

REF LFS-1.0

Lateral Flow Scanner

User Manual



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Section 1: Overview

1.1 Intended Use

The Rapid Response™ Lateral Flow Scanner is intended to be used as a documentation tool which stores the results of up to 5 Rapid Response™ Multi Drug Test Panels simultaneously, and automatically submits and transfers test reports via integration to the recipient's data management platform. This scanner is intended for use only with Rapid Response™ Multi Drug Test Panels for the detection of drug substances in human urine, in their intended use settings. The Rapid Response™ Lateral Flow Scanner does not modify the procedure or results of Rapid Response™ Multi Drug Panels.

1.2 Content of Kit

The following items are included:

1. Flatbed Photo Scanner
2. 5-Panel Scanner Template
3. USB 2.0 Cable

The following item(s) are not included but are required:

1. Label printer capable of printing patient specific QR codes.
 - a. Label size: to be determined by recipient's data management platform and BTNX Inc.
2. Recipient's data management platform (such as an ATS, EMR, EHR, or other patient data management systems).

Review and ensure that all pieces of equipment are provided. If any item is missing or damaged, notify the manufacturer.

1.3 Limitations

1. Rapid Response™ Lateral Flow Scanner is only compatible and intended to be used with Rapid Response™ Multi Drug Test Panels in their intended use conditions.
2. The Rapid Response™ Lateral Flow Scanner should not be used for result interpretation. The individual performing the Rapid Response™ Multi Drug Test Panels is responsible for result interpretation.
3. This device can only be used in conjunction with the Rapid Response™ Multi Drug Test Panels and the recipient's data management platform.
4. The Rapid Response™ Lateral Flow Scanner is intended to scan and transfer the data from the Rapid Response™ Multi Drug Test Panels to store in the recipient's data management platform.

1.4 Precautions

1. Avoid strong magnetic field, vibration, shock, corrosive gas, direct sunlight, or high humidity during storage or operation.
2. Do not clean the unit with substances such as gasoline, paint thinner, benzene compounds or other organic solvents to avoid any damage to the reader.
3. Follow all regulations when disposing the unit or its accessories.

Section 2: Installation and Setup

2.1 Software Integration

The Rapid Response™ Lateral Flow Scanner relies on software integration with the recipient's data management platform to function as intended. To start an integration and to learn more about the process, please reach out to support@btnx.com. The software integration will enable candidate data to be passed securely to the Rapid Response™ Lateral Flow Scanner and for result information to be passed securely back to each specific candidate profile on the recipient's data management platform.

2.2 Instrument Setup

Carefully unpack the Rapid Response™ Lateral Flow Scanner and inspect the reader to ensure that it has not been damaged during shipping. In case of damage, immediately contact the manufacturer. Complete steps 2.21 to 2.23 to set up the Rapid Response™ Lateral Flow Scanner.

2.21 Set up the Rapid Response™ Lateral Flow Scanner:

1. Connect the Epson Perfection V39 II Flatbed Photo Scanner to the computer using the provided USB 2.0 cable.
2. In your web browser, download and install drivers on the computer from https://epson.com/Support/Scanners/Perfection-Series/Epson-Perfection-V39/s/SPT_B11B232201

2.22 Install RRScanner™ software from the web:

1. Visit <https://www.btnx.com/rrscanner> in your web browser.
2. Select the Install button to download the installer (setup.exe).
3. Run the installer downloaded in the previous step.
4. Follow the instructions on screen to install the software.

