aLF Reader for suPARnostic® measurements

REF 9002770

CE IVD

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suPARnostic® Quick Triage

Refer to www.alf-reader.com for further instruction.
Or contact QIAGEN (aLF-info@qiagen.com) or ViroGates (info@virogates.com) for instructions in your language.

INTRODUCTION

The aLF lateral flow reader is used for the testing of suPAR. QIAGEN GmbH, Germany, is the legal manufacture of the aLF Reader. This reader can be used for multiple tests specified by QIAGEN[1]. For more information contact QIAGEN at www.alf-reader.com

This manual describes how to operate the aLF Reader for analysis of soluble urokinase Plasminogen Activator Receptor (suPAR) using the **suPARnostic® Quick Triage** (A003) lateral flow test (named suPARnosticQT or suPARnosticQT20). The aLF Reader is a highly sensitive, robust, and cost-effective measurement system for lateral flow tests. This flexible and reliable Reader, based on a ready-to-use concept, enables users to easily run lateral flow tests.

Before using the Reader, it is essential that the user read the User Manual for the aLF Reader from QIAGEN carefully.[1]
To use the aLF Reader it is required that the user is fully trained in how to operate the aLF Reader.

INTENTED USE

For professional use only. The aLF Reader, together with the suPARnostic® Quick Triage kit, is used for determination of suPAR in human EDTA plasma in ng/ml.

Interpretation of results must be made considering the patient´s clinical history and results of other diagnostic tests if available.

SUMMARY OF suPAR AS A MARKER OF DISEASE PROGNOSIS

suPAR is the soluble form of urokinase Plasminogen Activator Receptor (uPAR). The amount of suPAR is a measure of immune activation and inflammation. suPAR is a non-specific biomarker which is increased by the presence of disease. The higher the suPAR level, the higher the risk of disease progression and the worse the patient's prognosis.

PRINCIPLES OF ASSAY PROCEDURE

The suPARnostic® Quick Triage test is a lateral flow immunoassay. The device utilizes monoclonal rat and gold-conjugated mouse antibodies against human suPAR to give a quantitative measurement of the plasma suPAR level. The EDTA plasma is mixed with running buffer and is applied to the suPARnostic® Quick Triage device. During the 20 minutes of incubation, the plasma sample reacts with gold-conjugated anti-suPAR antibodies and migrates through the nitrocellulose membrane. The gold-conjugate containing sample suPAR is bound by a capture suPAR antibody at the Test line, while non-suPAR bound antibody is captured by the Control line (anti-mouse antibody).

aLF READER

Provided

- aLF Reader
- Guide for using suPARnostic quick triage
- Quick Start Guide
- Power supply
- Universal test drawer

Material not included

- suPARnostic® Quick Triage kit (#A003)
- DYMO LabelWriter 450

PRECAUTIONS AND RECOMMENDATIONS

- Do not expose the reader to excessive heat
- Do not expose the Reader to direct sunlight during operation.
- Protect the reader from high humidity and contact with liquids.
- Do not expose the reader to strong electromagnetic radiation.

STORAGE AND HANDLING

Place aLF Reader on a stable surface with enough surrounding space in order to easily insert the cassettes.

FUNCTIONEL DESCRIPTION

Hardware

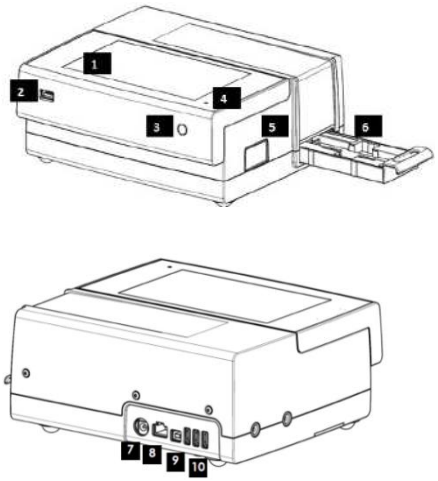


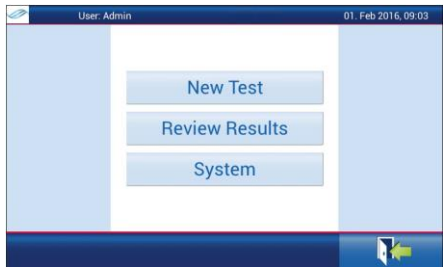
Figure 1: aLF Reader description.
1) Touch display, **2)** USB Port, **3)** Power button, **4)** Power indicator, **5)** Barcode reader, **6)** Drawer for test cassette, **7)** Connector for power supply, **8)** RJ port, **9)** USB-port (type B), **10)** USB port (type A)

aLF READER SET UP

1) Place the aLF Reader on a stable and level surface.
2) Plug the power supply cable into the connector at the rear end of the aLF Reader (**7**).
3) If needed: Connect the DYMO LabelWritter to Reader with the supplied USB cable.
4) Turn the device on by pressing the power button (**3**). Wait for the operating system to boot up.
   The main menu will appear on the touch screen display.
5) If needed, connect the Reader to LIS/HIS/middleware/ medical office information system via the QLC connect Server and all results will be automatically reported.
   Note: Contact QIAGEN for further information.

