Alere Scarborough, Inc.
10 Southgate Road
Scarborough, ME 04074

Urgent Field Safety Notice

Product Improvement for Alere™ BinaxNOW® *Legionella* Urinary Antigen Card used in conjunction with the Alere™ Reader

FSCA-identifier: 2018 11
Device Modification: Assay Procedure Update

November 2018

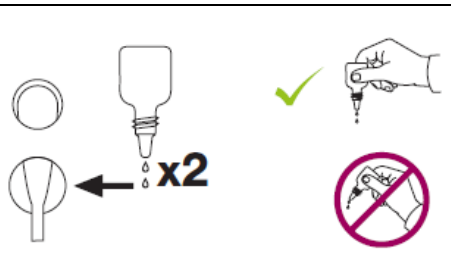
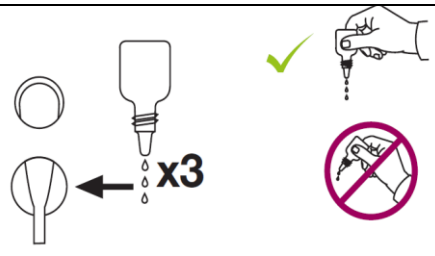
Dear Valued Customer,

Abbott is committed to innovation and continually delivering the highest quality diagnostic tests and best customer experience. We wish to inform you that we are implementing a product improvement through a revised assay procedure for the Alere BinaxNOW *Legionella* Urinary Antigen Card (Alere BinaxNOW *Legionella*), part numbers 852-100 and 852-012. Our records indicate that you have received at least one of these kits and the Alere Reader, part number LFR-000.

Product Part Numbers:
- Alere BinaxNOW *Legionella*: 852-100 and 852-012
- Alere Reader: LFR-000

Lot Numbers:
- All Lots within Expiry

New Update/Change to the Instructions for Use

	Existing Patient Test Procedure	New Patient Test Procedure
Procedure Change	Hold Reagent A vial vertically, ½ to 1 inch above the card. Slowly add **two (2)** free falling drops of **Reagent A** to the **BOTTOM** hole.	Hold Reagent A vial vertically, ½ to 1 inch above the card. Slowly add **three (3)** free falling drops of **Reagent A** to the **BOTTOM** hole.
Procedure Change - Illustrated		

This new procedure should be used, with immediate effect, for all Alere BinaxNOW *Legionella* tests interpreted with the Alere Reader.

A recent product innovation program found that when results are interpreted with the Alere Reader, specificity can be enhanced with a modification to the test procedure, without negatively impacting the sensitivity of the device. This was recently confirmed through an independent clinical study, which also confirmed the existing patient test procedure was performing within the claims documented in the product insert (Specificity = 95% with a 95% confidence interval of 91.0% - 97.6%). The assay procedure is being revised to apply an additional drop of Reagent A when testing patient samples, which optimizes assay performance. Study results concluded that specificity using the revised method increased 4.2%. The enhancement in specificity is an important incremental innovation with the assay and provides greater confidence in the test results.

Action to be taken by the user/distributor:

- Customers should commence using the updated Alere BinaxNOW *Legionella* assay procedure immediately if interpreting test results with the Alere Reader.
- Please complete and return the attached Acknowledgement Form within 5 business days.

Transmission of this Field Safety Notice:
Please communicate this Field Safety Notice to all those who need to be aware of it within the organization and to maintain awareness of this revised procedure until product containing the legacy procedure is consumed. Additionally, please communicate this notice to any organization where the affected product has been transferred or transfer this notice to other organizations where this action has an impact.

The undersigned confirms that the relevant Competent Authorities have been advised of this Field Safety Notice associated with the BinaxNOW *Legionella* improved assay procedure. A PDF of the revised product insert is available at www.alere.com as of the date of this letter. You may also contact Technical Service at the contact details below to request an updated product insert.

Should you require further information or have additional questions regarding the use of this product, please contact your local sales representative or Alere Technical Support using the contact information listed below for your location.

Sincerely,

Emily Deane
Senior Director Quality Assurance and Regulatory Compliance
Alere Scarborough, Inc.

TECHNICAL SERVICE CONTACT INFORMATION

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Please note: For any countries that do not have a fax number listed, the Ireland fax number should be used.