BinaxNOW™
LEGIONELLA
URINARY ANTIGEN CARD

Abbott

Procedure Card

This test is intended to be read by one method; either by the DIGIVAL™ OR Visually. Refer to BinaxNOW™ *Legionella* Product Insert for complete instructions. Complete Part 1 prior to running the test if using the DIGIVAL. If not using the DIGIVAL proceed directly to Part 2.

Part 1 - DIGIVAL™ Set-Up (if applicable)

For full set up instructions on using the DIGIVAL please refer to the user manual.
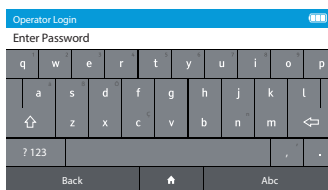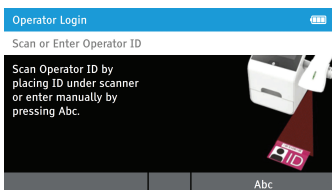
1 TURN ON THE DIGIVAL™
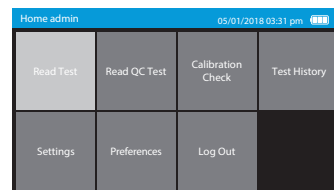Press the power button ⏻ on the front of the instrument.

2 ENTER OPERATOR ID AND PASSWORD
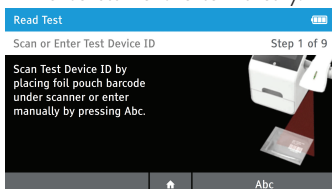Press 'OK' after entry.

3 TAP READ TEST
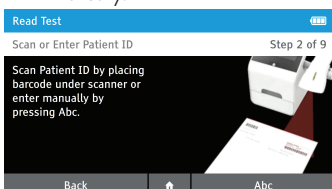This will start the reading process.

4 ENTER TEST DEVICE ID
Scan Test Device ID by placing Test Device foil pouch barcode under scanner or enter manually.
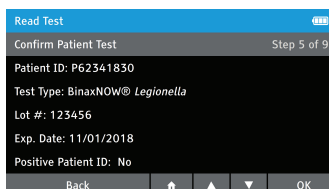
5 ENTER PATIENT ID
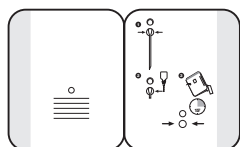Scan Patient ID by placing Patient ID barcode under scanner or enter manually.

Note: Default is Patient ID only, see additional options in the DIGIVAL User Manual.

6 CONFIRM DATA ENTRY
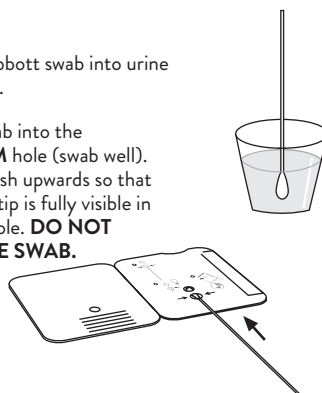Verify data on screen is correct and tap 'OK'.

Part 2 - Test Procedure

**1** Remove card from the pouch just prior to testing and lay flat on work bench.

2 Dip an Abbott swab into urine specimen.

Insert swab into the **BOTTOM** hole (swab well). Firmly push upwards so that the swab tip is fully visible in the top hole. **DO NOT REMOVE SWAB.**

3 Hold Reagent A vial vertically, 1/2 to 1 inch above the card. Slowly add three (3) free falling drops of Reagent A to the **BOTTOM** hole.

x3
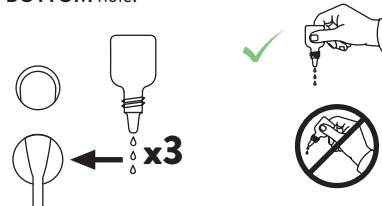
4 Immediately peel off adhesive liner from the test card. Close and securely seal the card.
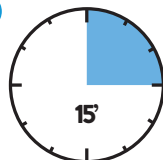
5 Read result 15 minutes after closing the card.
*Note: For convenience, the swab has been scored and must be snapped off **after** closing the card, in order to fit the DIGIVAL insert tray. Avoid dislodging the swab from the well when doing so.*

15'

Go to Part 3 if using the DIGIVAL™. If reading the test visually, go to Part 4.