2.23 Initial Setup of Settings:

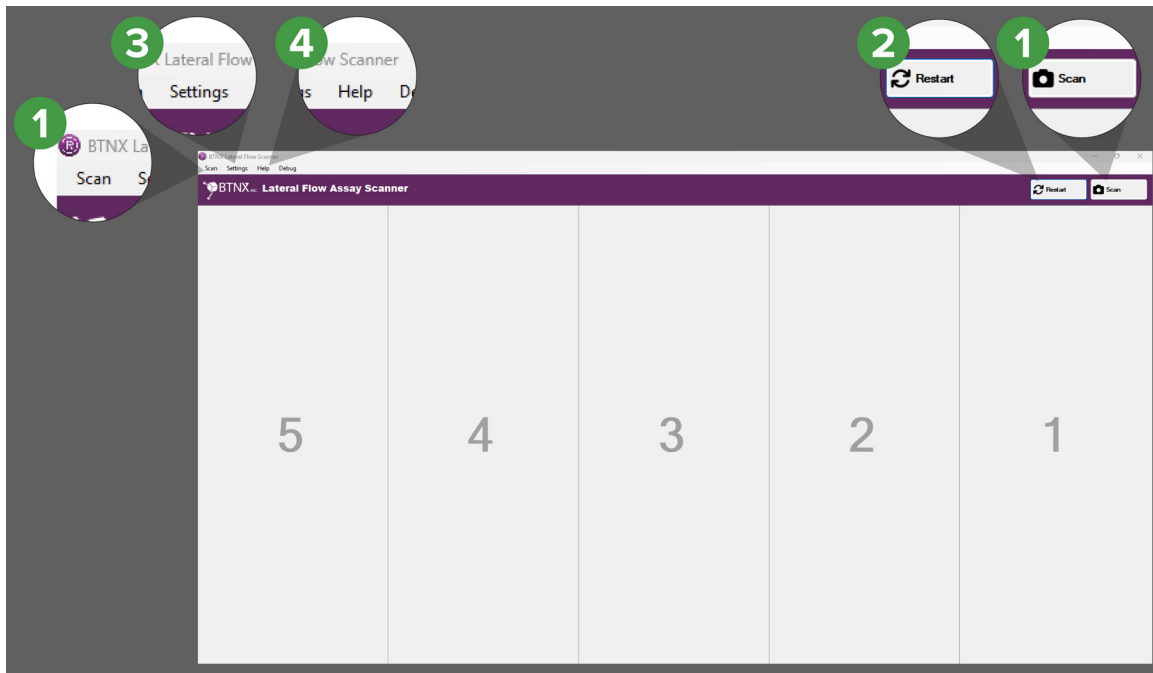
1. Once RRScanner™ is installed, open the program. The application will automatically search for any updates available before starting. Select "OK" for any updates that are available.
Note: The download may take several minutes. The download may prompt Microsoft Defender SmartScreen to prevent the update from running. When this screen appears, select the underlined "More info", and then select "Run anyway."
2. In the program, left click settings at the top left corner to open the settings menu. Select "Scanner." You will be prompted to enter the administrator password.
3. Once logged in, in the top right corner of the screen, select 'Epson Perfection V39 II Flatbed Photo Scanner' from the dropdown.
Note: The Scanner Settings listed in this drop down are already set to the optimal settings. They can be adjusted at any point.
4. Once settings are confirmed, select "OK" at the bottom of the screen.

2.3 Start-up Procedures

When the RRScanner™ program starts, an updater will run to ensure that the most current software is used. The main screen will open once the updater has finished running.

Section 3: Software Navigation

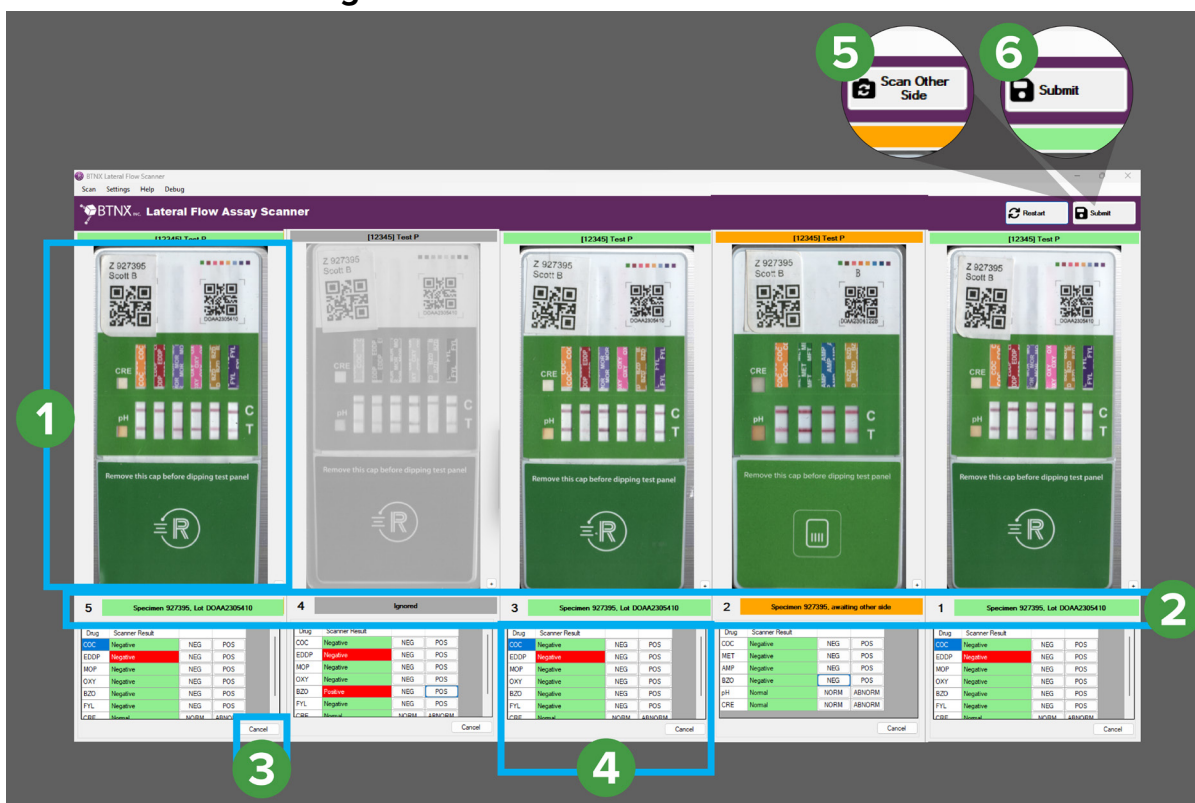
3.1 Main Screen Navigation



The RRScanner™ Software interface contains several components:

