Athelas

Athelas Home

User Manual & Package Insert

Athelas

For In Vitro Use Only

Manufactured for Athelas

1300 Terra Bella, #200, Mountain View, CA 94043

Support/Complaint Line:
Call 1-877-324-4332 (6AM-8PM EST)
Or email to: **support@athelas.com**

Table of Contents

Athelas Home

Prior to operating the device, please read this manual and contact the Athelas support team (1-877-324-4332) if further explanation is needed. An instructional session will be provided to you by your prescribing healthcare provider or a designated representative. You will be evaluated to ensure your understanding and competency on the Athelas Home system's operation prior to the system shipping or being set up.

Warranty

All Athelas devices are warrantied against defective material for a period of one year, starting on the customer's installation date. After warranty expiration date, service and repair are offered at fixed price. Warranty does not cover any malfunction, defect, or damage due to:

- Accident, neglect, or mistreatment of the instrument parts.
- Failure to operate, service, use, or maintain the product as stated by Athelas' Instructions for Use.
- Failure to use appropriate supplies specified for the Athelas system.

The Athelas Home has not been tested on patients being treated with iron chelating agents.

A CLIA Certificate of Waiver is required to perform the test in a CLIA Waived setting. Please contact your state department of health or visit http://www.cms.hhs.gov/clia for more information. Laboratories with a Certificate of Waiver must follow the instructions for performing the test. Please read the complete test procedure before performing the test.

Athelas Home

Indications for Use

The Athelas Home is indicated for the quantitative determination of white blood cells (WBC) and Neutrophil percentages (NEUT%) in capillary whole blood from fingerstick for patient self-testing with results viewable by healthcare professionals, and in capillary or K2EDTA venous whole blood for multiple-patient use in point-of-care settings. For self-testing, the Athelas Home is intended to be used by a single person and should not be shared. The Athelas Home is only to be used with Athelas Test Strips. The Athelas Home is intended for adult patients (aged 21 and older) at risk of neutropenia. For self-testing patients with psychiatric conditions, clinical judgment should be exercised when deciding the end-user and based on the instructions for use (IFU), the treating physician should determine which patients are competent to perform the test by themselves. Results obtained with the Athelas Home should not be the sole basis for patient diagnosis, treatment, or management of leukopenia and neutropenia, and all results should be evaluated by a healthcare provider. Prescription Use Only.

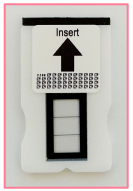
Components

1.

2.

3.

4.



5.

1. **Athelas Device**
2. **AC adapter**
3. **Athelas Test Strip**
4. **Athelas Auto-Check Strip**
5. **User Manual**

Required Items (Not Included):

Smartphone

Required for connecting device to Wifi.

Computer with Internet Access

Required for initial setup, test running and results viewing.

Lancets for capillary draw

Springing-loaded lancets of puncture depth 2mm are recommended

Setup Instructions

Important: Always move and handle device with care. If the packaging is damaged, contact Athelas distributor upon opening.

Prerequisites for installation:

- Make sure that power is available
- Ensure access to reliable Wifi or ethernet connection
- Ensure firewall settings are open for port 443
- Find a stable, dust free surface which can support device weight
- Do not place the device in a location with excessive sunlight exposure, or temperature fluctuations
- Protect device against water to prevent damage
- Complete full training on the system by thoroughly reading this document.

Setup Instructions

Open the package and place the device on a clean, stable surface.

1. Plug in the power adapter into the power inlet on the device located on the lower back side (as pictured).

2. Download and install the CSAN Pronto app on a smartphone or tablet. Ensure that the latest version of the app is installed and that your device meets the minimum system requirements: iOS 15.1 or Android 7.0.

Optional: use Ethernet port on the top of the device for internet access.

Cybersecurity & Network Information

Access Control & Authentication

- Keep your Athelas login credentials secure and avoid sharing them.
- Use strong passwords and update them periodically.
- Report any suspicious login activity to Athelas support immediately.

Secure Network Connection

- When connecting your device to WiFi ensure that the device is connected to a secure network.
- Use firewall protected network with appropriate anti-malware software installed.
- The firewall should only accept known incoming connections and block unauthorized network access on port 22. The firewall should provide access to api.athelas.com on port 443.
- Communication between Athelas device and cloud server is encrypted using HTTPS with TLS 1.2.

