

Smarter solutions, **better outcomes**

For Emergency Use Authorization only. For *in vitro* diagnostic use. Rx only



 LumiraDx™ Platform



Diagnostic-led care is changing ... introducing the LumiraDx Platform.

LumiraDx recognizes the need to provide more effective, cost-efficient healthcare for everyone. We make diagnostic-led care simpler and more accessible with smarter connected diagnostics and diagnostic-led care solutions to enable better health, better experiences and better outcomes.

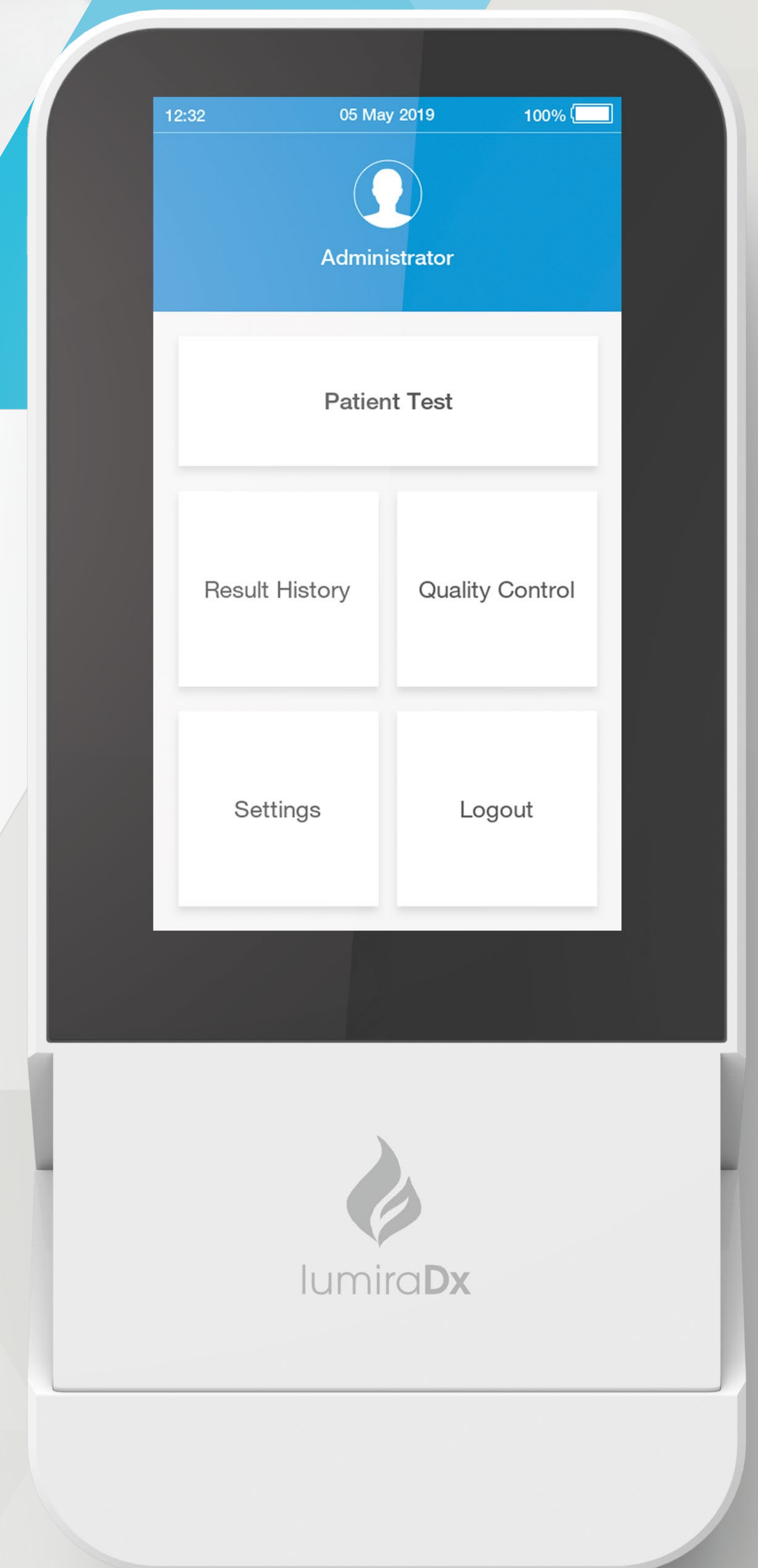
The LumiraDx Platform is designed to transform patient care with a high-performance solution that meets all the needs of point of care diagnostics.



