

Nexus IB10

Quick User Guide v1.0



Disclaimer:

This Quick User Guide refers to CE-IVD marked products based on the Nexus IB10 technology. These products are certified and approved for the European Economic Area (EEA) only.

Human diagnostic use of such products may be subject to local regulations. This Quick User Guide does not replace or substitute for the Instructions for Use of the respective products. The products may only be used for the intended use defined in their respective Instructions for Use.

CONTACT DETAILS/ FIRST LINE SUPPORT

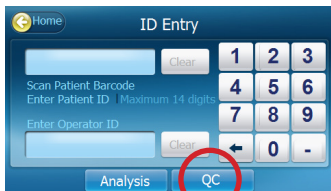
1 How to use EQC

Nexus IB10 EQC is for testing a performance check of the Nexus IB10 system. Performance checks of the system should ideally be carried out once on a daily basis prior to patient testing. **NO SAMPLE PIPETTING**

- 1.1** From the Home Screen press “New Analysis”

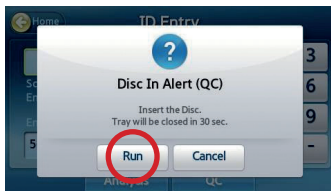


- 1.2** Press “QC”



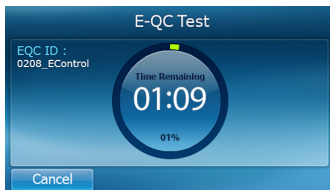
- 1.3** Tray opens. Load EQC disc

- 1.4** Press “Run”



- 1.5** Nexus IB10 will detect the EQC and run test

- 1.6** EQC test takes approximately two minutes to run and displays/prints results



- 1.7** Confirm all EQC results show as “pass”

- 1.8** If results display “Fail”, clean the EQC disc with a lint free, dry tissue. Repeat the process. If results still display “Fail”, contact your local technical support

2 How to run a patient sample on Nexus IB10

2.1 Ensure patient sample is equilibrated to room temperature and gently mixed by inversion. (check IFU for compatible anti-coagulant for the test)

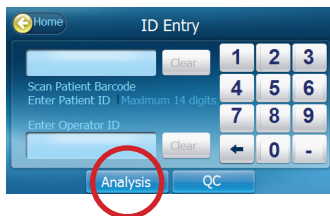
2.2 Pipette sample onto Test disc using a precision pipette fixed or adjusted to 500 μ L (for details see next page “how to pipette a sample”)

2.3 Press “New Analysis”



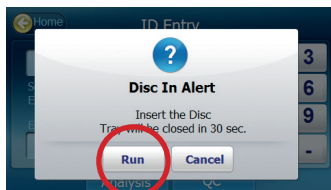
2.4 Enter patient ID or optionally scan barcode with a barcode reader

2.5 Press “Analysis”



2.6 Once the tray opens, place the test disc onto the tray

2.7 Press “Run”



2.8 Nexus IB10 will detect the product type and run test

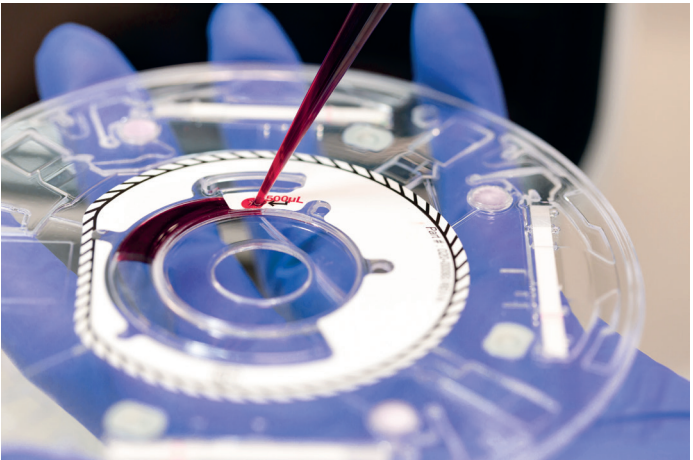
2.9 IB10 sphingotest assay will run for 20 minutes*; results can be recorded or printed out



*22 minutes for IB10 sphingotest® DPP3

3 How to pipette a sample

- 3.1 Using a precision pipette (fixed or adjusted to 500 μL), slowly draw sample into the pipette tip, avoiding bubbles
- 3.2 Positioning the tapered pipette tip at a 45 degree angle, pierce the X on the red dot to expose the sample channel inlet on the Test disc
- 3.3 Slowly express the patient sample into the inlet applying minimum but continuous force on the pipette plunger



- 3.4 Express sample to the First Stop on the pipette.
Do NOT express sample to the second stop; overfilling will cause invalid results

4 Result interpretation guide for controls, EQC and real patient results

The diagram shows a test result screen with various fields and annotations. Red lines connect descriptive labels to specific data points on the screen.

