QASSAYLATERAL FLOW READER

Instructions for use

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1. Intended use

Photometric lateral flow strip analyzer aimed at professional 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.

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

2. Intended User

The device is intended for professional use.

3. Principle of Operation

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, which also includes visual operating instructions for the user. The lateral flow strip is placed on the corresponding adapter tray of the diagnostic kit and 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.

4. Product Accessories

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

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. ○ Maximum dimensions: 25x6 mm

5. Material Supplied

The packaging includes the following items:

No.	DESCRIPTION	MODEL	QUANTITY
1	Qassay Lateral Flow Reader Visible or Qassay Lateral Flow Reader DUAL	Q1A-VIS-USB o Q1A-DUO-USB	1

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

6. Test Procedure

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

- Reader: temperature 5-40°C, 20-90% RH and stable ambient light, avoid sun exposure.
- Diagnostic Kit: See the relevant instructions for use for details.
- Qassay app installed on smartphone

Turning the device on/off

To turn on the device, press and hold the power button for 1 sec, until the status LED lights up in blue. Similarly, to turn off the device, press and hold the power button for 1 s until the status LED turns off. In the event that this LED turns red, it must be charged, as indicated in section "8. Battery Charging Instructions"

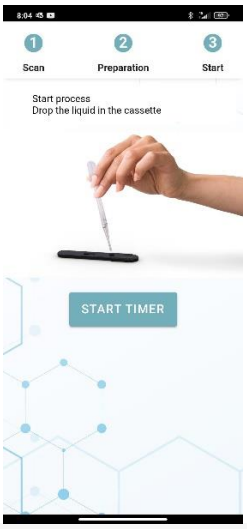
New test

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 table:

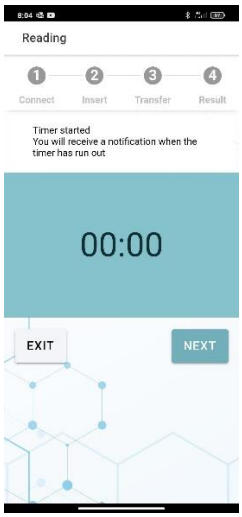
1. Identify the type of strip using a QR code

2. Prepare the sample as directed in the instructions for use of the diagnostic kit

3. Place the sample, and start the timer

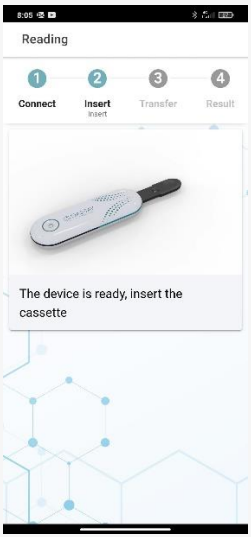


4. Wait for the timer to finish

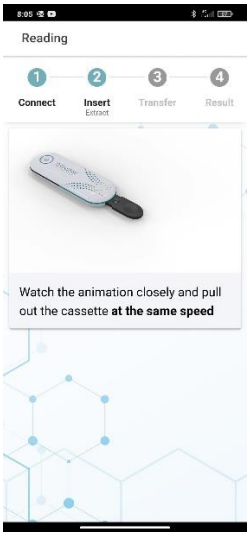


5. Pair the device to the mobile phone

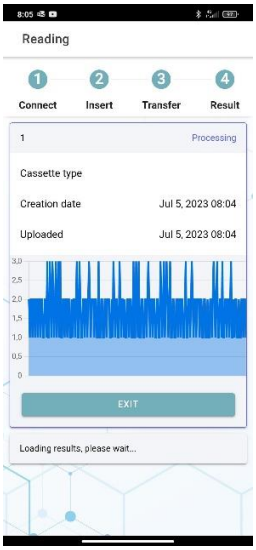
6. Insert the cassette inside as shown in the video



7. Remove the cassette as shown in the video



8. The result will be displayed on the screen



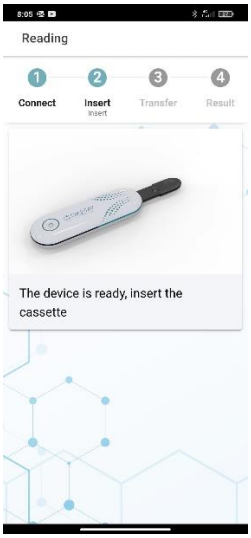
Quick test

The "Quick test" mode of operation allows you to perform several consecutive readings with a single reader, with less information about the preparation flow. The flow is as described in the following table:

1. Pair the device to the mobile phone

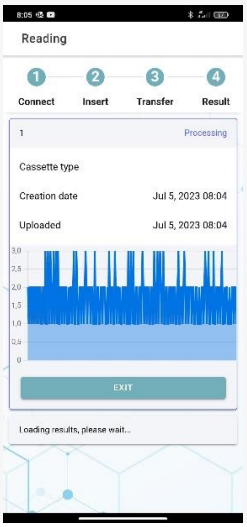
2. Identify the type of strip using a QR code

3. Insert the cassette inside as shown in the video

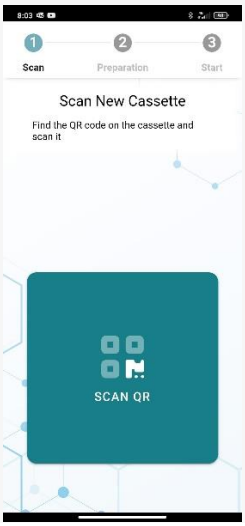


4. Remove the cassette as shown in the video

5. The result will be displayed on the screen



6. Start the process in step 2



7. 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.

