QASSAY LATERAL FLOW READER

Instructions for use

INTRODUCTION

INTENDED USE

Photometric analyser of lateral flow assay aimed at professional healthcare use. It allows the qualification, semi-quantification and/or quantification of the intensity of the test and control lines in lateral flow strips for in vitro diagnostics. The scope of the samples tested, and the target population is defined by the manufacturer of the diagnostic kit. The integration of Qassay Lateral Flow Reader with the Lateral Flow Strip is not within the scope of this product. The quantification of the analyte to be analysed is the responsibility of the manufacturer of the diagnostic kit. The operation of the device is manual, the device is reusable and powered by an internal battery rechargeable by a USB-C port.

INTENDED USER

The device is intended for indoor use in clinical settings for healthcare professional use.

OPERATING PRINCIPLE

The Qassay Lateral Flow Reader integrates a light source and a multi-channel light sensor, which allow qualitative, semi-quantitative or quantitative measurement of control and test lines on a lateral flow strip.

The reader connects wirelessly to a mobile app or PC. The lateral flow strip is manually inserted and removed when prompted by the application. The data captured by the reader is sent by the application to the cloud, where it is processed. The results obtained are returned to the application.

IN THE EVENT OF AN ADVERSE EVENT

'Serious adverse event' means any adverse event that led to any of the following:

(a) a patient management decision resulting in death or an imminent life-threatening situation for the individual being tested, or in the death of the individual's offspring,

(b) death,

(c) serious deterioration in the health of the individual being tested or the recipient of tested donations or materials, that resulted in any of the following:

(i) life-threatening illness or injury,

(ii) permanent impairment of a body structure or a body function,

(iii) hospitalisation or prolongation of patient hospitalisation,

(iv) medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function,

(v) chronic disease,

(d) foetal distress, foetal death or a congenital physical or mental impairment or birth defect.

If the user becomes aware of a serious adverse event while using the device, they are responsible for reporting the serious adverse event to the competent authorities of the country in which the user or patient is located, as well as to the responsible body."

The responsible body is the legal manufacturer of the diagnostic kit (Qassay Lateral Flow Reader + lateral flow strip), and it is the one that must report incidents related by the analyser to P4Q Health S.L.U.

The directory of competent authorities for national European medical devices can be found at the following link:

www.health.ec.europa.eu/medical-devices-sector/new-regulations/contacts_en

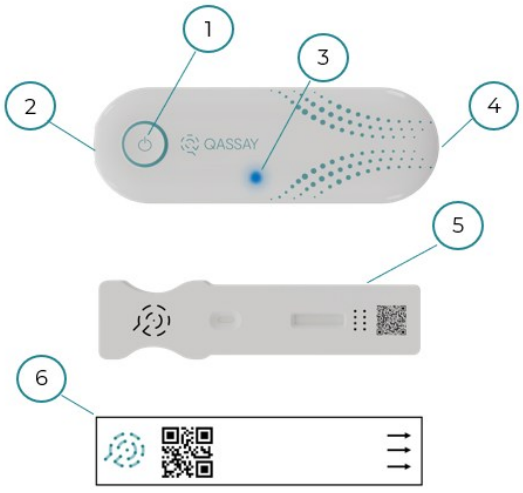
DESCRIPTION

DEVICE DESCRIPTION

The Qassay Lateral Flow Reader is a photometric lateral flow strip analyser aimed at professional healthcare use. It allows the qualification, semi-quantification or quantification of the intensity of the test and control lines in lateral flow strips for in vitro diagnostics. The scope of the samples tested, and the target population is defined by the manufacturer of the diagnostic kit (Qassay Lateral Flow Reader + Lateral Flow Strip). The integration of Qassay Lateral Flow Reader with the Lateral Flow Strip is not within the scope of this product.

The device consists of two parts, one static and one mobile. The static part is the Qassay Lateral Flow Reader (a hardware) and the moving part is a lateral flow strip of the diagnostic kit to be analysed which is inserted manually.