Security Event Logging & Anomalous Condition Detection

Athelas device automatically monitors security-relevant events, including:

- Unauthorized login attempts
- Network connection anomalies
- Unexpected configuration changes

In case of security events, users will receive notifications via www.clinic.athelas.com.

For initial setup use CSAN mobile app. Use secure Wi-fi with appropriate credentials when connecting the device.

Wireless Specifications
Wireless Technology: IEEE 802.11b/g/n, Bluetooth 5.0 Classic, Bluetooth Low Energy
Operating Frequency: 2.4 GHz
Effective Range: 50 meters
QoS: Low-latency communication with error correction.

Port	Protocol	Direction	Purpose
443	HTTPS	Outgoing	Secure data transmission to cloud server
80	HTTP	Outgoing	Initial network configuration

Cybersecurity & Network Information

Cybersecurity Incident Response & Recovery

- If you notice unusual device behavior, including unexpected login attempts, network connection anomalies or any communications asking for personal information, contact Athelas support immediately.
- Athelas will reset the device to restore normal operation. Follow the instructions provided by Athleas support.

Data Protection & Privacy

- Use the device only in environments where unauthorized physical access can be controlled.
- Data transmitted to the cloud is encrypted and protected; however, users should keep their computer and network safe by using secure passwords and trusted connections.
- Only authorized personnel should have access to **www.clinic.athelas.com**.

Updates & Maintenance

- Ensure that the device remains connected to the internet for updates.
- Athelas devices are updated automatically via secure network and no action from the user is required to apply appropriate security updates.

End-of-Life & Decommissioning

- Notify Athelas in case of disposing of the device.

Use Strong Passwords
- Make them long
- Make them random (use mixed-case letters, numbers and symbols)
- Make them unique
- Change passwords regularly

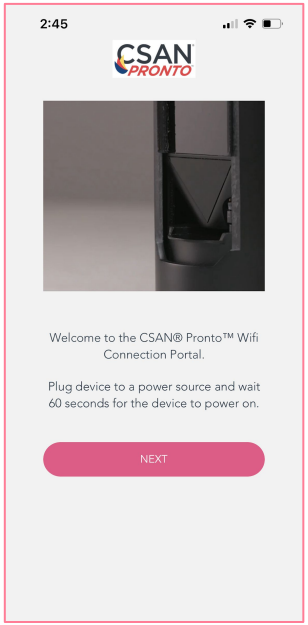
Use secure network

Use firewall protection with anti-malware software.

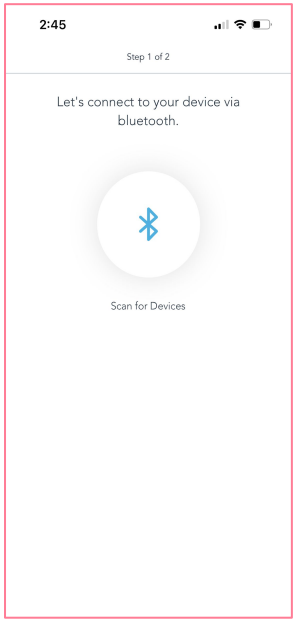
Software Bill of Materials (SBOM)
The SBOM for this device, including software components is available at: **clinic.athelas.com/support/sbom.** The SBOM is updated with each software release.

Connecting Device

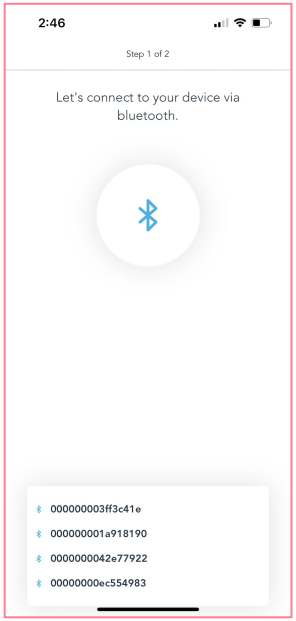
1. On your phone, open CSAN application.