Annotations and their corresponding data:

- Date and time of measurement:** Date: 2019/Jun/06 03:59 pm
- Person who runs the test:** Operator ID: admin
- Patient ID or name:** Patient ID: 1-16
- Test type:** Panel Type: sphingotest Troponin -gg
- LOT number of the test that was performed:** Lot No.: R7001M5L
- Serial number of the instrument:** Serial No.: H00JM3AD400002T
- Current software version on the instrument:** App Ver.: 2.01.00, Panel Ver.: 1.10.00
- Internal control line of the performed test:** Control line: Valid
- Upper or lower reference limit:** URL: .10
- Quantitative patient result:** 0.12 ng/mL

Table of Test Results:

Analyte	Result	Unit
A Tnl	0.12	ng/mL
Tnl	URL: .10	

Recommended reference limit only

5 How to use external controls

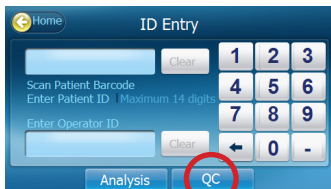
5.1 Bring external controls to room temperature and gently mix well

5.2 Using a precision (fixed or adjustable) pipette, pipette 500µL onto disc

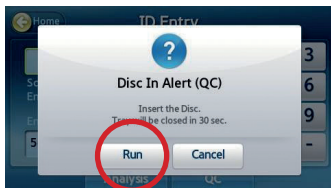
5.3 Press “New Analysis”



5.4 Press “QC”

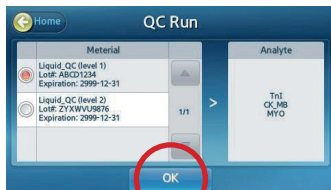


5.5 Tray opens, load test disc and press “Run”



5.6 Select “QC level”

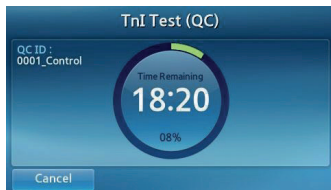
5.7 Press “OK”



5.8 Nexus IB10 Instrument will detect the product type and run test

5.9 Test results display/print in 20 minutes*

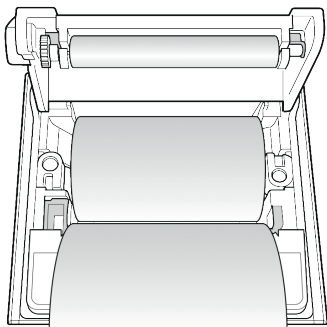
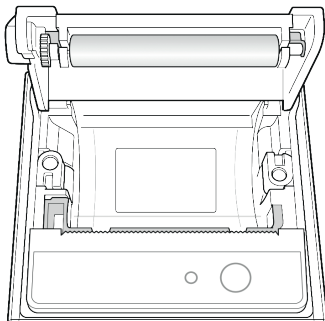
5.10 Refer to the Controls product insert or reference documentation for assigned values and verify results are within range



*22 minutes for IB10 sphingotest® DPP3

6 How to exchange paper roll

- 6.1** Open the paper lid (pull the lid upward by the handle)

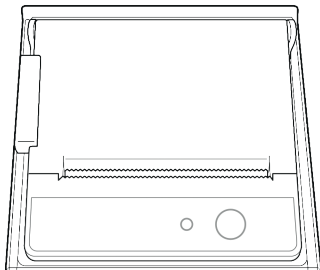


- 6.5** Close the lid and make sure that the paper is positioned between the lid and the front of the printer

- 6.2** Remove the used roll

- 6.3** Unwind a new paper roll so that the leading edge comes out from the bottom, facing the user

- 6.4** Gently insert a new roll into the receptacle, and confirm that the paper comes out through the front of the printer while holding the leading edge



7 Key Technical Specifications

CATEGORY	ITEM	SPECIFICATIONS
Input/Output	Thermal Paper (recommended)	HANSOL PAPER 65GSM Paper width (58 mm, 2.36") Paper roll size: max. 40 mm (1.57") weight 60g
	Barcode Scanner (optional)	USB-HID (Human Interface Device) Type 1D Barcode Scanner (rated current less than 500 mA) *Model# Hyperion 1300g made by Honeywell is recommended
Interface	Ethernet	10/100 Base-T
	USB Host	2 USB 1.1 ports
	USB Client	USB 2.0 port
Optical	Light Source	Backlight Unit (BLU) with LED
	Detection	CMOS Image Sensor
Memory Capacity	Maximum Memory Capacity	5000 reports for regular tests
Power	AC Adapter	Input: AC 100 – 240 V, 1.5 A, 50 – 60 Hz Output: DC 19 V, 4.74 A, 90 W
Operating Environment	Temperature	15 °C – 32 °C (59-89,6°F)
	Humidity	0 – 85%
Storage Environment	Temperature	-20 °C – 40 °C (-4-104°F)
	Humidity	0 – 85%
Dimension		177 mm (W) x 330 mm (D) x 177 mm (H)