AlphaBioScreen® Legionella Antigen Urine Rapid Test

REF Best.-Nr.: APH-ABS-001-ST

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CE

Instructions for Use

Intended Use

AlphaBioScreen® Legionella Antigen Urine Rapid Test is a visual, immunochromatographic rapid assay for the qualitative detection of *Legionella pneumophila* serogroup I antigen in human urine samples. The test results are intended for use in the diagnosis of *Legionella pneumophila* infections.

AlphaBioScreen® Legionella Antigen Urine Rapid Test is for in-vitro-diagnostic use only.

Test Principle

AlphaBioScreen® Legionella Antigen Urine Rapid Test is a sandwich solid phase immunochromatographic assay. To perform the test, an aliquot of urine sample is added to the sample well (S) of the test cassette. The sample migrates through a membrane containing anti-legionella serogroup I antibodies coupled to red coloured colloidal gold particles. If the sample contains *Legionella pneumophila* serogroup I antigens, the antigen will bind to the antibody-coated colloidal gold particles to form antigen-antibody-gold-complexes. These complexes move through the membrane by capillary action towards the test line (T) on which antibodies specific to *Legionella pneumophila* are immobilized. The test line becomes visible if the antigen-antibody-gold-complexes are binding to the antibodies along the line and precipitate. The control line (C) indicates that the test has been performed correctly.
If Legionella antigen is not present or the concentration is below the detection limit of the test only the control line (C) will appear. The test is invalid if the control line (C) does not appear.

Materials provided with the kit

- 20 test cassettes
- Instructions for Use
- Positive Control (0.17 ml) of *Legionella pneumophila* serogroup I Antigen, sufficient for 1 application, in screwed caps with red lids.
- Negative control (0.17 ml) of *Legionella pneumophila* serogroup I antigen, sufficient for 1 application in screwed caps with yellow lids.

Materials required but not provided

- Timer
- Pasteur pipettes or pipette (150 µl) with tips

Storage and Stability

- AlphaBioScreen® Legionella Antigen Urine Rapid Test has to be stored at +2°C to +30°C and is valid until the expiry date printed on the pouch. **Do not freeze**.
- Do not remove the test cassette from the foil pouch until directly before use.

Precautions

- Read the complete instructions for use before performing the test.
- Avoid contamination of the sample and test components.
- Do not use kit components after the expiry date.
- Do not mix components of different batches.
- Wear protective gloves and clothing while handling kit components and samples.
- Patient samples, used test cassettes, and positive controls may contain infectious agents and should be handled and disposed as potential biohazards.
- Dispose all used materials in appropriate containers. Treat as potential biohazards and dispose according to local regulations.

Sample Collection and Storage

- Urine samples must be collected in clean, sterile standard containers and should be tested directly if possible.
- Urine samples can be stored at room temperature for a maximum of 24h or at +2°C to +8°C for a maximum of 5 days. For longer storage freeze the samples at -20°C.
- Frozen samples must be thawed and brought to room temperature prior to use.
- Avoid repeated freeze and thaw circles.
- Homogenize all samples thoroughly.

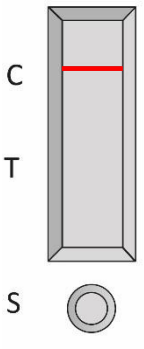
Preparations

1. Take the number of test cassettes corresponding to the number of samples.
2. Bring test cassettes and samples to room temperature.
3. Remove the test cassettes from the sealed foil pouches directly before use.
4. Label test cassettes with sample number or name.

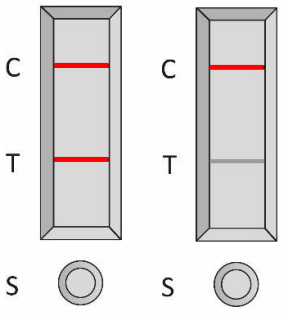
Assay Procedure

1. Pipette 3 drops (Pasteur pipette) or 150 µl (pipette with tips) of urine to the sample well (S).
2. Read the result after 15 minutes. Strong positive samples may show results earlier than low positive samples. Results read later than 15 minutes may not be accurate.

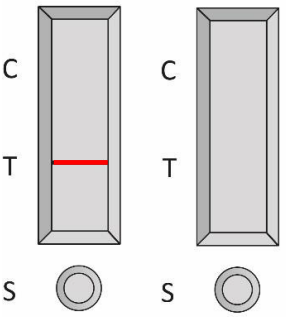
Results



Negative Result:
A red line appears only in the control region (C). There is no red line visible in the test line region (T). No Legionella antigen was detected in the urine sample.



