direct +358 9 547 68 172
Mobile +358 400 562 162
Fax +358 9 505 3441
Email: hanna.kostia@medixbiochemica.com