MEASURMENT PERFORMANS

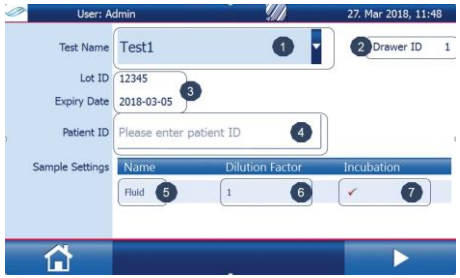
1. To start a new test, Press the "New Test" field on the touch screen display.



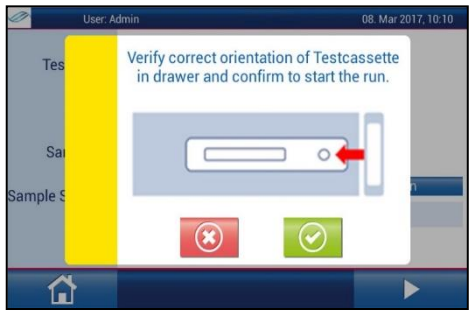
2. Choose the preferred measuring method by scanning the barcodes provided in the suPARnostic® Quick Triage (A003) kit;
   Choose the *suPARnosticQT* program for subsequentially tests (place device with sample on the table and wait for 20min before loading in the Reader) or the *suPARnosticQT20* for loading the device and the aLF Reader will do the measurement after 20 min incubation.
3. Using the internal 2D- barcode scanner, scan the 2D-barcode provided in the kit.

NOTE: keep the barcode in a vertical angle.

4. Test method name **(1)**, Lot ID **(3),** and Sample Settings **(5-7)** will automatically appear on the screen.



5. Scan the 2D-barcode with the Patient ID or write the Patient ID.
6. Open the tray on right side of the reader. Insert the Lateral Flow device with the patient ID to the left, closest to the reader, and the sample well to the right after adding the patient sample.



7. Touch the "forward" button to proceed and confirm that the cassette has been inserted in the correct orientation.

CALCULATION OF RESULTS

The aLF Reader automatedly performs the calculation of suPAR levels.
The suPARnostic® Quick Triage device has to be used with the reader to give correct values.

The suPAR result will be displayed in ng/ml.
The suPAR value should be within the range 2-15 ng/ml. If the result is out of range, it will be shown as < 2.0 ng/ml or >15 ng/ml, and the value cannot be considered as accurate and precise. If the display shows INVALID, an error has occurred during the measurement. Re-run the sample and if the result is INVALID again, check the extensive instruction on the internet, or contact ViroGates for support on phone number +45 2113 1336 or by email to info@virogates.com

The reader scan the test- and control line and determine the intensity of the lines. The calculation to estimate the suPAR value is based on the test line. The aLF Reader uses a batch specific method for each batch of Quick Triage devices for the calculation. To load the right method scan the provided barcode. The batch specific method is uploaded to the Reader when scanning the provided barcode. The method contains a calibration curve that the reader uses to convert the T-Line's intensity to ng/ml suPAR.

The mathematical calculation is made with a linear curve based on 6 reference samples with known concentrations and a buffer only sample.

OBTAIN RESULTS

The test results will appear on the screen after the test run has finished.

1) Touch the "Print" button to print the results with DYMO LabelWriter or touch the "Export to USB stick" button to save the data in .csv format on USB.

If reader is connected via QLC connect Server to LIS/HIS/middleware/medical office information system all results will be automatically reported. For more information contact Qiagen at aLF-info@qiagen.com

QUALITY CONTROL

The suPARnostic® Quick Triage uses the C-Line as the internal quality control.
The result is faulty if the C-line does not appear on the device after an otherwise successful run of plasma sample.

When the Quick Triage device is used with the aLF Reader it will automatically display if any error has occurred. The reader also has an internal quality control which is run every time the reader is turned on.

READER CALIBRATION

The aLF Reader is a highly sensitive optical Reader for qualitative measurements. When the Reader is turned on a self-calibration check is performed. If the calibration is out of range, the Reader will display an error on the display.

ASSAY PROCEDURE

For measurement of suPAR levels the suPARnostic® Quick Triage (Code No. A003) have to been used (see IFU www.virogates.com/support/user-instructions).

LIMITATIONS OF TEST

Clinical diagnosis should not be based on the result of the suPARnostic® Quick Triage test alone. Interpretation of results must be made considering the patient's clinical history and results of diagnostic tests, if available.

EXPECTED VALUES

All individuals have a measurable suPAR level, and in healthy blood donors (N=9305) the median suPAR level for men aged 18–65 years old is 2.22 ng/mL (25-75% interval from 1.76–2.90 ng/mL)[2], and for women 18-65 years old 2.56 ng/mL (25-75% interval from 2.05–3.23 ng/mL)[2]. In patients attending emergency departments the suPAR level is around 3-6 ng/ml[3,4,7] and in patients with severe disease and organ failure, suPAR is often in the double-digits[5,6]. The higher the suPAR level, the higher the risk of disease progression and the worse the prognosis.

REFERENCES

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