1. **Scan** – Located on both the top left and right corner of the screen. Selecting scan will prompt the scanner to scan the panels on the template.
2. **Restart** – Located in the top right corner of the screen and in the dropdown menu under **Scan** in the top left corner. Selecting restart will clear the RRScanner™ of any scanned images.
3. **Settings** – This menu option allows users to change scanner settings, view scanned image logs, and select the option for a 5-minute timer. When selected, the timer will run each time the **Scan** option is selected.
4. **Help** – Allows the user to check for updates to the software and for software version information.

3.2 Results Screen Navigation



1. **Slot** – Refers to the five divided sections on screen which will display the corresponding scanned panel image. These five numbered sections are also reflected on the Lateral Flow Scanner Template.
 - a. Double-sided panels will always show side A on top and Side B below.
2. **Status Bar** – The status bar is a colour-coded bar that will indicate the following statuses:
 - a. **Green status bar** – The panel has been scanned and is ready to be submitted.
 - b. **Orange status bar** – The panel has been scanned and is ready to be flipped for the second side to be scanned.
 - c. **Red status bar** – The panel has an error and cannot be processed until resolved or cancelled.
 - d. **Grey status bar** – Test has been cancelled and will not be submitted with the processed batch of tests.
3. **Cancel** - Allows the operator to cancel a specific test. This will prevent that test from being submitted.
4. **Result Section** - Indicates the results for all parameters scanned in the panel.
 - a. **NEG button** – Clicking this button will change the associated result to negative.
 - b. **POS button** – Clicking this button will change the associated result to positive.
5. **Scan other Side** – This option will replace the scan button once the first side of a double-sided test has been scanned.
6. **Submit** – The submit button will replace the scan button once all sides of the panel are scanned. Selecting submit will transfer all results captured (excluding cancelled results) to the recipient's data management platform.

Section 4: General Operations

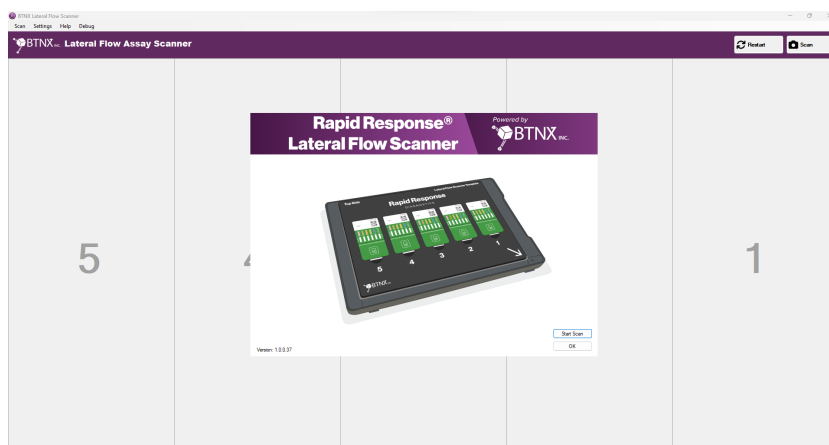
To use the RRSScanner™ Software:

4.1 Before You Begin:

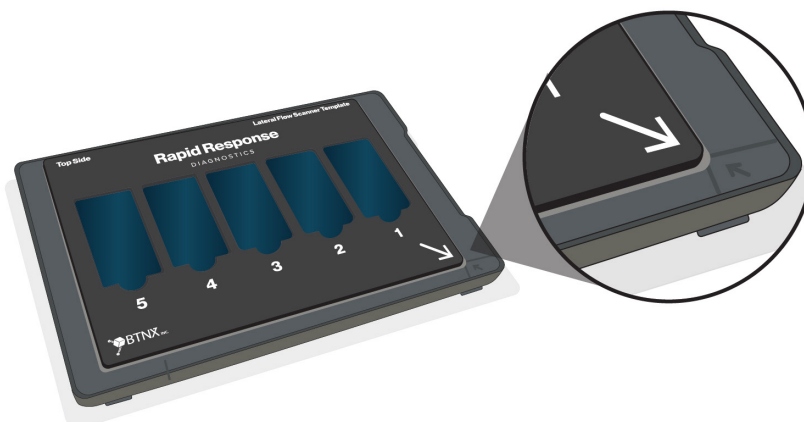
1. Collect and label patient specific urine samples in collection cups according to your organization's standard procedure.



