KEY-CODE: **FRI00560**
80538, 80540, 80541, 80542
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p 1/9
English

FUJIREBIO

REF **80538 INNO-LIA HCV Score**
REF **80540 INNO-LIA HIV I/II Score**
REF **80541 INNO-LIA HTLV I/II Score**
REF **80542 INNO-LIA Syphilis Score**

IVD CE 0459

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Summarized Test Procedure in addition to the instructions for use of the INNO-LIA Score products

Note changes highlighted

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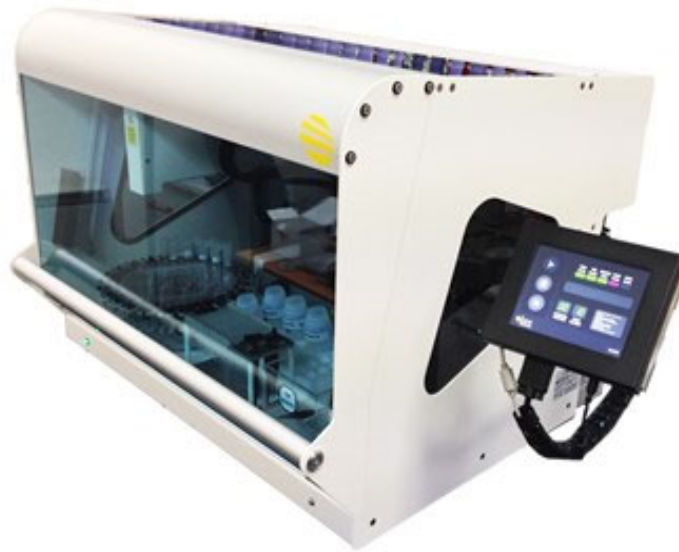france@fujirebio.com

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8:00 – 17:00 GMT+1

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Summarized Test Procedure

This summarized test procedure is a quick guide to perform an INNO-LIA Score test on the *RoboBlot*.

Before using the instrument for the first time, read the detailed "RoboBlot User Manual" which is provided with every instrument.
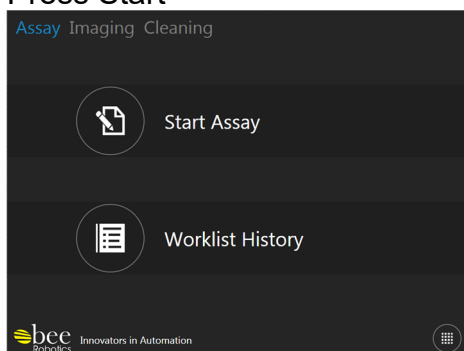
I. Setup of Instrument

1. Switch the instrument ON

- Use the ON/OFF switch on the right side of the instrument to switch the instrument ON
- Wait until the initialization is done and the instrument displays:
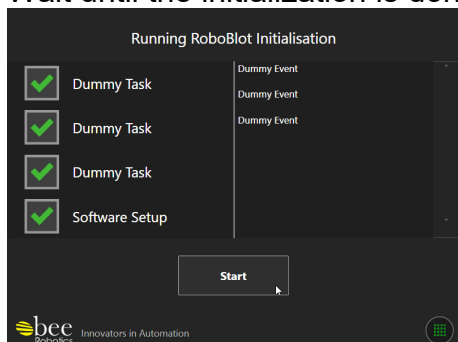

- Press Start

- The RoboBlot is in standby mode and ready to start an INNO-LIA test

# II. Reagent Preparation and Start Run

1. Select a test procedure

- Bring the reagents to room temperature (see instructions for use of the assay)
- When starting a test manually on the RoboBlot, press the "Start Assay" key
- Type the name of your test in the "Worklist Name" field
- Select the assay protocol you wish to run
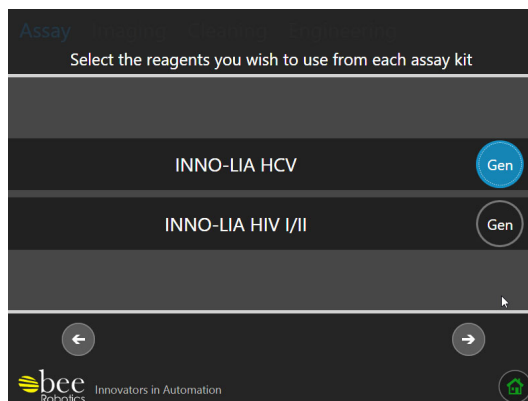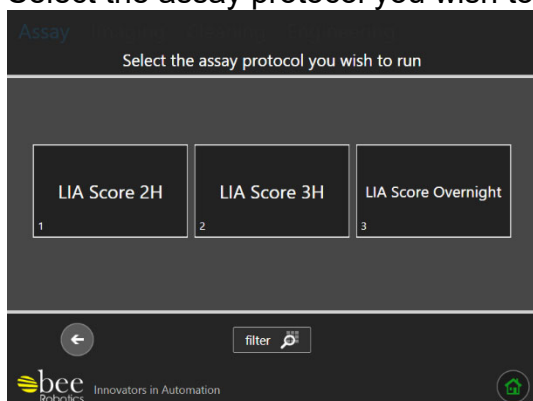
- Select the Starting well on the tray from where the assay will begin