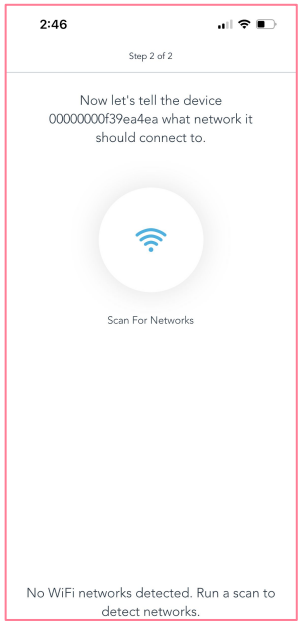
2. Press the Bluetooth button to scan for devices and connect to Bluetooth.



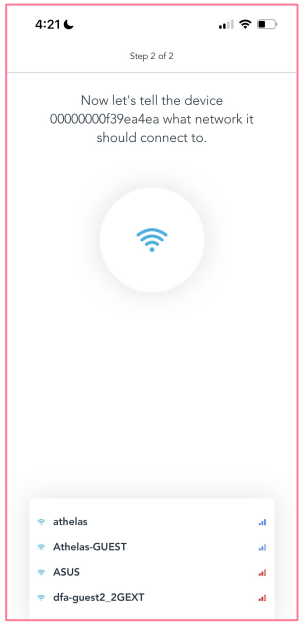
3. Once the device is found, the screen will prompt you to select 'Pair Device.'



Connecting Device

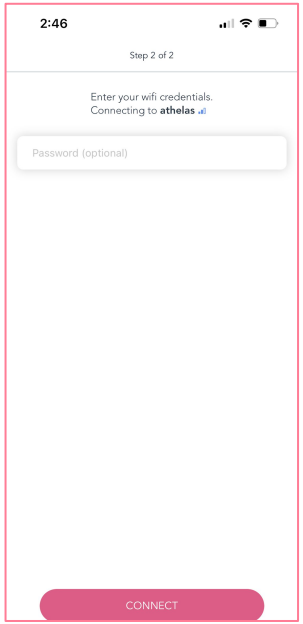


4. Tap the wifi button to search for wifi networks available.

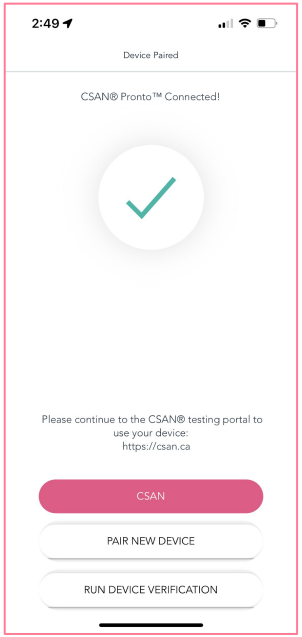


5. Click on the network you wish to join.

6. Enter the network password and hit "Connect" to finishing pairing the device.

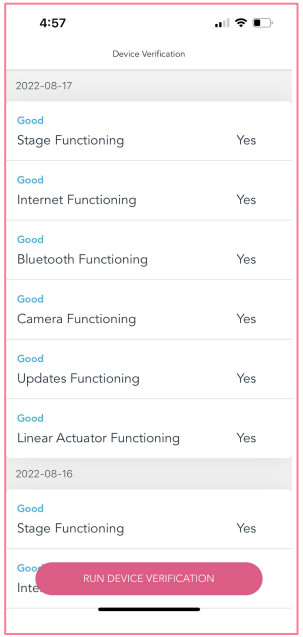


Connecting Device



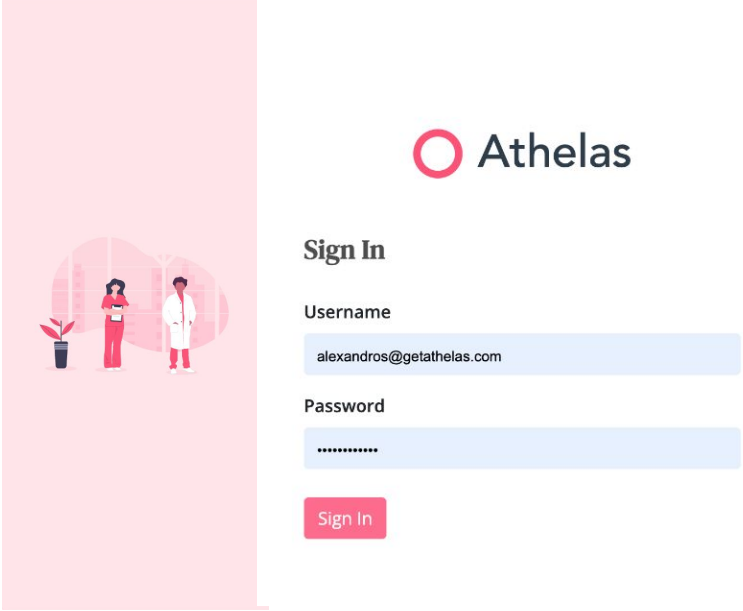
7. Finish Connecting.

