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

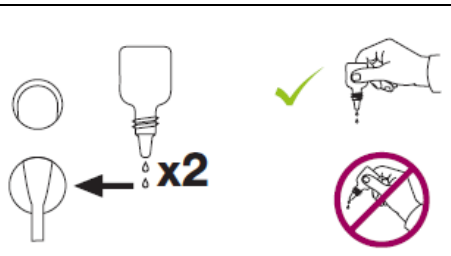
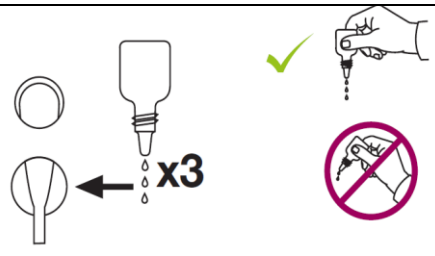
Dear Valued Customer,

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

Region/Territory	Telephone	E-mail
Benelux (Belgium, Luxembourg) & Netherlands	+44 161 483 9032 Option 3	EME.TechSupport@alere.com
Norway & Denmark	+47 24056810	NODK.TechnicalSupport@alere.com
Sweden & Finland	+46 8 544 812 14	SWFI.TechnicalSupport@alere.com
Ireland and UK	+44 161 483 5884 Option 3	EME.TechSupport@alere.com
France	+33 139 46 83 18 Option 3	techsupport.france@alere.com
Germany/Austria	+49 221 27143-0 Option 3 for Technical Support – press 1 for all products	TechnicalService.DA@alere.com
Italy	+44 161 483 9032 Option 3	EMETechSupportIT@Alere.com
Spain	+34 936 008 008	EMETechSupportES@alere.com
Switzerland	+41 (0)44 782 60 70 Option 1 -French- Press 2 Option 2 -Italian- Press 2 Option 3 -Swiss German- Press 2 Option 4 -German- Press 2	serviceCH@alere.com
Czech Republic, Portugal	+44 161 483 9032 Option 3	EME.TechSupport@alere.com
Middle East (ME)	+44 161 483 9032 Option 3	ARCIS.TechSupport@alere.com

FSN Fax Number	
Country	Number
Switzerland	+41815880108
UK	+35391680102
Ireland	+35391680102
Spain	+34935222134
France	+33170826128
Germany	+4922196694509
Portugal	+35391680102
Austria	+43732210311
Netherland	+31137998007

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

Field Safety Notice Acknowledgement Form

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

Dear Valued Customer,

Please complete this form within 5 business days to confirm your receipt of this Field Safety Notice (2018 11), and return the completed, signed form to:
Email: Field.Safety.Notifications@alere.com or
Fax: (see contact information attached) or
Mail original document to: Alere International Limited, Parkmore East Business Park, Ballybrit, Galway, Ireland.
Please complete this form even if you did not receive any of the affected product.

Facility Name	
Address	
Print Full Name of Person Completing the form	
Print Title of person completing the form	
Phone	
Email address	

Please Select One: I am a: Customer _____ Distributor_____

If you are a Customer:

I have received the Field Safety Notice and understand the instructions.

Yes: _____ No: _____

Signature: _____Date: _____

If you are a Distributor:

I have notified all my customers that have been shipped the Alere™ BinaxNOW® Legionella Urinary Antigen Card and the Alere™ Reader and have provided this verification form for them to complete.

Yes: _____ No: _____

Signature: _____Date: _____

☐ Please check box if you have no record of receipt of this product and will therefore take no further actions. Thank you!