The user interface is located in a mobile app or PC, which guides the user through the use of the device. It sends the data to a cloud platform for data processing and the result is reported in the app. The device is turned on and off via a button, and the status of the device is displayed on the Qassay Lateral Flow Reader itself via a status LED. The following figure shows the main components of the device:



No.	NAME	DESCRIPTION
1	On/off button	Button that can be used to turn the device on and off
2	USB-C port (charge only)	USB-C port, charging functionality only
3	Status LED	LED that indicates what status the device is in
4	Test housing	Housing where the test is inserted
5	Lateral Flow Assay	Lateral Flow Assay (Not Included)
6	QC kit	QC kit to check device performance

The device is accompanied by a support software, Qassay Studio, which is used to manage the types of strips and batches of these types of strips. The support application is also used to generate calibration curves associated with each batch of strips. Instructions for use of the support software are distributed separately.

PERFORMANCE FEATURES

The performance characteristics of the device are as follows:

- Inter-device CV: < 10%[1]
- Intra-device CV: < 10%[1]

The analytical and clinical performance characteristics must be studied and validated for each of the diagnostic kits.

[1] Inter-device CV and intra-device CV values studied for a single test type, each test must have its own performance studies to declare this data

MATERIAL SUPPLIED

The packaging includes the following items:

No.	DESCRIPTION	MODEL	QUANTITY
1	Qassay Lateral Flow Reader	Q1A-DUO-USB	1
2	QC kit	PQ21001-QC-000	1
3	USB-C cable	900CABUSBAC	1

Unwrap the box carefully and check the materials. If any part is damaged or missing, please contact your local distributor.

PRODUCT ACCESSORIES NOT INCLUDED

For the correct operation of the Qassay Lateral Flow Reader, the following additional material is required:

Mobile Device Android (minimum v10) or iOS (minimum iOS 13)	Internet connectivity (Wi-Fi or cellular) Bluetooth connectivity (minimum v4.0) GPS Connectivity Minimum screen resolution 5" CPU capacity (minimum ARM 1.6 GHz) and RAM (minimum 2 GB) Rear Camera
Qassay App (Available on the Play Store, iOS App Store or Qassay website)	The Qassay app is designed for use with the Qassay device. Guide the user step-by-step through the entire process with visual messages and images.
Diagnostic Kit	The preparation procedure is described in the instructions for use of the diagnostic kit.

BATTERY CHARGING

The device has an internal battery, not accessible by the user, rechargeable via the USB-C port on one end of the device. The device's status LED turns sinusoidal purple while charging, and once fully charged it turns static green. The full charge time from 0% to 100% is about 2 hours. (5V/100 mA; Pmax 1 W).

DEVICE STATUS

The device has different status, identifiable via the status LED:

ACTION	STATE
Incremental Blue Gradient	The device is turning on
Decrescent Blue Gradient	The device is shutting down.
Rapid blue flashing	The device is looking for mobile devices to connect to
Slow blue flashing	The device has been paired to a mobile device
Sinusoidal purple	The device battery is charging and the device off
Rapid purple flashing	The device is on while charging and pairing
Slow purple flashing	The device is on while charging and connected
Rapid red flashing	The device is in a low battery state and pairing
Slow red flashing	The device is in a low battery state and connected
Solid green	The devices battery is fully charged
Rapid green flashing	The device battery is full USB connected, and pairing
Slow green flashing	The device battery is full USB connected, and connected to a device

WARNINGS AND SAFETY CONSIDERATIONS

- For accurate results, the instructions for use should be followed.