Smart diagnostic platform

The LumiraDx Platform is an innovative, next generation point of care system that combines a small, portable instrument, advanced low cost test strip and seamless digital connectivity. Its proprietary technology enables it to deliver exceptional point of care clinical performance, while being simple and easy to use.

- Performance referenced to laboratory test
- Portable instrument, seamless connectivity
- One simple, intuitive test workflow
- Fast results in minutes
- All common clinical samples
- Room temperature storage



Platform technology

The LumiraDx Platform and tests are designed on similar principles as lab analyser systems to deliver accurate results compared to laboratory reference assays across a number of parameters in a portable, easy-to-use point of care solution.

Comparison of design principles of the LumiraDx Platform compared to laboratory analysers

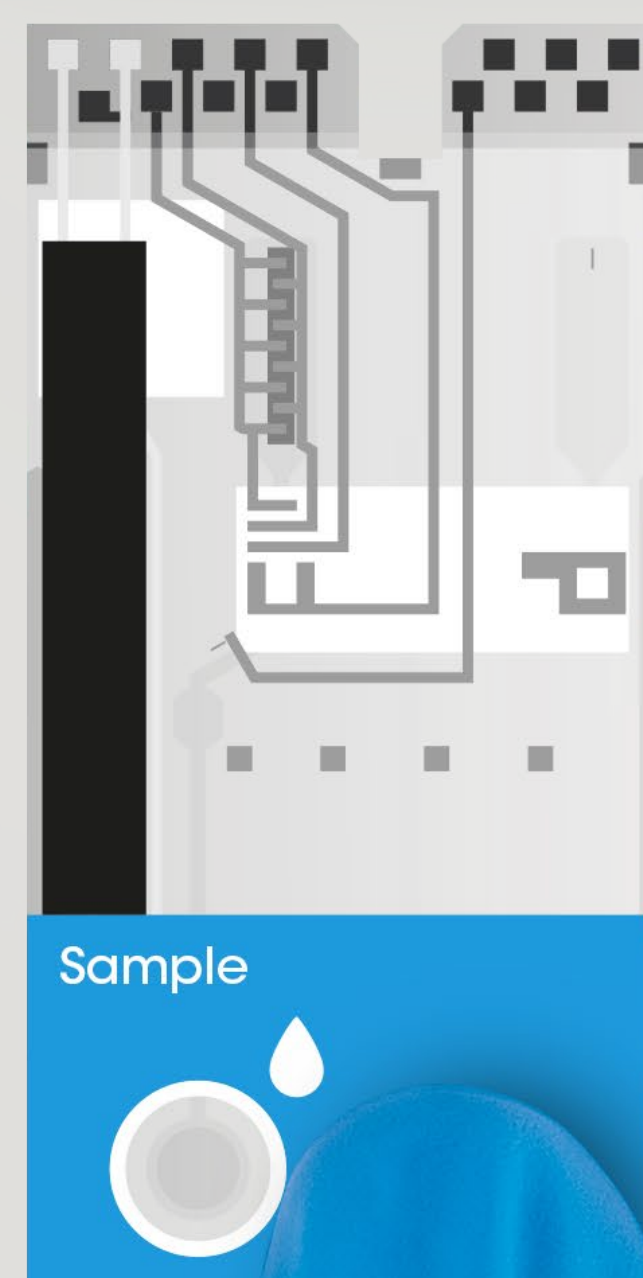
	LumiraDx Platform	Lab Analyser
Common measurement method	Fluorescence / electrochemistry	e.g. Fluorescence / chemiluminescence
Precise fluidic control	Internal micro pumps	Syringe pumps
Reducing sample matrix bias	Measurement in liquid-free environment	Multiple buffer washes
Control of non-specific binding	Surface coating / blocking agents	Surface coating / blocking agents
Calibration bias	Calibration to standard lab reference sample and assays	Calibration to standard lab reference sample and assays
Assay precision	Materials, reagents, manufacturing process and assay controls	Chemistry, reagents and assay controls



