lumira**Dx**™ Platform Specifications

Designed to transform patient care –
a high-performance platform that meets
all the needs of point of care testing.

Components

• LumiraDx Instrument
• LumiraDx Test Strips
• LumiraDx Connect (integrated diagnostic connectivity solution)

Description

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
   • Small sample size including capillary blood
   • Room temperature storage

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
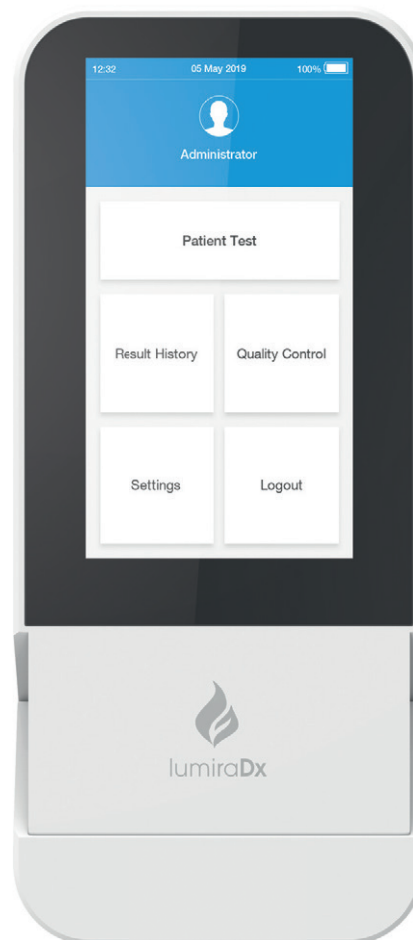portable, easy to use point of care solution.

Quality Assurance

• Instrument and Test Strips are highly integrated and have several quality control functions.
  Automated checks of the correct functioning of the Instrument at power on and during operation.
  This includes:
    - Electrical component operation, heater operation, battery charge state, mechanical actuators
     and sensors and optical system performance
    - Test Strip positioning, optics, hematocrit and Test Strip expiry
    - Monitoring of Test Strip performance and controls during test runtime
• Ability to perform Quality Control Tests using LumiraDx Quality Control to meet regulatory
  compliance requirements
• Onboard Quality Control (OBC) assay for some tests (see Test Strip Product Insert)

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
Overcoming 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

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 – coming soon
Barcode scanner	For patient ID scan, User ID scan for login if using a connected Instrument, and Quality Control solution lot number scan

LumiraDx Connect

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

For more information contact LumiraDx Customer Services by Email: customerservices@lumiradx.com or at lumiradx.com

Not all products are available in all countries and regions. Please check with your local LumiraDx sales representative or distributor for availability in specific markets.

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