- For proper use of the diagnostic kit, see the specific instructions for use.
- Clean the reader according to the instructions specified below.
- Do not use the reader if it is visibly damaged.
- Always perform the tests under the indicated environmental conditions.
- Do not use the reader near strong electromagnetic fields.
- Do not attempt to open the reader case.
- Handle the device with care and avoid falling to heights greater than 1 meter.
- Follow the guidelines of local authorities to dispose of the device.
- The device is reusable.
- If the device is not responding, please press and hold the power button for 20 seconds to reboot the system.
- The device meets the requirements for a Grade 2 pollution level, do not expose it to higher degrees of pollution.
- The device has a shelf-life of 5,000 readings. The user is responsible for the use of the device after this time.
- Wear gloves when handling the reader.
- The device must be used indoors.
- The degree of tightness of the device is IPX0.
- The device can be used up to 4000 m above sea level.
- For waste collection, the disposal instructions given by the legal manufacturer of the diagnostic kit must be followed
- If the QC procedure is failed, the device shall not be used anymore.
- Check if the QC kit has no visible damage or deformation. If so, please contact your distributor.
- Make sure to store the QC kit on its bag inside the provided box after each use.
- For reaction time of the applicable test please refer to the instructions for use of the diagnostic kit
- In case of any inconvenience with the test, please replace it with a new test
- UV light is present, please keep away from eyesight the inner part of the device during operation
- Please use only accessories recommended to be used with the device
- In case of malfunction of the device, please contact your distributor

TEST PROCEDURE

INITIAL PREPARATION

If you've never used a Qassay Lateral Flow Reader before:

- First, read these instructions for use.
- Download and install the "Qassay" app from the Play Store, iOS Apple Store or the Qassay website.
- If needed, contact your distributor to get an invite to create a user to the platform

Please do charge the battery of the device before first use as stated in “Battery Charging”.

If you are using the diagnostic kit for the first time, carefully read the relevant instructions for use and familiarize yourself with the process.

Before you begin, make sure you are in a suitable environment to take the test:

- Reader: temperature 5-40ºC, 20-90% RH and stable ambient light, avoid sun exposure.
- Diagnostic Kit: See the relevant instructions for use for details.

The test should be kept out of the Qassay device until instructed to do so by the app. If the extraction speed is not adequate, the mobile application will ask you to repeat the reading, via the following message in the bottom of the display: “Reading error. Please, insert the test again”.

The app could deem the test as invalid, if it detects there is abnormal signal or a long time has passed since the reaction time expired, which would use the message “Invalid Test”.

QASSAY IDENTIFICATION

Each reader must be identified with a QR code and a unique device identifier (UDI) that allows the Qassay to be identified, on the label on the back of the device. For example:

(01) Global Identification Number (GTIN), 8445982000075

(11) manufacturing date, 22/01/2024

(10) Batch number, 059955

(21) Serial number, A101023654

In the application, devices are identified with the following structure: QASSAY-(last 4 digits of serial number). For example, the device with serial number A101023654, would show the QASSAY-3654 device.

FIRST TIME PAIRING (BLUETOOTH PIN)

The first time a device is paired to a smartphone device, it will be asked to input a 6-digit PIN to encrypt the communication. The PIN is available in the label of the device alongside the 🔒 symbol and on the box.

TURNING THE DEVICE ON/OFF

To turn on the device, press and hold the power button for 2 s, until the status LED turns blue incrementally until it starts flashing. To turn off the device, press and hold the power button for 2 s until the status LED turns off.