- Select the Number of Samples and indicate if you want to run the Positive and/or Negative control
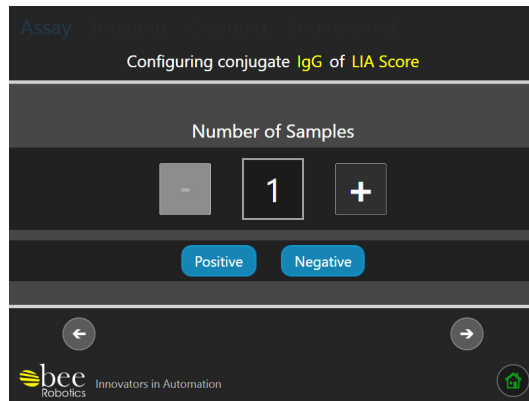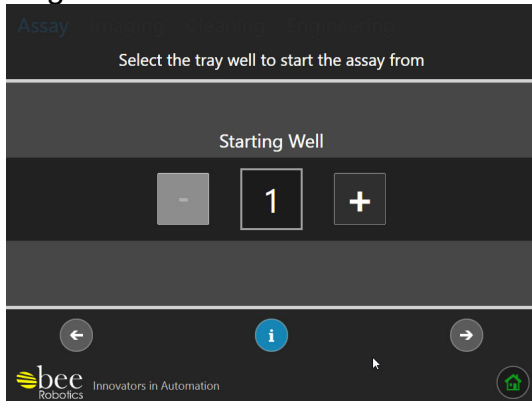

REMARK:

- *The numbering on the tray starts at 0, but the starting well on the screen is the absolute position in the tray.*
  e.g.: Starting well 5 = number 4 on the tray

- *When starting a Run that was prepared in the LiRAS software, select "Assays Worklists" – "Pre-Generated Worklists" and indicate your pre-generated worklist. Follow the instructions on screen as described below to start the run*

- Configure the first tip picking position and fill the rack as shown. Use only dedicated tips (see references)
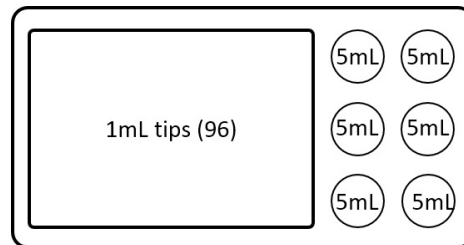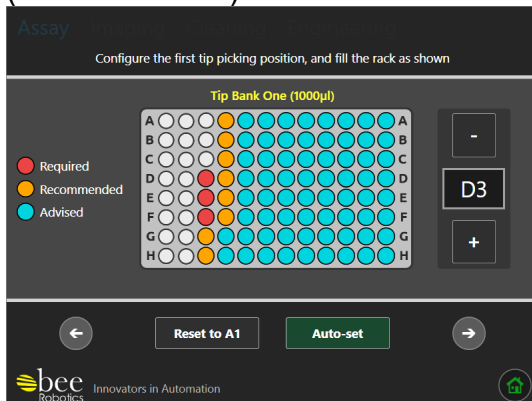

- The volumes required for this run are calculated by the instrument. Fill the dedicated bottles with minimum the amount of reagents indicated in the software
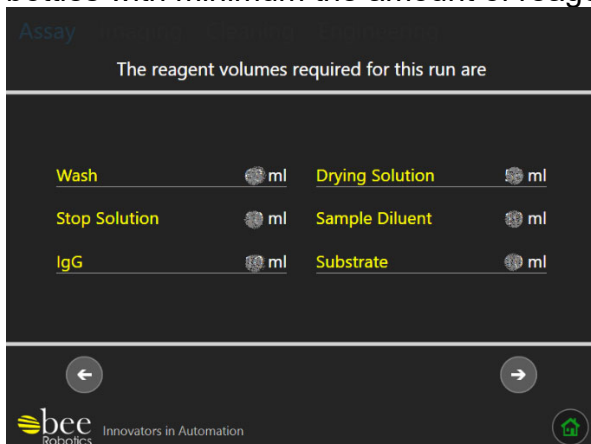
- Insufficient reagent will pause the instrument during the run