2. Launch the RRSScanner™ Software.

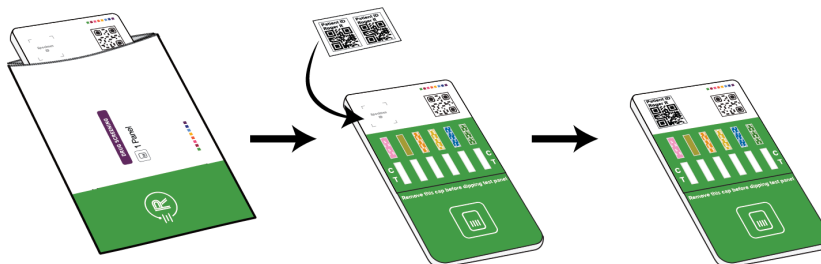


3. Place the 5-Panel Scanner Template onto the Flatbed Scanner so the arrow at the bottom right of the Template lines up with the arrow on the Flatbed Scanner.



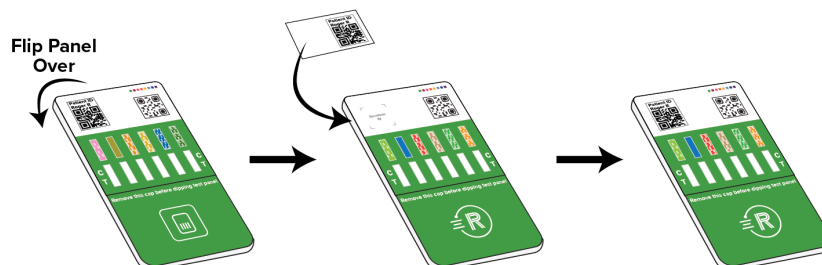
4.2 Prepare the Rapid Response™ Multi Drug Test Panels for Scanning:

1. Print a patient specific QR code label from your data management platform using the label printer connected to the computer.
2. Remove up to five Rapid Response™ Multi Drug Test Panels from their sealed pouches. Place a patient specific QR code sticker in the top left corner of each panel over the square labeled “Specimen ID.”

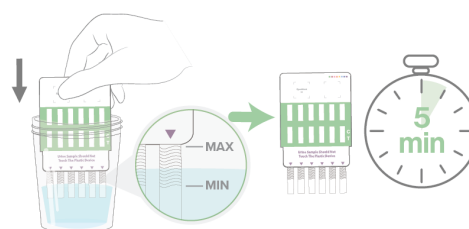
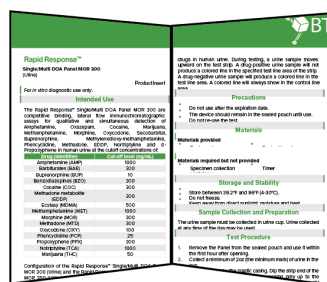


Note: Do not open pouches until you are ready to affix the QR code stickers and perform the test.

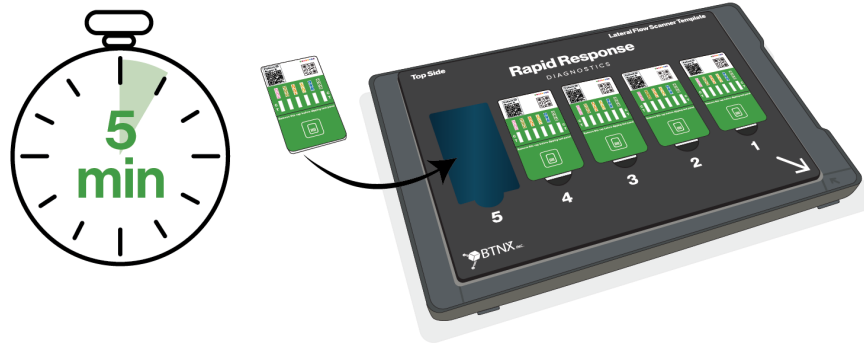
- a. **Double-sided panels** will require two QR codes. After the first sticker has been attached, flip the panel over and place a second QR code sticker on the reverse side of the panel.



3. Follow the testing procedure outlined in the Product Insert supplied with the Rapid Response™ Multi Drug Test Panel kit to test each patient sample.