ACCESS TO THE APPLICATION

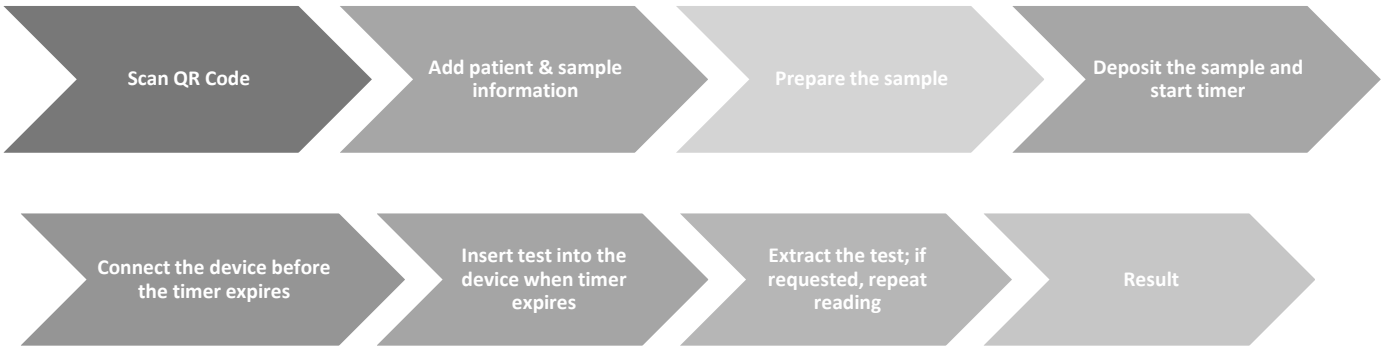
The Qassay app is available on both the Google Play Store and the iOS App Store for free. Access to the application is done with the credentials provided by the distributor.

MODES OF OPERATION

The Qassay app offers the modes of operation described in the following sections.

New test

The "New test" mode of operation allows a reading of the entire preparation flow to be carried out with on-screen instructions. The flow is as described in the following flowchart:



Test Queue

The "Test Queue" mode of operation allows you to perform several consecutive readings with a single reader. Whenever a test has been prepared and the timer is ongoing, a New Test can be prepared, and the timer will

be tracked in the app as well. You can make as many tests as required, you will have all the timers ongoing on the "Test Queue" menu.

Test menu

This section allows the user to select which test wants to see information of the available test. This option is only available for lay-users.

Results

This module allows you to view the latest results made by that user. If you click on a card, it will show the result from the reading, and if it is still pending, it will let the user analyze the reading (Analyze a test after app exit).

ANALYZE A TEST AFTER APP EXIT

If after starting the timer, the user gets out of the app, when getting back a pop-up will be displayed to let the user analyze the previous test. If they press Accept, the process will be resumed.

QC PROCEDURE

There is a Quality Control (QC) procedure implemented in the app to ensure the device maintains its functionality along its shelf life. The QC kit shall be stored inside the packaging for proper maintenance. In case of damage to the QC kit please contact your distributor.

The QC is enabled in the "Profile" section, Quality Control button. The app will ask the user to scan the QR code on the QC kit, then connect the device, insert the QC kit inside the reader until it touches the back of the tunnel, and then press the QC Check button. The device will make some internal checks which will last about 5 seconds, and afterwards the results (PASS or FAIL) will be displayed on screen. If the result is FAIL, the device shall not be used.

OVER-THE-AIR UPDATE

The device has a built-in functionality for over-the-air update of the firmware (FUOTA). This feature is available at the "Profile" section, check for updates button. The device will just be updated in case there is a more recent firmware version available than the one installed. The update process status will be shown in the display and once finished the user will be notified.

INTERPRETATION OF RESULTS

The reader measures the intensity of the test and control lines in the lateral flow test to measure the levels of the analyte specified in the diagnostic kit. It is advisable to confirm the results by means of a liquid chromatography-mass spectrometry (LC-MS/MS) test.

COMMON ALERTS AND ERRORS

In case of any error, the app will alert the user and suggest an action. Please follow the on-screen instructions.

ERROR	ACTION	EXPLANATION
Device won't turn on	Charge your device using the USB-C port	The battery of the device is low. To ensure proper operation, please charge the device via the USB-C port
Test Not Found	Check that you are reading the correct QR code	The code on the scanned test is not found in the database. Please make sure you are reading the correct code.
Reader not compatible	Please use a DUAL reader instead	The test you are trying to read is fluorescence, but the reader is only visible.