2. Prepare the reagents

- Prepare the Drying solution, a 20% (V/V) EtOH solution
- Fill the original, dedicated bottles with the correct reagents and place them on the corresponding spaces in the reagent holders, minimum volumes are indicated on screen
- Add the Positive and Negative control bottles on the dedicated place in the reagent holder
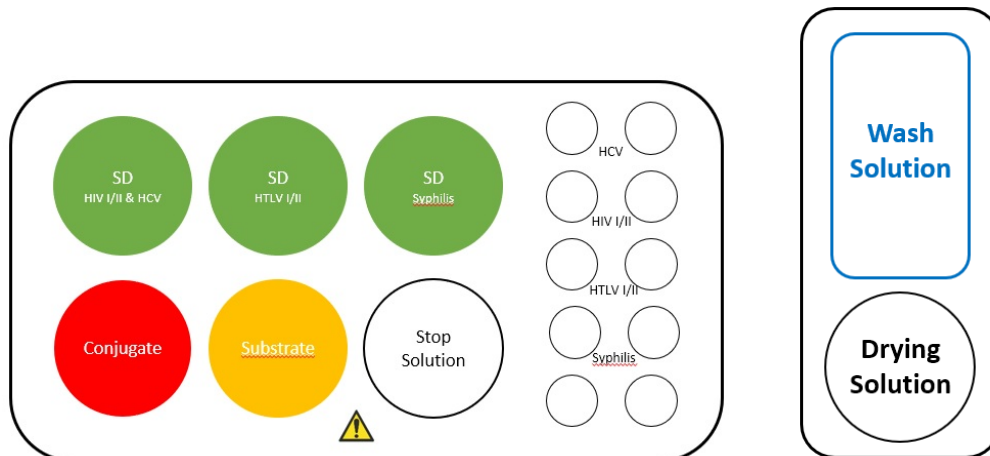
For INNO-LIA Score assays:

INNO-LIA Test Reagents	Preparation
Sample Diluent *(Green)*	Ready-to-use
Wash Solution *(Blue)*	1/5 in distilled water
Conjugate *(Red)*	Ready-to-use
Stop Solution *(White)*	Ready-to-use
Substrate *(Yellow)*	Ready-to-use
*Drying Solution * (Black)*	20% EtOH solution

* not included in the INNO-LIA Score kit. Should be prepared in the lab and has a 30-days stability (opened and unopened)

3. Start run and add samples

- Load samples in the sample carousel starting at position 1
  Make sure the sample tubes are positioned straight in the carousel, with the barcodes facing outwards

  REMARK:take into account a recommended dead volume of 1 mL and the required sample volume according to the assay IFU's

- Add the correct number of strips with the membrane side up and the strip label to the top, in the tray by using tweezers
- Load both reagent holders in the instrument and install the tubing's (wash and drying sol)
- Empty the tip waste container
- Load the tray with the strips in the instrument and close the holders
- Load the 1 mL tip rack and add 4 black 5 mL tips in the holder in the correct positions