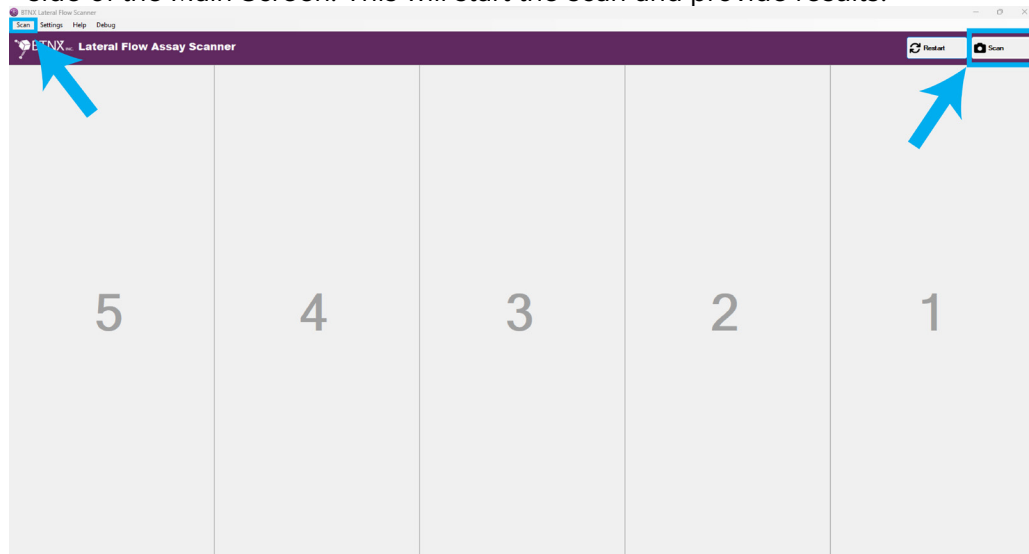


4. Wait the required five minutes after dipping each panel, as described in the Rapid Response™ Multi Drug Test Panel Product Insert. After the five minutes have elapsed, place the panels onto the template on the Rapid Response™ Lateral Flow Scanner. Up to five samples can be analyzed at a time.

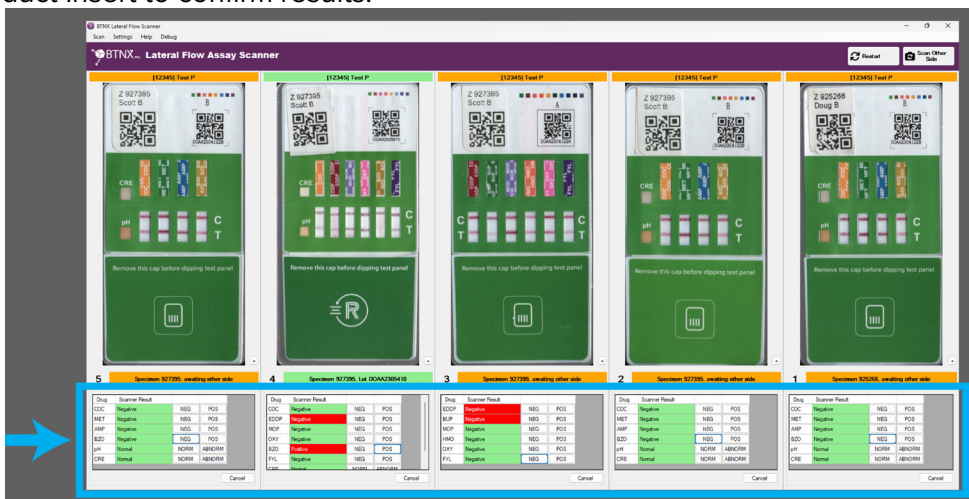


4.3 Running the RRScanner™ Software

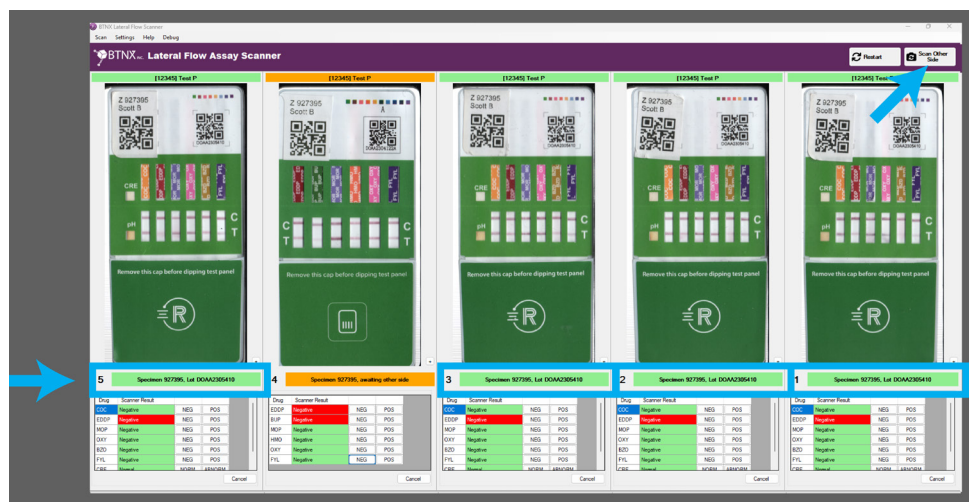
1. After the panels have been placed on the Rapid Response™ Lateral Flow Scanner, select “Scan” on the RRScanner™ Software using the button on either side of the Main Screen. This will start the scan and provide results.