"'Run Device Verification" shows device status and verification.



Logging-in

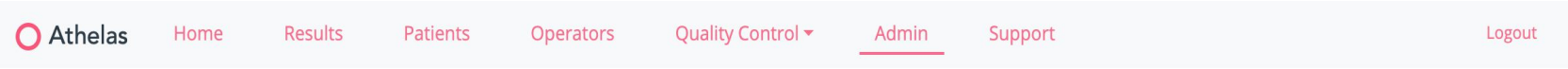
Sign in to **clinic.athelas.com** with Athelas provided login. Follow the instructions on the screen to start the test.

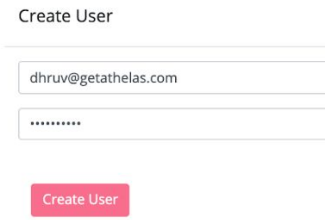


Administration (for administrators only)

If you are using Athelas device at home, please skip this page and go to page 16.

The following information is for administrators at point-of-care settings.
The administrator can manage operators and users that have access to running tests at a given site.





Click the **Admin tab** on the top panel to go to the administrator screen.

To create a new user account click on a "**Create User**" button and follow the instructions.

To deactivate an existing user, click "Options" and choose "**Deactivate User**" option to deactivate a given user account.

To manage sites click "Options" and choose "Edit Sites" to manage site access.

Sample Collection

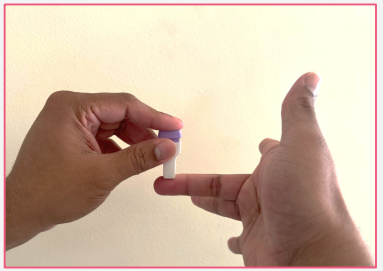
Important: Always exercise caution when working with lancets and blood. Ensure that your working area is properly cleaned before and after sample collection.

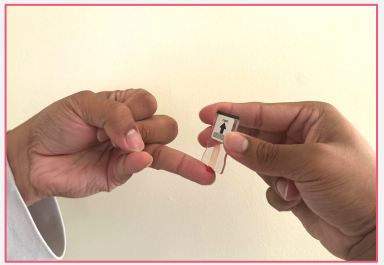
Patients with serious psychiatric conditions (such as those using the medication clozapine), motion disorders, visual impairments, or other health issues that may impair their ability to run a test on the Athelas Home, should have their samples collected and run by a designated and able caregiver.

For at-home patients with psychiatric conditions, clinical judgement should be exercised when deciding the end-user, based on the instruction of Athelas Home, the treating physician should determine which patients are competent to perform the test by themselves.

Sample Collection (for home users)

Capillary whole blood from fingerstick





1. Open "Athelas Test Strip" package, take one test strip out and set aside.
Do not use if strip is damaged or visibly dirty.

2. Clean fingertip with disinfecting wipe and allow to dry completely before puncturing.
Use the fleshy sides of the ring or middle finger.

Lightly hold pressure at the fingertip and puncture the finger using the lancet.

3. Wipe away the first two drops using a clean cotton ball or lint-free wipe (ex. Purell Lint Free Wipes). Re-apply pressure until another drop of blood appears.

4. Place the test strip at about a **45 degree angle** towards blood drop and do not detach the finger from the strip until strip is completely filled. Improper filling may cause air bubbles in test strip. If test strip window is not fully filled, discard strip and repeat measurement. If bubbles present, discard strip. Wipe off excess blood.

5. Let sample rest for about 5 minutes before running test. Do not wait more than 30 minutes before testing strip.

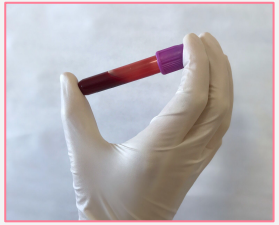
Do NOT reuse test strip!