- Empty the waste bottle
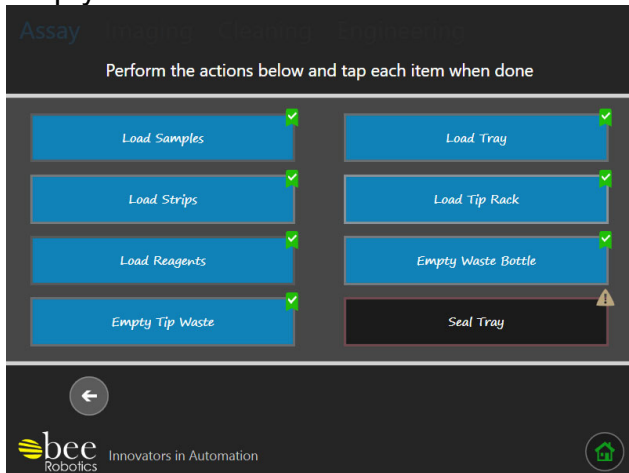
- When running an **overnight protocol**, cover the tray with an adhesive sealer (the sealer added in the INNO-LIA kit can be used for this purpose) (see references)
- Place the sealer, above the markers covering appr. 80% of the troughs to prevent evaporation and leaving enough room on top of the tray to aspirate and dispense the wash solution
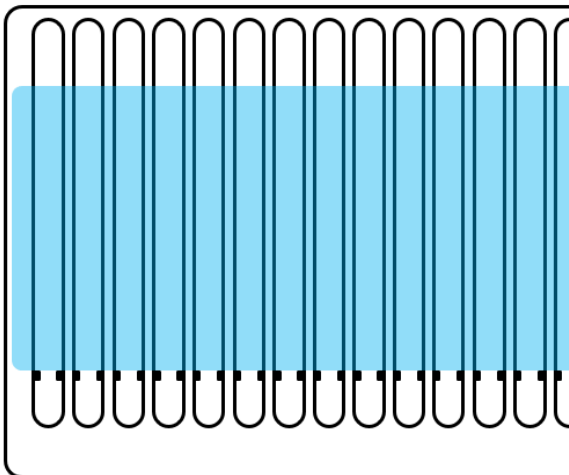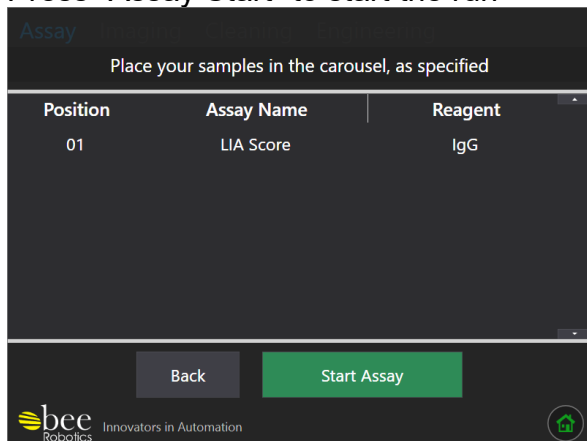

- *Incorrect positioning of the sealer, might lead to hampering of the instrument*
- Mark the checkbox to continue
- Push the "Scan" button to scan the sample barcodes (if option is activated)
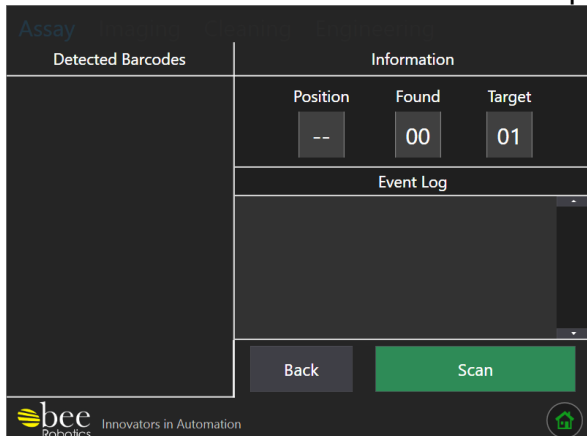
- Press "Assay Start" to start the run

- After adding the samples, the instrument will prompt to check if the strips are still positioned correctly, facing upwards (remove the sample carousel if wanted)
- Press "Resume" to continue the run

4. Drying and scanning the strips

- When the test is done, the instrument will prompt you:
  "*Drying is about to start. Please remove the seal from the tray and ensure that the strips are positioned and oriented correctly, then press Resume to continue.*"
- Remove the sealer, check that the strips are faced upwards and press resume
- Scanning of the strips will automatically start after one hour drying
- If running a LiRAS pre-generated worklist, the images will be automatically transferred to the interpretation software

III. Cleaning

- At the end of the assay, click on the cleaning icon to start the cleaning (section 5.2 in user manual)
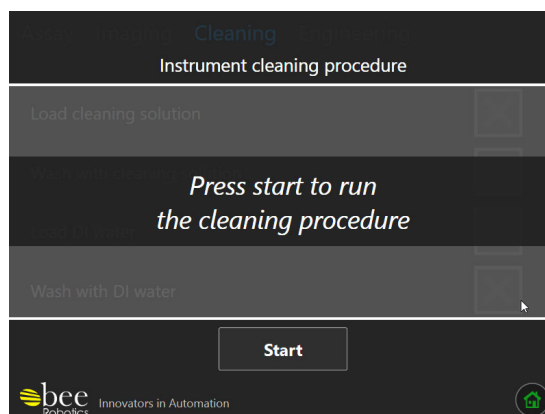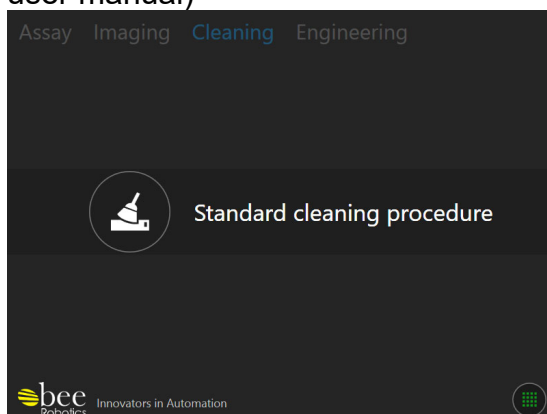