Procedure Card

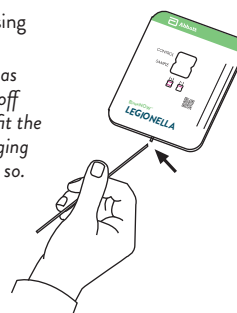## Part 3 - Result Interpretation – Using DIGIVAL™

The DIGIVAL may be set to two different modes (Walk Away and Read Now).
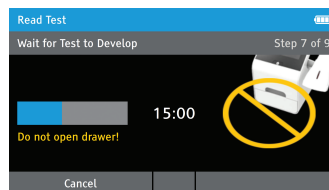For full instructions on using the DIGIVAL please refer to the user manual.

1a READ NOW:
At the 15 minute read time, open drawer, insert test device with the barcode and result window facing up and close drawer. DO NOT OPEN THE DRAWER until Test Results appear on the screen.
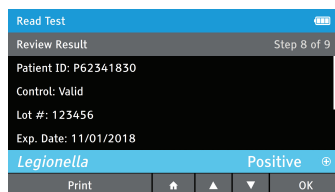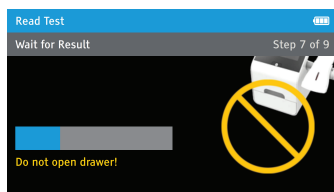


```
Read Test
Insert Test Device                    Step 6 of 9
Open drawer, insert Test Device
and close drawer to continue.
          Back          🏠
```

OR

1b WALK AWAY MODE:
Once the test device is securely closed, immediately open the DIGIVAL drawer, insert test device and close drawer. The DIGIVAL will automatically time the test development and read the result at the read time.

```
Read Test
Wait for Test to Develop              Step 7 of 9

                           15:00
Do not open drawer!
          Cancel
```

2 READ TEST RESULTS
Once test is complete, tap 'Print' to print test results.

```
Read Test
Wait for Result                       Step 7 of 9



Do not open drawer!
```

```
Read Test
Review Result                         Step 8 of 9
Patient ID: P62341830
Control: Valid
Lot #: 123456
Exp. Date: 11/01/2018
Legionella                      Positive    ⊕
   Print        🏠    ▲    ▼       OK
```

3 DISCARD TEST DEVICE
Open drawer, remove test device and close drawer. The Home screen will automatically appear.


```
Read Test
Discard Test Device                   Step 9 of 9
Open drawer, discard Test
Device and close drawer to
return to Home Screen.
          Back
```
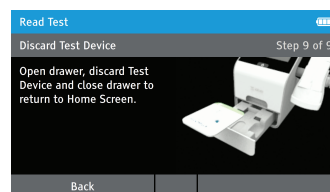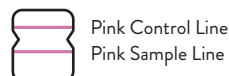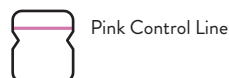

⚠ **DO NOT REINSERT TEST DEVICE ONCE A RESULT HAS BEEN OBTAINED.**

Part 4 – Visual Result Interpretation only (See Part 3 for result interpretation by DIGIVAL™)

A negative specimen will give a single pink-to-purple colored Control Line in the top half of the window, indicating a presumptive negative result. This Control Line means that the detection part of the test was done correctly, but no *L. pneumophila* serogroup 1 antigen was detected.

A positive specimen will give two pink-to-purple colored lines. This means that antigen was detected. Specimens with low levels of antigen may give a faint patient line. Any visible line is positive.

If no lines are seen, or if just the Sample Line is seen, the assay is invalid. Invalid tests should be repeated. If the problem persists, contact Abbott Technical Service.

Pink Control Line

Pink Control Line
Pink Sample Line

No Control Line

Sample Line Only

CE

2°C / 30°C

ℹ

Abbott
BinaxNOW *Legionella*
Urinary Antigen Card
with DIGIVAL

Procedure Card

Size:
8 in x 11 in

Printed Colors

CMYK

**Incoming Inspection Colors
(For Reference Only)**
Colors below are not used for printing

PMS 2995 U
Primary Blue

PMS 2269 U
Light Green

PMS 303 U
Dark Blue

PN: IN852101
Rev: 4

Date of Last Revision:
4.7   2019/03/05