



Urgent Field Safety Notice. 20th August 2014

REF – PL.7052 Lugols Iodine Solution. Lot No. K18044

Dear Customer

We have been alerted to the potential content of a Gram Negative Bacillus in the product, a full investigation has been carried out here at Pro-Lab Diagnostics.

In accordance with ISO13485 and the *In-vitro* Diagnostics Directive,

1. All end users are advised to quarantine any stock on hand pending disposal.
2. Contact the distributor to request replacement product.
3. Contact person at Cruinn Diagnostics (The Distributor) - Vicky Fitzgerald
Vicky.Fitzgerald@cruinn.ie (+353) 01 6297400

Actions taken by the manufacturer

1. Quarantine of remaining stock of lot number K18044 at Pro-Lab Diagnostics
2. Repeat all quality control on retention samples both internally and with an external independent laboratory.
3. Conduct full audit trail on manufacturing, raw material lots used, suppliers of raw materials and production equipment.
4. Contact all customers who had received lot number K18044
5. Replace all product.
6. Conduct Root Cause Analysis.
7. Implement Corrective Action

The results of the above are as follows.

1. PL7052 Lot Number K18044 was manufactured in accordance with our SOP Manufacturing Instructions on 28th April 2014. 100 units.
2. Quality control has been repeated internally and independently on retention samples and no abnormalities have been detected. Testing however of two units returned has shown the presence of a Gram Negative Bacillus.
3. A full audit trail has been conducted to ensure correct handling and processing of all raw materials. This audit trail included QC on the RO water, all specifications have been met.
4. All customers have been contacted and the product withdrawn and replaced. All product has been replaced.
5. The root cause analysis has concluded that a single filling line had silicon tubing that contained residual water. This line is used for the dispensing of RO water, RO water is used

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in all production processes. As the filling line had not been used for several weeks, and missed a cleaning run, it is concluded that a Biofilm had formed in the water and contaminated part of lot number K18044. This Biofilm has been confirmed as Gram Negative Bacillus.

6. Corrective action.
 - a. The filling line tubing has been disposed of and a full clean down actioned for the Cole Palmer Peristaltic Pumps used.
 - b. New filling lines have been installed and an additional check is in place in accordance with a revised SOP for tube handling and drying during the RO dispensing stage of production.
 - c. To ensure the process is once again sterile, the filling room has been completely sterilised and all glass wear associated with the production of Grams Iodine solutions has been destroyed and replaced.
 - d. In accordance with ISO13485, all staff involved in production processes for the stains have been fully briefed and are aware of the situation. This action has been recorded in all training files and signed by individuals for full compliance.

Should you have any questions, or require any further documents relating to the root cause or corrective action, please let me know.

Yours sincerely

Mark Reed

General Manager. Pro-Lab Diagnostics