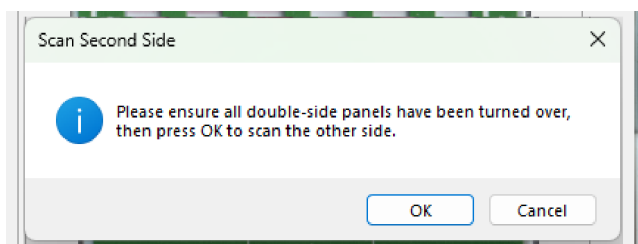
2. Once the scan is completed, the panel image will appear in the slot and the preliminary results will appear in the results section. The preliminary results shown are predictions of what the result should be, which the users must review before continuing. Follow the *Results Interpretation* directions supplied in the Product Insert to confirm results.



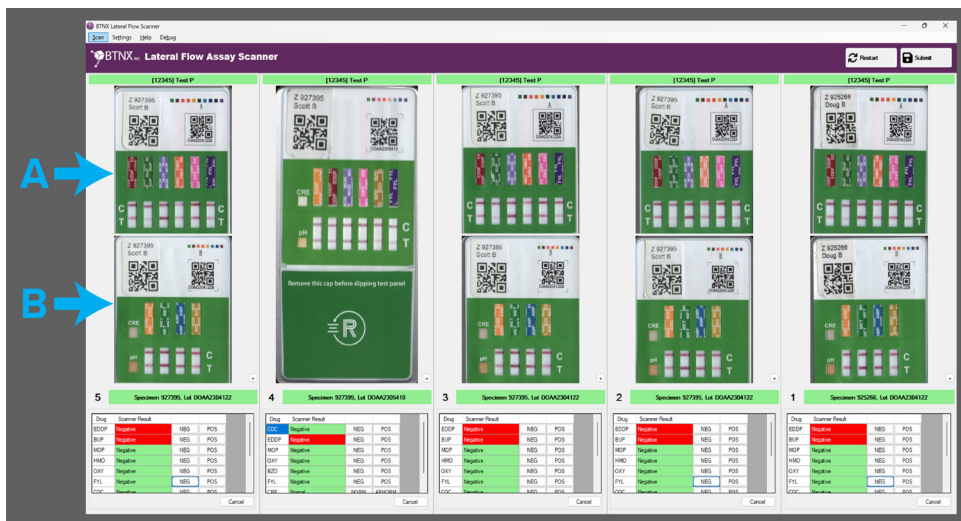
- a. **For Two-Sided Panels:** below the slot (panel image) will change to orange. Pick up each double-sided panel and turn it over to its reverse side, placing it back into the template. Select “Scan other side” from the top right corner of the RRSscanner™ software.



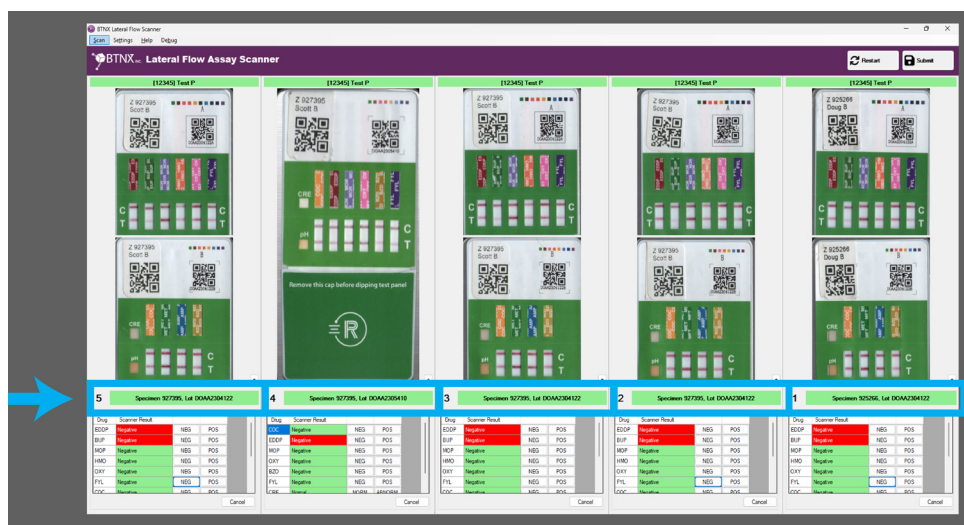
- b.** A pop-up (see image below) will appear asking you to confirm that the panels have been flipped, select “OK” and continue after ensuring panels have been flipped.