Platform design features

The highly integrated LumiraDx Test Strip and Instrument deliver the following features:

- Fluorescence or electrochemistry measurement for assays
- Portable, lightweight design with a rechargeable battery
- Lot Calibration File transfer to the instrument by RFID tag
- System controls for strip positioning, electronics, optics, temperature, and test strip expiry
- Magnetic particle capture for immunoassays
- Immunoassay measurement in a liquid-free environment
- On-strip sample fluid position sensors
- Precise sample fluidic control

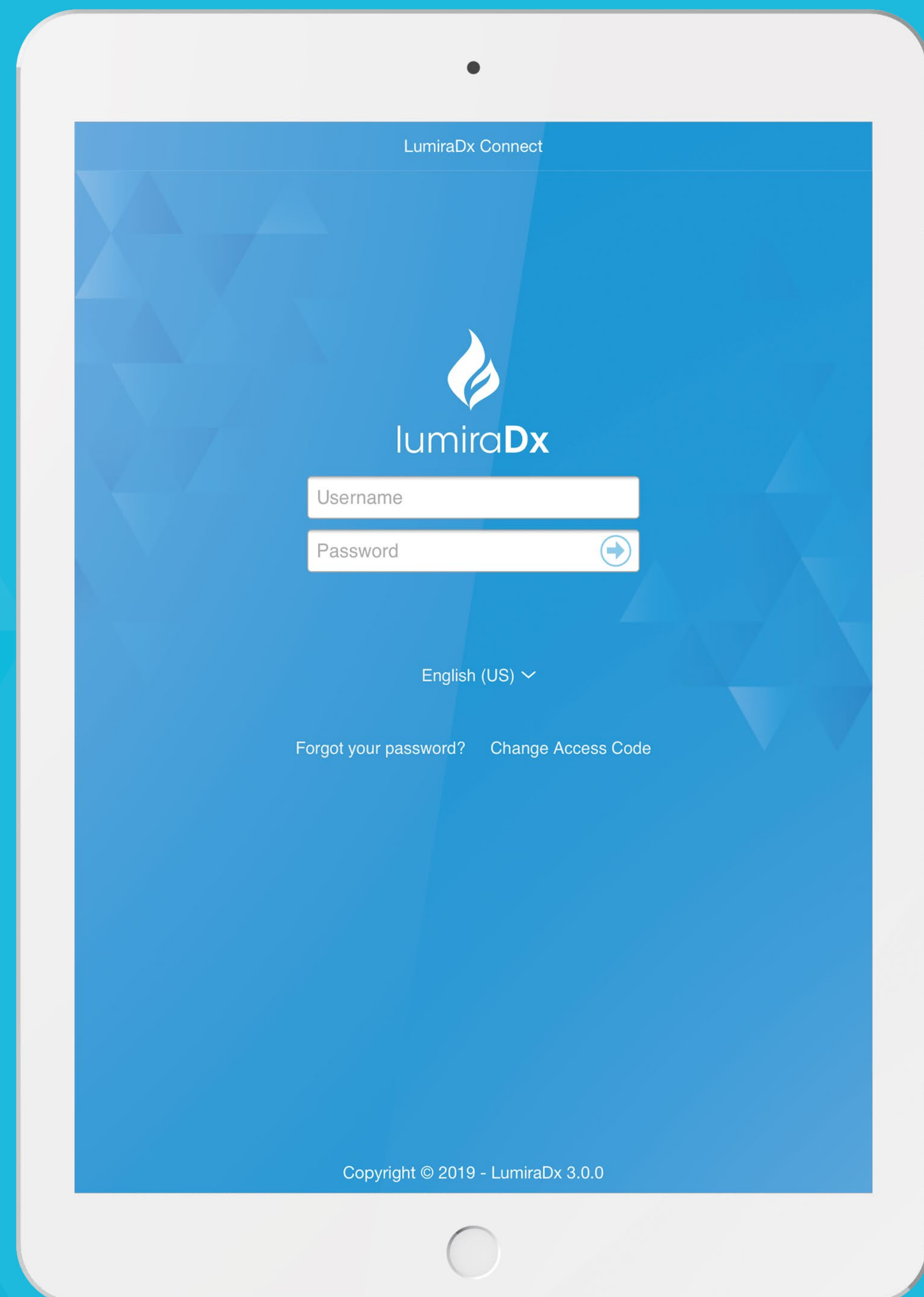


Platform tests

LumiraDx Tests are produced on a bespoke, high-throughput manufacturing line delivering precisely engineered microfluidic test strips at low cost.

- Using small clinical samples, the assays run in tiny chambers - less than 1 μL per chamber from a 15 μL sample
- Platform results are compared to standard laboratory assays using the appropriate laboratory sample as a reference
- Can be used to measure a number of parameters
- Test strips can be stored at room temperature
- Liquid Quality Controls are available





Connectivity designed differently

LumiraDx Connect is a smart, integrated connectivity platform that uses the latest cloud-based technology designed for use with the LumiraDx Instrument. LumiraDx Connect ensures easy, secure transfer of results from the LumiraDx Instrument to Connect Manager or to a patient's record.

- **Connect Manager** – cloud-based services provide all capabilities to remotely manage and configure instruments, view test results and simplify workgroup provisioning. Can be used with mobile, tablet or PC.
- **EHR Connect** - enables the transfer of results from the Instrument to the patient's health record

The LumiraDx Platform instrument can be used in 3 modes: Standalone, Managed or EHR Connected.

Portable & versatile

Designed to deliver for multiple tests, wherever needed.*

- The size and weight of the instrument make it portable. A carry-case is available for ease of transport
- Tests can be performed in numerous care settings*
- Convenient, room-temperature storage of the LumiraDx Test Strips
- Uses internal rechargeable battery or mains power

* Not currently approved for use in ambulances.