Sample Collection (at point-of-care settings)

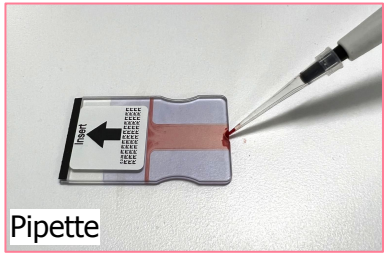
Capillary or K2EDTA venous whole blood

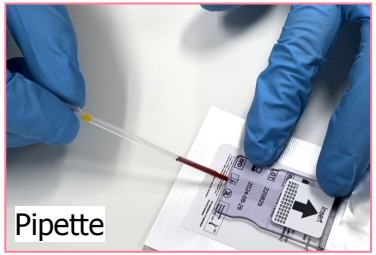
Use any capillary or venous blood collection method that conforms to hematology best practices and standard phlebotomy procedures. You can use fingerstick method for capillary blood or a pipette to fill a test strip.

Test samples within 24 hours. If venous blood has been stored at refrigerated temperature, allow it to reach room temperature (15-35 °C or 59-95 °F) before testing.



Mix the tube of blood thoroughly by using a mechanical mixer or by manually inverting tube 10-15 times. Use pipette to retrieve specimen.





Important: Blood should be filled in one continuous process until the test strip is completely filled. The blood source and strip should be angled at 45 degrees for proper flow.

Do NOT reuse test strip!

Let sample rest for about 5 minutes before running test.
Do not wait more than 30 minutes before testing strip. If test strip window is not fully filled, discard strip and repeat measurement. Wipe off excess blood.
Discard strip if bubbles are present.

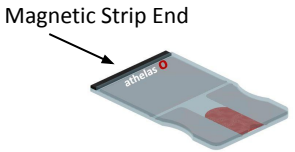
Prepare for a Test

To run the test, place the test strip into the base of device within the insertion tray. Make sure the test strip is filled in all the way, right side up with the black magnetic strip facing upwards and towards the device. The test strip should magnetically snap to the back of the device tray.

Note: If sample is improperly inserted (i.e. not fully in, upside down, facing wrong direction), the system will detect this and render a warning.

Make sure the magnetic strip end is facing the device when inserted.

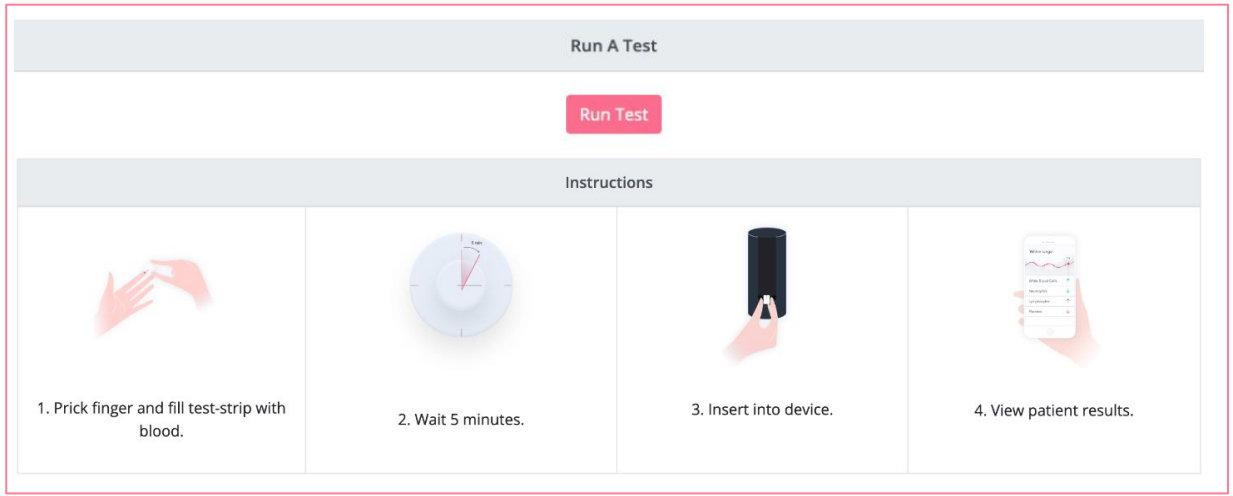
A blue LED light indicates that the test strip is properly inserted and device is ready.