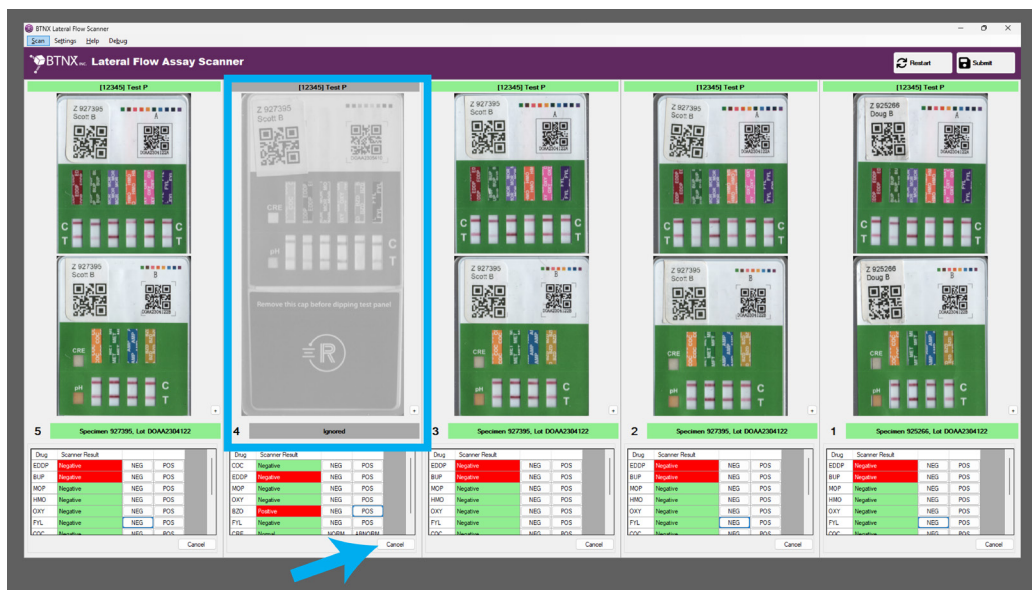
- Once the second side is scanned, both scanned sides of the panel will appear in the slot. The predicted results of Side A of the panel will appear on top and side B of the panel will appear below it.



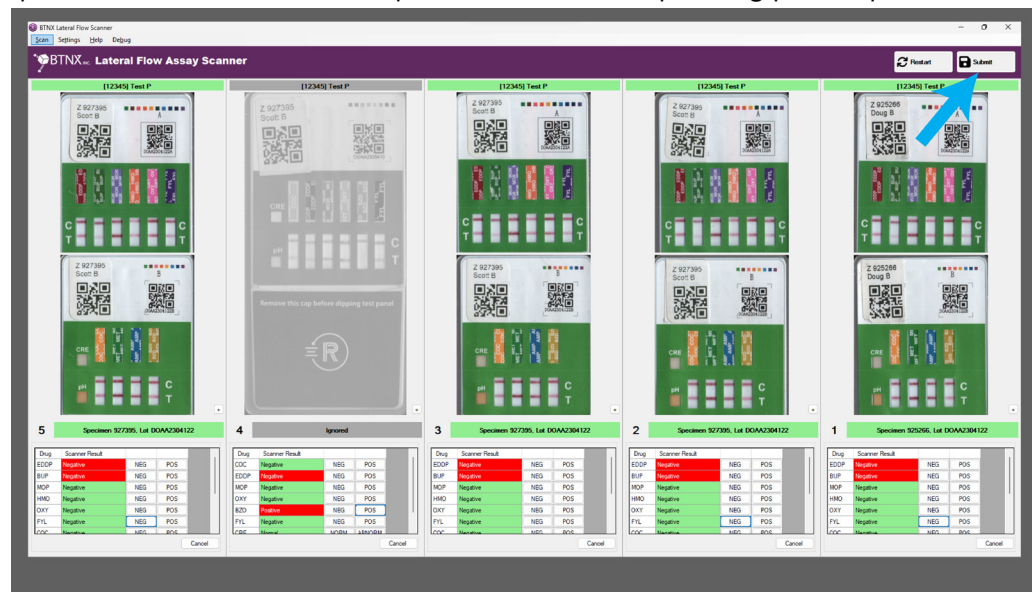
- Once the scan is complete a green indicator will appear in the Status Bar of each panel. Review all results before submitting. Follow the *Results Interpretation* directions supplied in the Product Insert to confirm results.