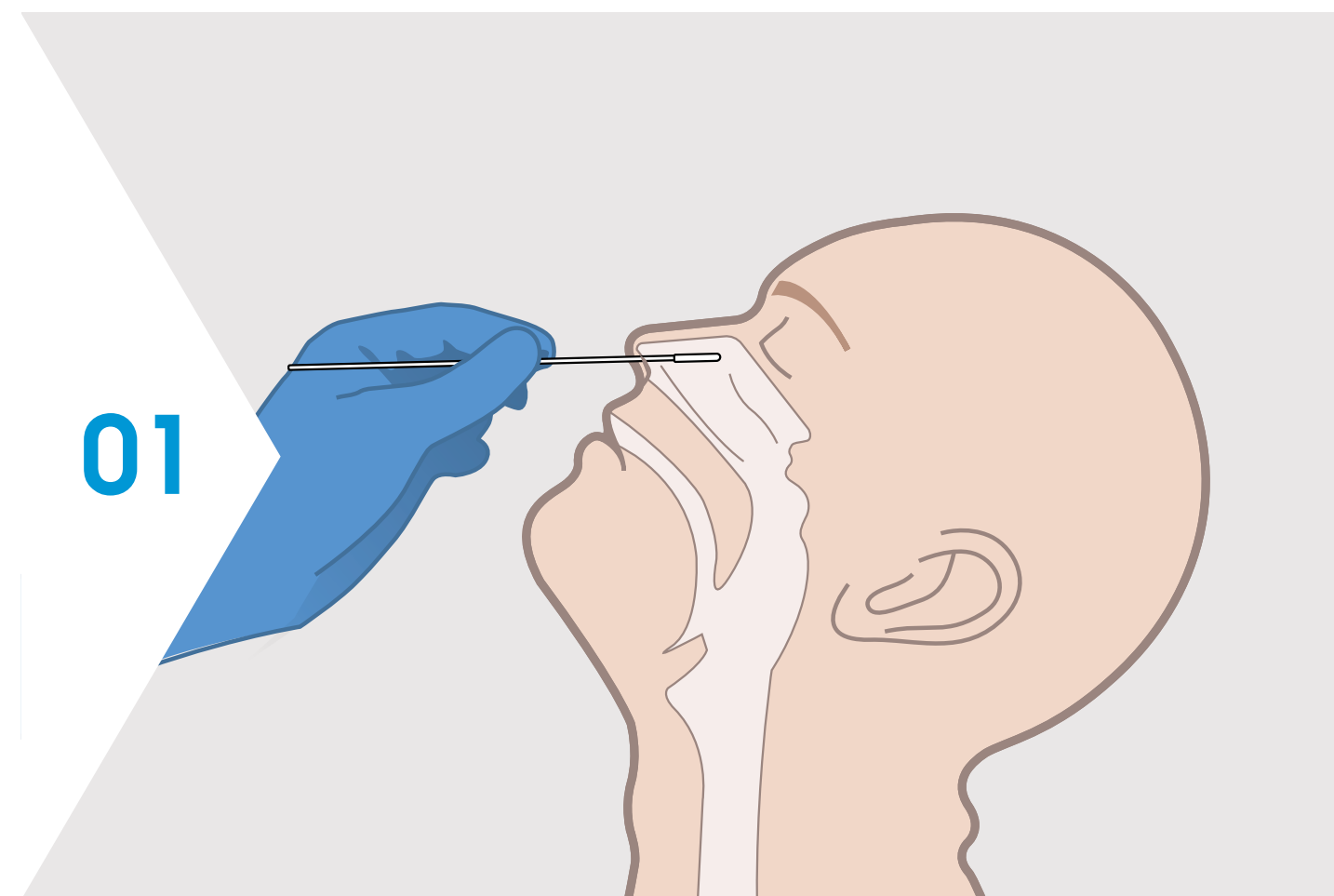


Accurate & fast

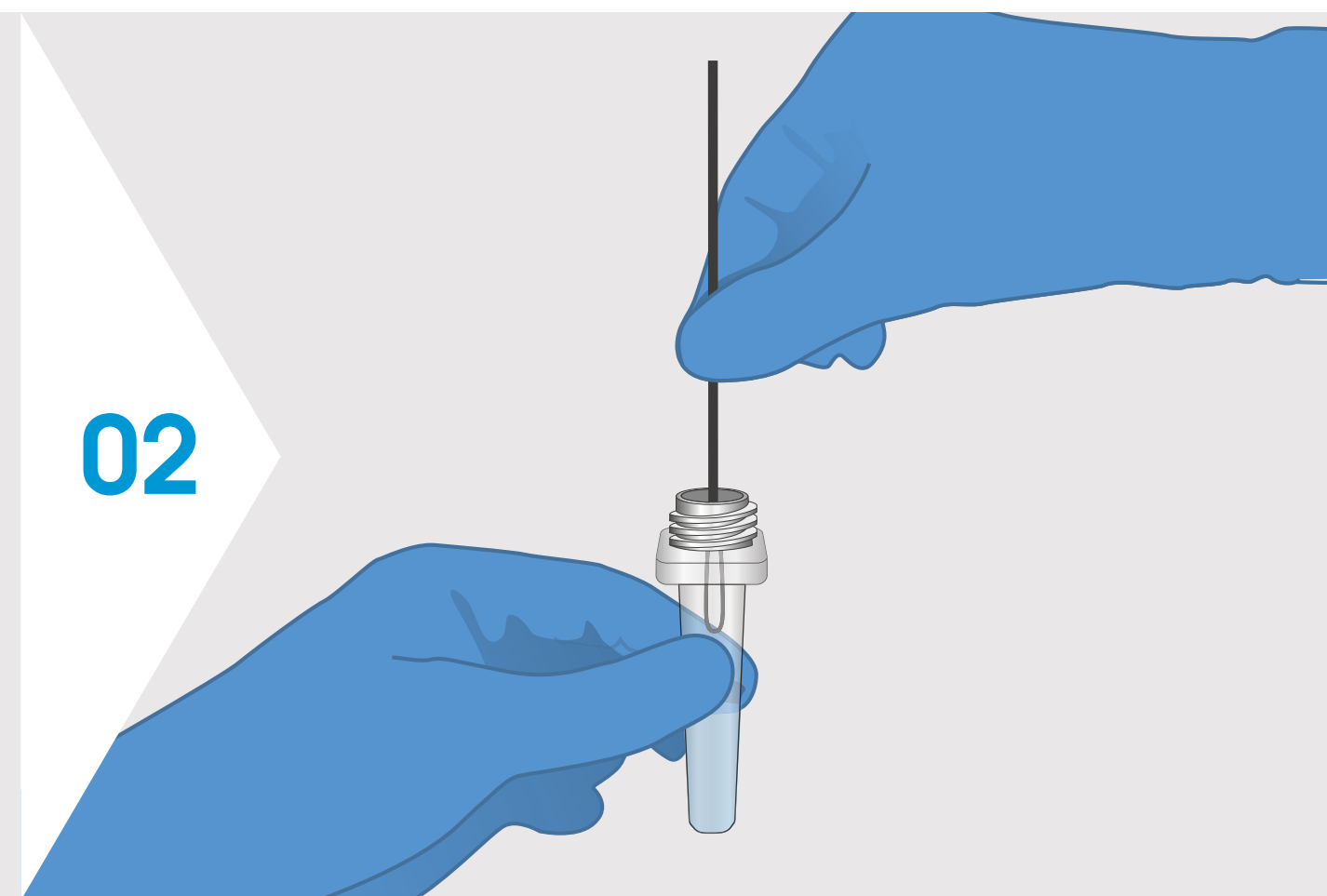
Helps healthcare professionals to provide the appropriate care pathway to patients sooner.

