# Product Correction
## Sofia® Legionella FIA

November 3, 2015

Dear Valued Customer,

Quidel Corporation has determined that the Sofia Legionella FIA may give a false positive result in some cases due to Rheumatoid-like factors present in the urine of some patient specimens.

In keeping with our quality policy, we are sending this Product Correction notification and requesting that you replace the Package Insert that was supplied in the Sofia Legionella FIA test kit with the new Package Insert provided with this letter. This new Package Insert specifically includes Rheumatoid Factor as an interfering substance and recommends a method for testing these particular patient specimens.

Rheumatoid-like factors have been associated with the occurrence of false positives with immunoassays for the detection of *Legionella* antigen in urine.[1,2] Where a false positive is suspected, it is recommended to heat the urine specimen at 100°C for 5 minutes followed by a 15-minute centrifugation step (1000 X g), and repeat testing with the processed specimen in the Sofia Legionella assay.[1,2] The inclusion of the heating step denatures the Rheumatoid-like factors (thus removing its interference within the assay), while the heat-stable *Legionella* lipopolysaccharide (LPS) antigens remain unaffected. The above-stated recommendation for urine sample heating and centrifugation are in accordance with the *Legionella* antigen specimen processing procedures that are outlined within the referenced peer-reviewed literature.

The Sofia Legionella and Sofia analyzer have no quality issues related to this notification, the only correction needed is to the Package Insert.

Please perform the following steps:

- Inspect your inventory, destroy the old Package Insert, and replace it with the new Package Insert.
- Once this is completed, **please e-mail the attached Inventory Assessment Form to technicalsupport@quidel.com or FAX the form to Quidel at (858) 552-7905.** Please complete the form even if you no longer have inventory available so that we can complete the reconciliation process.

Quidel is sending this notification because we are committed to supporting our valued customers. If you have any questions or need more information, please contact Quidel Technical Support at technicalsupport@quidel.com or (858) 552-1100, Monday – Friday, 7am – 5pm PST.

Sincerely,

Thomas Clement
VP, Regulatory / Clinical Affairs and Quality Assurance
**Quidel Corporation**

1 ASM Press Clinical Microbiology Procedures Handbook
2 The American Journal of Medicine (1982)

# Product Correction
## Sofia® Legionella FIA
## Customer Inventory Assessment Form

**Description:** Sofia Legionella FIA
**Catalog Number:** 20244
**Lot Numbers:** All

**Purpose of Operation**:
To identify current inventory and replace the old Package Insert with the new Package Insert.

**Instructions:**

- Determine if you have any Sofia Legionella FIA kits that are within expiration. – Expired kits should be discarded.
- If yes, replace the old Package Insert with the new Package Insert.
- Complete this form even if you no longer have Sofia Legionella FIA inventory.
- E-mail or FAX this fully completed form to Quidel Technical Support at technicalsupport@quidel.com or (858) 552-7905.

I confirm that the old Package Inserts were replaced with the new Package Inserts OR that we do NOT have any kits of Sofia Legionella FIA.

By:_____ Date:_____

Print Name:_____ Title:_____

Facility Name:_____ Telephone #:_____

Facility Shipping Address:_____

Distributor: _____

Please contact Quidel's Technical Support at (858) 552-1100, option 2 or technicalsupport@quidel.com, if you have any questions or require assistance. Please retain a copy of this document for your files.