The mobile device's Bluetooth is turned off	Enable the Bluetooth of the mobile device from the system settings	The phone's Bluetooth communication is not activated. Please go to the system settings of your mobile device and enable Bluetooth communication.
Camera permissions turned off	Enable camera permissions on the mobile device from the system settings	Camera permissions are turned off on the mobile device. Please go to your mobile device's system settings and enable camera permissions.
Failed Pairing	Retry the connection	Pairing with the device has failed. Please reconnect.
Reader not connected to smartphone/tablet	Retry the connection	The reader is not connected to the smartphone/tablet. Please reconnect
Test has been removed fast/slow	Insert the test back into the reader and remove at a constant speed	The test has been extracted too fast or too slow and the reader has not been able to acquire data properly. Please reinsert the test into the reader and perform a constant speed extraction.
Device not connected	Make sure the device is on and it is paired via PIN	The app could not establish connection with the Qassay. It could be because the device is not switched on or it is not paired via PIN
Expired strip	Scan a QR code for a batch that is not expired	The batch scanned is expired
Invalid Test	Repeat procedure with a new test	The test has been deemed invalid due to:: - Long time after reaction time - Missing control line - Unexpected signal

MAINTENANCE

REGULAR MAINTENANCE

Maintenance of the Qassay Lateral Flow Reader is essential to ensure proper operation of the device.

Before each use:

- Inspect the device, and make sure it is clean and visibly undamaged.
- Check that the battery is charged.

After each use, clean the outside of the Qassay and store it in its container to prevent dust and contamination from entering.

Before cleaning, make sure the device is turned off and unplugged. Wipe the outside with a damp cloth with one of the following products:

- Soapy water.
- Isopropyl alcohol (dissolved in 70% water)

Do not clean any of the internal or interior surfaces.

If you suspect that the reader is not in perfect condition, do not use it and inform the responsible body (specified in the section "In the event of an adverse event").

Precautions:

- Do not immerse the device in liquids and make sure no fluids enter the unit.
- Do not sterilize the device.
- Do not use cleaning agents such as bleach and ammonia.
- Do not use abrasive agents such as strong solvents such as acetone, bleach or derived agents.
- Do not insert anything into the slot other than the test or QC kit supplied by the manufacturer.

STORAGE & TRANSPORT

The device must be stored and transported under the following environmental conditions:

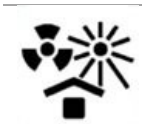
- Temperature: -20 - +50°C
- Relative humidity: 20-90%
- Avoid direct contact with the sun

DEVICE RECYCLING

Do not dispose of the device in regular household waste. Follow local regulations for the disposal of electronic waste.

GLOSSARY OF SYMBOLS

SYMBOL	TITLE	EXPLANATION
	Legal manufacturer	The legal manufacturer of the device
	Reference Number	Medical Device Reference Number
	Batch number	Device Lot Number
	Serial Number	Device Serial Number
	In Vitro Diagnostic Medical Device	Medical Device for In Vitro Diagnostics
	Date of manufacture	Date on which the medical device was manufactured
	Refer to the instructions for use	The instructions for use must be read before using the device
	Unique Device Identifier (UDI)	A tag that contains the device's unique identifier (UDI) information
	Patient Information Webpage	Website where the patient can obtain more information about the medical device
	Precaution	Caution should be exercised when using the device or near the device near where the symbol is located, or to indicate that under current conditions the operator should exercise caution to avoid unintended consequences.
	Humidity Limit	The humidity limits to which the medical device can be safely exposed
	Temperature Limit	The temperature to which the device can be safely exposed
	Non-Sterile Medical Device	The medical device is not in sterile condition

	Stay Out of Radiation	The device should be kept out of direct radiation exposure
	Stay Dry	The device should be kept dry and water ingress should be prevented
	Bluetooth® Low Energy Connectivity [1]	The medical device contains Bluetooth® Low Energy connectivity
	Waste Recycling	The device, being an electronic waste, cannot be disposed of in a normal trash
	CE Marking	The device complies with the European regulation of medical devices for in vitro diagnostics

REVISION HISTORY

REVISION	DATE	MODIFICATION
K	2025-06-04	Changed reference to Q1A-DUO-USB-002

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