- Load the cleaning solution in Wash and Drying bottles (4% Bleach or 4% SDS solution) and press "OK"
- After soaking, remove the cleaning solution, replace by deionized water and push "OK"
- Push "Done" after cleaning has finished

IV. Connection with LiRAS (IP-address)

When using the RoboBlot Device in combination with the LiRAS for Infectious Diseases software, follow these steps to obtain the IP address of the RoboBlot:

- Connect the instrument to the local network with the ethernet cable provided with the instrument
- On the instrument touch screen, press the button to open the options menu:
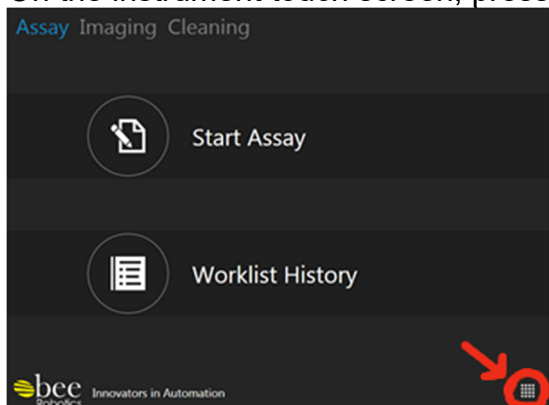
- Press and hold down on the Bee Robotics logo in the center of the screen. This activates Engineering Mode
- Navigate on the screen to **Engineering > General setting > Networking > Network service addresses:**
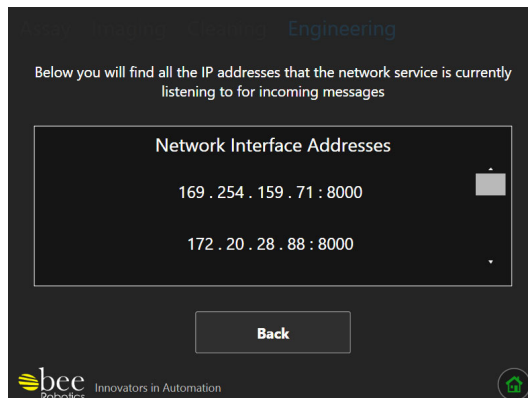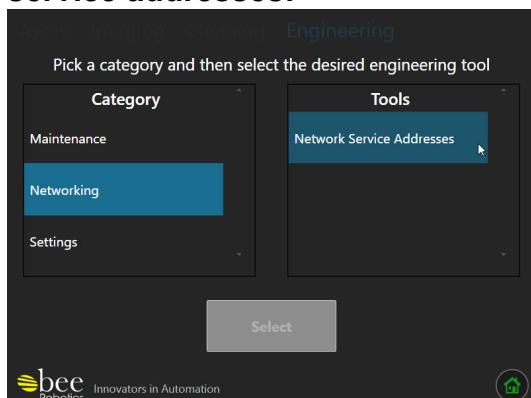
- Take note of the IP addresses and port number on the screen
- The device should have 2 IP-addresses. If the first address does not work, try the 2^(nd).

V. Calibration of the RoboBlot scanner

- When calibrating the RoboBlot scanner, use the 3 mm grey scale (see references) on the first position of a tray, with the label facing to the top of the tray
- Follow the instructions in LiRAS to calibrate the RoboBlot scanner

WARNING: The 3mm grey scale is only intended for calibration of RoboBlot devices, not for other scanning devices.

VI. References (FRE order codes)

- Trays:	**80742**	RoboBlot Tray 48	10 trays/pack
- 1 mL tips:	**80743**	1000 µL Disposable tips (RoboBlot)	10 trays (96 tips)
- 5 mL tips:	**80744**	5000 µL Disposable tips (RoboBlot)	10 trays (24 tips)
- Sealers:	**81061**	RoboBlot Sealers	20 sealers/pack
- Grey scale:	**81100**	Grey scale package RoboBlot	3 grey scales-3mm

VII. Trademarks

- INNO-LIA is a trademark of Fujirebio Europe N.V., registered in US and other countries.
- RoboBlot is a trademark of Bee Robotics Ltd.