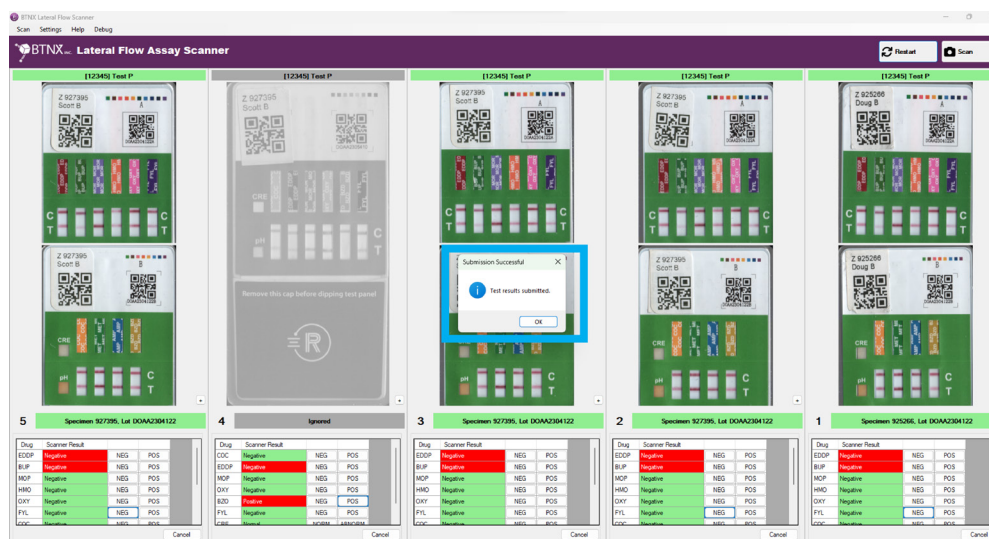
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- If any result is identified as incorrect, the panel can be cancelled from the RRScanner™ Software by selecting “Cancel” under the results section. Results from cancelled panels will not be submitted and will be greyed out on screen. Re-test the patient’s urine sample with a new panel and repeat the scanning procedure listed above.
- After the results have been confirmed, select “Submit” at the top right corner of the screen to submit the results to the integrated recipient data management platform, each result will be uploaded to its corresponding patient profile.



- If the results have been successfully submitted, a pop-up will appear with the message “Test results submitted.”



- The scan is complete and results have been uploaded. Select “OK” to scan new patient samples. Select “OK” or X to exit.

Section 5: Maintenance

5.1 Cleaning the Flatbed Scanner

- Disconnect the USB cable.
- Clean the outer plastic with a cloth dampened with mild detergent and water.
- If the scanner glass gets dirty, clean it with a soft, dry cloth. If the glass surface is stained with grease or some other hard-to-remove material, use a small amount of glass cleaner on a soft cloth to remove it. Wipe off all remaining liquid.

Caution: Do not use a hard brush, alcohol, or paint thinner to avoid damaging the scanner. Do not use oil or other lubricants inside the scanner or let water get inside it. Do not open the scanner case. Do not press the surface of the scanner glass forcefully. Do not scratch or damage the scanner glass. A damaged glass surface can decrease the scan quality.

Note: Do not spray glass cleaner directly onto the scanner glass. Make sure that dust does not accumulate on the surface of the scanner glass. Dust can cause spots in the scanned images.

5.2 Cleaning the Acrylic Lateral Flow Scanner Template

The Lateral Flow Scanner Template should be cleaned several times a year, or more often as needed. The template can be cleaned with alcohol and mild detergents.

- Remove the Lateral Flow Scanner Template from the scanner.
- Clean the template using alcohol wipes, or a cloth with detergent and water.

Note: Ensure the template is completely dry before placing it back in the Scanner.

Appendix A. Catalog

Replacement components and new parts may be ordered from your local sales representation, through sales@btnx.com or at T+ 1 (888) 339-9964 (Monday – Friday 9:00 AM – 5:00 PM EST)

Product Name	Catalog Number	Components	Quantity
Rapid Response™ Lateral Flow Scanner	LFS-1.0	Epson Perfection V39 II Flatbed Photo Scanner	1
		5-Panel Scanner Template	1
		USB 2.0 Cable	1
Flatbed Photo Scanner	LFS-SCAN1	Epson Perfection V39 II Flatbed Photo Scanner	1
		USB 2.0 Cable	
Replacement 5-Panel Scanner Template	LFS-ACC1	5-Panel Scanner Template	1

Appendix B. Manufacturer Contact Information

BTNX Inc.

722 Rosebank Road,
Pickering, ON L1W 4B2, Canada
www.btnx.com



Technical Support Contact:

T+ 1 (888) 339-9964
support@btnx.com

Monday – Friday 9:00AM-5:00PM EST

Sales Contact:

T+ 1 (888) 339-9964

sales@btnx.com

Monday – Friday 9:00AM-5:00PM EST

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