- Clinicians have access to rapid and actionable diagnostic results
- Accurate results compared to laboratory reference tests
- LumiraDx Instrument performs automated functionality checks when power is turned on and during operation
- Test Strip performance and controls are monitored during test runtime
- Quality Control tests using LumiraDx Quality Control solutions can be performed to meet regulatory compliance requirements

Step by step



- Collect patient sample



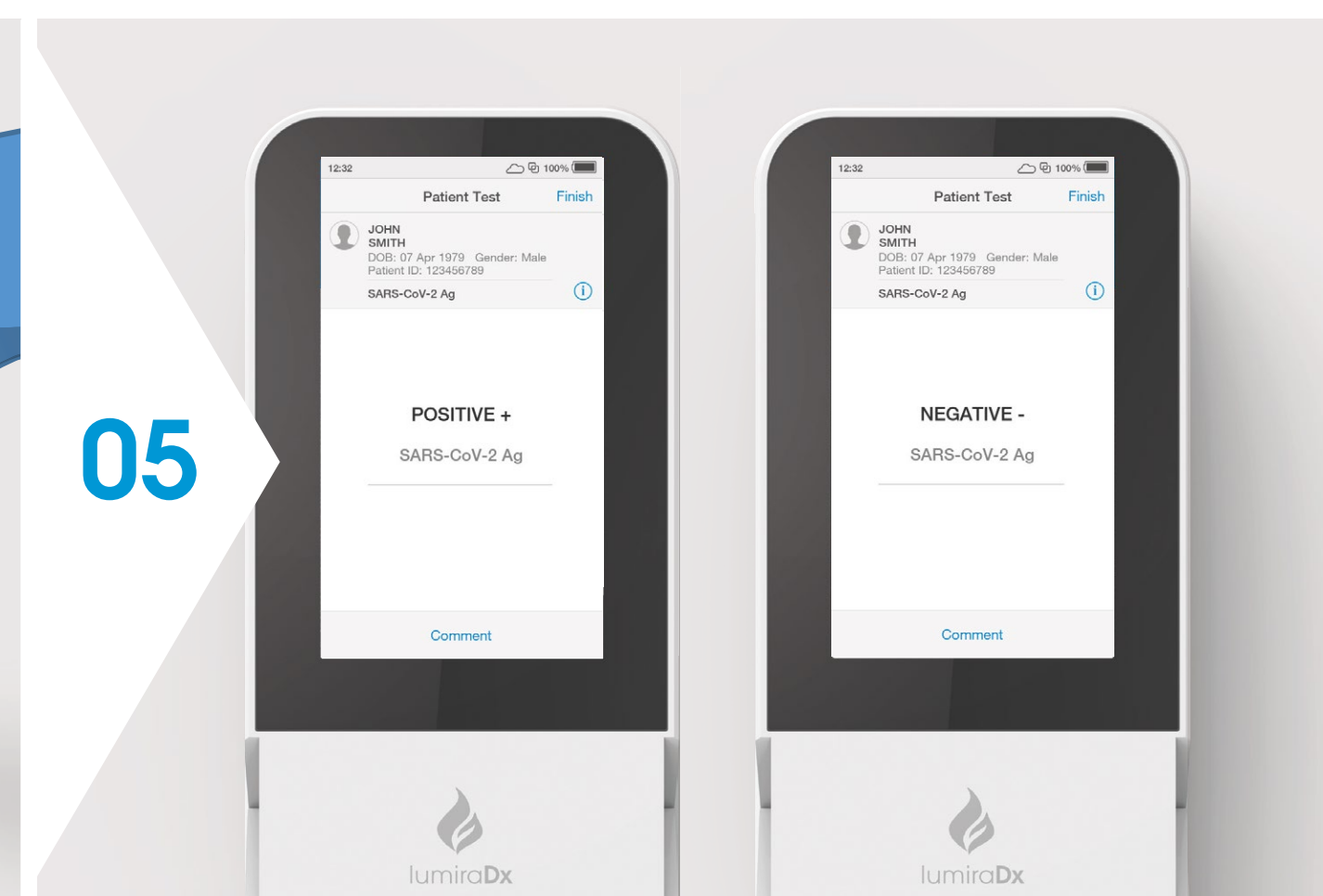
- Prepare sample



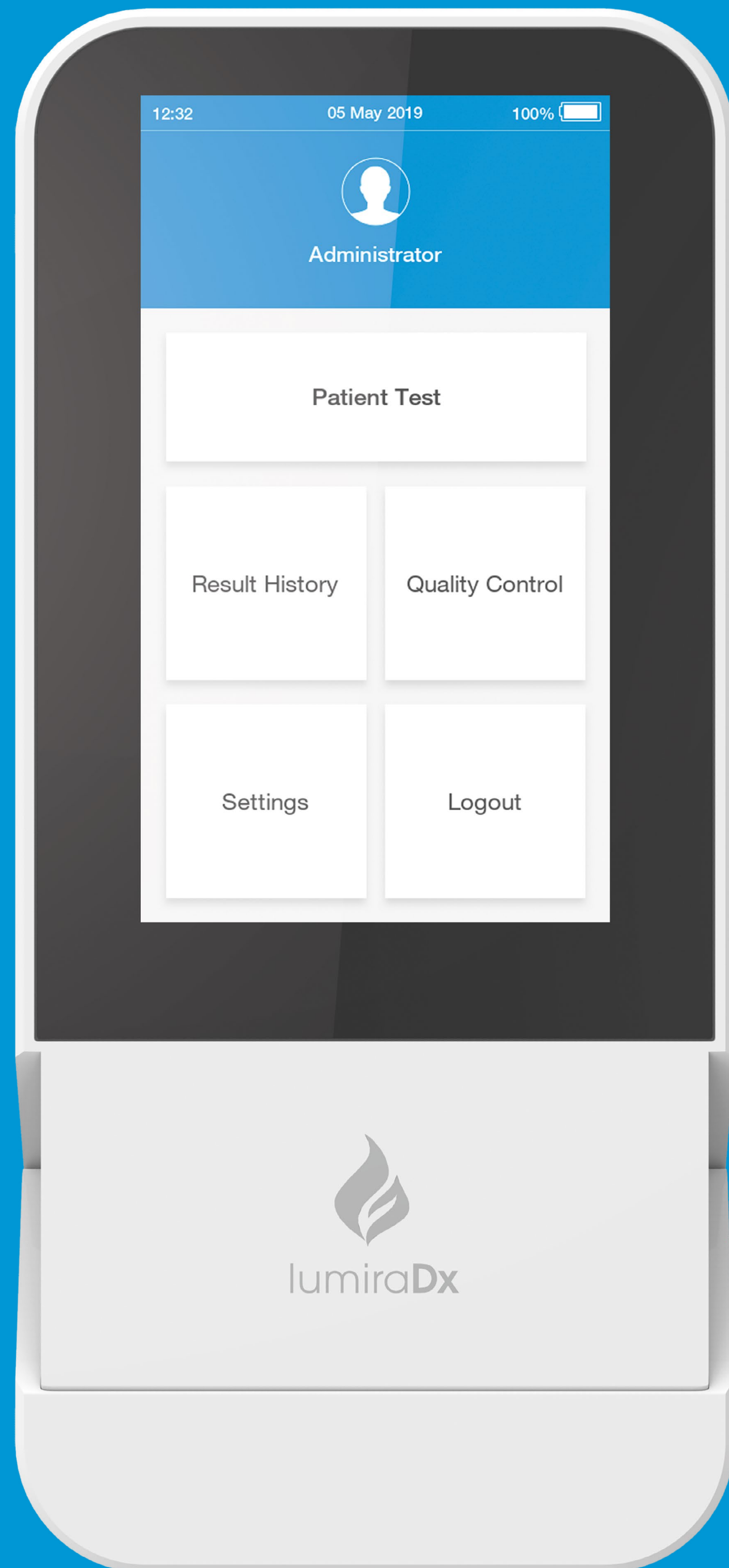
- Insert Test Strip



- Apply & run



- Report results



Simple & patient-friendly

Improves user and patient experience.

The LumiraDx Platform is designed to be easy to use and intuitive, requiring only basic training:

- Step-by-step guidance is provided on the screen at each stage of the test
- The simple touchscreen works like a smartphone
 - Functions and settings are clearly visible and accessible
- Results are delivered quickly and conveniently at the patient's side

Smart & connected

Smart connectivity ensures simple, secure and safe management and data sharing:

- Automatic instrument pairing and data upload
- Remote instrument and workgroup management
- Data can be uploaded to the patient's health record (EHR) anywhere
- Enables efficient and informed co-operation and oversight by care teams
- LumiraDx Connect uses the latest encryption technologies to ensure security and privacy requirements are met

- Power
- Connect



lumiraDx

Instrument specifications

Dimensions	210 mm x 97 mm x 73 mm
Operating temperature, range	Between 15 °C and 30 °C (59 °F and 86 °F)
Storage temperature, range	Between -10 °C and 50 °C (14 °F and 122 °F)
Operation	In Standalone mode or one of two Connected modes: 'Managed' and 'EHR Connected'
Relative humidity	10-90 % (non-condensing)
Maximum altitude	3000 m (9840 feet) operating
Data storage	1000 test results with date, time and comments
Communications	2 x USB ports RFID reader 13.56 MHz, 0 dBi (EIRP) Bluetooth low-energy 2.4 GHz ISM band, 2400 MHz to 2483.5 MHz, 0.5 dBm (ERP)
Power supply unit	Input 100-240 V / 50-60 Hz / 1.0-0.5 A Output: 12 V / 3 A
Battery	Lithium ion polymer 7.4 V 5000 mAh Approx. 20 tests per charge cycle
Weight	1100 g
Display	High contrast touchscreen with a wide viewing angle
Portable device	Instrument is portable and designed to be used on a level, stable surface
Maintenance	Not required – no serviceable parts
Lot Calibration File install	Place the Test Strip carton RFID tag against RFID reader of the Instrument
Ancillary devices	Connect Hub and Connect App for Connected mode; Barcode scanner; USB Memory Stick for software updates; USB Result Printer
Barcode scanner	For patient ID scan, User ID scan for login if using a connected Instrument, and Quality Control solution lot number scan



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Product is not available in all countries and regions. Please check with your local LumiraDx sales representative or distributor for availability in specific markets.

Regulatory status of the LumiraDx SARS-CoV-2 Ag Test in the US

This test has not been FDA cleared or approved; this test has been authorized by FDA under an EUA for use by authorized laboratories. This test has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the virus that causes COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.