Positive result:
A distinct red line appears in the test line region (T), additionally to a distinct red line in the control region (C). The color intensity of both lines may differ.



Invalid result:
The control line (C) above the test line (T) does not appear within 15 minutes after sample addition. Missing or delayed development of the control line (C) indicates an inaccurate assay performance or defective kit components.

AlphaBioScreen® Legionella Antigen Urine Rapid Test is a qualitative test for the detection of *Legionella pneumophila* serogroup I antigen in human urine. Healthy patients are free of Legionella and show negative results. A positive result indicates the presence of Legionella antigen in the sample.

Result Reading with the CUBE® Reader

1. Provide the supplied RFID card after sample testing.
2. The CUBE® Reader is switched off and the display is blank.
3. To switch on the CUBE® Reader press the button briefly (<1 second).
4. After activation an acoustic signal sounds briefly and the display shows **ON**.

Please note: If the CUBE® Reader has the option to show the last saved result, the first information presented on the display will be the last saved result. Press the button again briefly (<1 sec) and the display will change to **ON**.

5. For immediate measurement press the button briefly (<1 sec), the display will show **RFID**.
6. The test configuration is uploaded via RFID. Place the supplied RFID card onto the top of the device until the configuration data has been uploaded (acoustic signal). After the RFID data has been transmitted successfully the CUBE® Reader displays **TEST**.
7. With the AlphaBioScreen® Legionella Antigen Urine Rapid test cassette placed on a flat and horizontal surface, place the white loading tray of the CUBE® Reader on top of the cassette as shown below.

8. Place the CUBE® Reader on top of the loading tray. The notch in one corner of the CUBE® and the corresponding counterpart on the loading tray will guide you to the correct position.
9. The CUBE® Reader is still displaying **TEST** to indicate that it is ready to perform the reading. To start the measurement press the button briefly (<1 sec).

10. The CUBE® Reader will perform the measurement within a few seconds while showing **RUN** on the display.
11. An acoustic signal will occur as soon as the measurement is completed and the result is shown on the display. The test line result is qualitative and will display **Leg POS** in the event of a *Legionella* positive result, **Leg VLP** in the event of a very low *Legionella* positive result and **NEG** in the event of a *Legionella* negative result.
12. If storage of the test result is required press the button for 3-4 seconds. An acoustic signal will sound when the data is saved and the display will show **SAVE**.

Please note: The CUBE® Reader has an internal memory capacity for more than 100 readings. If the internal memory capacity has been reached, all new results will be saved while overwriting previous saved results in chronological order.

13. To start the next measurement, press the button briefly (<1 sec) to return to **ON**. Proceed with point 7 of this IFU.
14. If the CUBE® Reader is not in use for more than 50 seconds it will automatically turn off. Please note: There is no active way to shut down the CUBE® Reader.

Expected Values

AlphaBioScreen® Legionella Antigen Urine Rapid Test is a qualitative assay for the detection of *Legionella pneumophila* serogroup I antigen in urine samples. Healthy patients are free of *Legionella* and produce a negative test result. A positive test result is an indication for the presence of *Legionella* antigen in urine.

Limitations of the Procedure:

Test results should be interpreted only in combination with other clinical and laboratory information available to the physician. The test does not indicate the quantity of antigen.

Quality Control:

The assay contains an internal quality control. The control line (C) is an internal procedural control. The appearance confirms sufficient sample volume and a correct performance of the assay. Following GLP standards, the use of positive and negative controls is required. This can be achieved by using the positive and negative controls provided with the kit. Pipette 3 drops (ca. 150 µl) of the positive and the negative control respectively to the sample wells (S) of unused test cassettes. Read the results after 5 minutes as described in the section **Results**. Do not use test results, if the result of the controls are not as expected. In this case repeat the test or contact your supplier.

Clinical performance

	Reference Method			
Alpha BioScreen® Legionella Antigen Urine Rapid Test		**Positive**	**Negative**	**Total**
	Positive	45	1	46
	Negative	2	43	45
	Total	47	44	91

Performance Data:

Sensitivity: 95.74 %
Specificity: 97.73 %
Accuracy: 96.70 %

Lower limit of detection: 10^5 CFU/ml

Symbols

REF Catalog number	CE certified
Temperature limit	Consult the instructions for use!
LOT Batch No.	Manufacturer
Use by date JJJJ-MM	IVD In vitro Diagnostic
No. of assays in the kit	

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