8. Battery Charging Instructions

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

9. 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
Cassette Not Found	Check that you are reading the correct cassette	The code on the scanned cassette is not found in the database. Please make sure you are reading the correct code.
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
Tray has been removed fast/slow	Insert the tray back into the reader and remove at a constant speed	The tray has been extracted too fast or too slow and the reader has not been able to acquire data properly. Please reinsert the tray into the reader and perform a constant speed extraction.

10. Warnings

- 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 30 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 lifespan of two years from the date of manufacture of the device. 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.

11. 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.
- Open the app and follow the on-screen instructions for use and register as a user.

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

12. 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 case of incident").

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 adapter tray supplied by the manufacturer.

13. Storage and Transportation Conditions

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

14. Analytical Performance Characteristics

For sensitivity, specificity, accuracy, linearity and analytical precision please see the instructions regarding the test kit. The protocol for establishing these statistical measures for the reader (EP05, EP06, EP09 and EP15) in combination with the specified test is supplied to the legal manufacturer of the immunoassays.

Disclaimer: The results shown in this document are those of the clinical research conducted for the Hb1Ac analyte; This data should be taken as supplementary information.

The accuracy of the Qassay Lateral Flow Reader has been studied for the HbA1c analyte by comparing it with the results obtained with an HPLC (High Precision Liquid Chromatography) device, which is the gold standard for analytical measurements.

- The sensitivity of the Qassay Lateral Flow Reader is 4% Hb1Ac
- The accuracy of the Qassay Lateral Flow Reader is < 15%
- The accuracy of the Qassay Lateral Flow Reader has been studied with two samples measured as 5.2% HbA1c and 10.9% HbA1c by the HPLC device.
    - Repeatability has been studied by replicating the same sample 20 times, making a total of 40 samples (C.V. < 15%)
    - Reproducibility has been studied by replicating the same sample 30 times, making a total of 60 samples (C.V < 15%).

15. In the event of an incident

'Major incident' means any incident which, directly or indirectly, could have had or has had any of the following consequences:

(a) the death of a patient, user or other person;

(b) the serious impairment, temporary or permanent, of the health of a patient, user or other person;

(c) a serious threat to public health;"

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

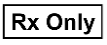
The responsible body is the legal manufacturer of the diagnostic kit (Qassay Lateral Flow Reader + lateral flow strip), and it is the one that must report incidents related by the analyzer to P4Q Health S.L.U.

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

Although the device has been studied to meet comprehensive safety standards and trials, certain adverse events may occur on a larger scale of use. The goal of the communication system is to identify the technical causes of incidents in order to modify procedures, design, manufacturing, or usability to protect patients.

16. Glossary of Symbols

SYMBOL	TITLE	EXPLANATION
	Maker	The legal manufacturer of the device
	Catalog Number	Medical Device Catalog Number
	Batch number	Device Lot Number
	Serial Number	Device Serial Number
	In Vitro Diagnostic Medical Device	Medical Device for In Vitro Diagnostics
	Prescription use	Medical device only on prescription
	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	The medical device contains Bluetooth® Low Energy connectivity
	E-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
	FCC Symbol	The device complies with the *Federal Communication Commission* (FCC) provisions on radio frequency devices

17. Qassay Identification

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

(01)01053213000004(17)270522(10)321TQS(21)6585HR7C08

(01) Global Identification Number (GTIN), 01053213000004

(17) expiry date, 27/05/2022

(10) Batch number, 321TQS

(21) Serial number, 6585HR7C08

18. Document Registration

REVISION	DATE	MODIFICATION
D	2024-06-06	FCC/ISED regulatory notice update

19. Legal Manufacturer

P4Q Health S.L.U.
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48810, Alonsotegi (Bizkaia) – SPAIN
Tel.: (+34) 94 498 2028
Fax.: (+34) 94 498 0413
E-mail: nchealth@p4q.com
Web: www.p4q.com

20. FCC/ISED regulatory notice

This device complies with Part 15 of the FCC Rules and contains transmitter(s)/receiver(s) in compliance with Innovation, Science and Economic Development Canada's licence-exempt RSS(s). Operation is subject to the following two conditions:

(1) this device may not cause harmful interference, and
(2) this device must accept any interference received, including interference that may cause undesired operation.

This device is approved for portable use conditions without distance restrictions regarding RF exposure compliance under FCC 2.1093 and ISED RSS 102 standards.

Le present appareil est conforme aux Part 15 des FCC Rules et contiens émmeteur(s)/récepteur(s) exempts de licence conformes aux CNR d'Innovation, Sciences et Développement économique Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes :

(1) l'appareil ne doit pas produire de brouillage;
(2) l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

Cet appareil est approuvé pour des conditions d'utilisation portables sans restrictions de distance concernant la conformité à l'exposition aux RF selon les normes FCC 2.1093 et ISED RSS 102.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

—Reorient or relocate the receiving antenna.

—Increase the separation between the equipment and receiver.

—Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

—Consult the dealer or an experienced radio/TV technician for help.

Any change and/or modification without the express approval by the party responsible for compliance could void the user's authority to operate the equipment.