

Field safety Corrective Action

2016-11-29

Alegria® Anti-Intrinsic Factor

Alegria® Anti-Mycoplasma pneumoniae IgM Abs.

Dear

Unfortunately, we have to let you know that we had to recall our products

Alegria® Anti-Intrinsic Factor, ORG 247, lot 1612319

and

Alegria® Anti-Mycoplasma pneumoniae IgM Abs., ORG 915MX, lot 1612153

from the market.

Problem description:

It has become to our attention that there is a defect in the foil sealing with these product lots that could cause wrong results.

We found that the sealing of the assay strip by the upper metal foil can be untight. This can cause leaking of strip's liquids and can influence the stability of the components. There a risk for incorrect results.

Cause of defect:

The cause of the defect was a problem in the sealing process during production. Please note that only Alegria® Anti-Intrinsic Factor, ORG 247, lot 1612319 and Alegria® Anti-Mycoplasma pneumoniae IgM Abs., ORG 915MX, lot 1612153 are affected. We will take corrective actions to prevent reoccurrence of this problem.

ToDo:

Not all kits of both product lots are affected, but because error can't be detected easily, all remaining kits should not be used any longer and should be discarded. Please inform customers who received this lot. Please also inform your local authorities.

To identify already tested kits, the product strip's barcode can be used.

- Alegria® Anti-Intrinsic Factor, ORG 247, lot 1612319, strip's code is 247171134057xxxx
- Alegria® Anti-Mycoplasma pneumoniae IgM Abs., ORG 915MX, lot 1612153, strip's code is 915571142438xxxx

In the attachment you find the following:

- The notice-form we have to use for the German competent authority, BPharM to give official notice. They will inform all other European authorities.
- The Field Safety Notice which summarizes the reason for this recall.
- The form to fill in all details and send back to ORGENTEC after you have informed customers and recalled and/or destroyed remaining kits

We apologize for this inconvenience.

Please let us know if you have any questions.

With best regards,