Make sure the magnetic end of the strip is inserted first into the device.

Running a Test

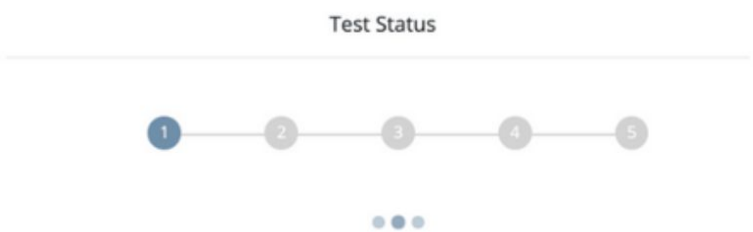
1. Once strip is correctly inserted and device blue LED lights up, the test is ready to run.
2. Click the "Run Test" on clinic.athelas.com and confirm the information required to start the test.



Running a Test

3. The device will now take multiple images of the test sample and render a result on the screen after a few minutes. The test status will show the steps remaining for completion.

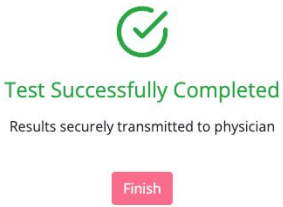
4. While test is running you will see the status on the dashboard update. The device will have a white LED light indicating a test is running.



Results (for at-home users)

This page is for Home users only. If you are using Athelas device at point-of-care setting, please skip this page and go to next page (page 24).

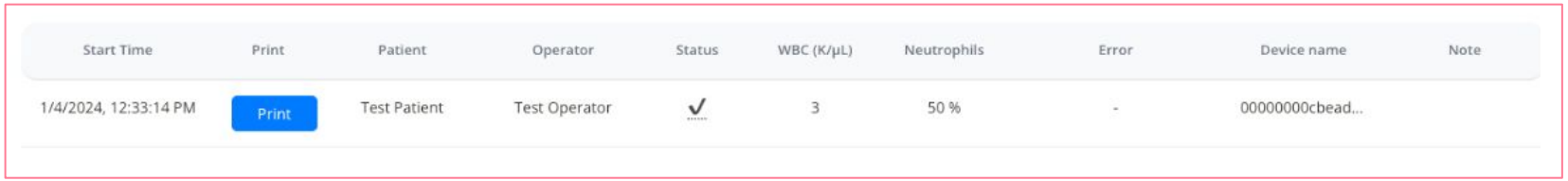
5. Once the test is complete, the LED light will return to blue light and a window will popup in the dashboard to display the success or any errors that might have come up.



6. After the test is complete, the strip can be removed from device. Discard strip after results are generated. Please consult your local authorities for advice on proper disposal.

Results (for point-of-care settings only)

5. Once the test is complete, the LED light will return to blue light and the "Test Results" will popup in the dashboard to display results as well as any errors or flags (for administrators roles only) that might have come up.



6. The results will be displayed on the screen along with the patient identifier. These results are informational and not diagnostic or prescriptive. If a quantitative measurement is not displayed on the screen, one of the error flags listed in Section Errors & Flagging may appear.

7. After the test is complete, the strip can be removed from device. Discard strip after results are generated. Please consult your local authorities for advice on proper disposal.

Error Codes and Messages (for at-home users)

In case of an error, Athelas Home generates the Error Codes. Please note that full error codes and flags information is viewable to the designated healthcare provider. After 3 successive errors, the system is remotely locked out and the healthcare provider is alerted to check-in with the patient and ensure proper training.

Error	Potential Cause	Recommended Action
The test strip has not been filled correctly	Error in the test strip, blank, or incomplete fill	Dispose the test strip and fill another one.
The test strip does not contain a uniform distribution of cells	Blood sample was not properly collected	Dispose the test strip and fill another one.
Optical/Test-Strip Error	Dust, debris or imager focus issue	Dispose the test strip and fill another one.
Hardware System Error	Actuator, processing board or WiFi module issue	Reboot the system and try again.
Test Strip Reverse Insertion	Test strip was inserted in the wrong orientation	Insert the strip with magnetic strip facing upwards towards the device and rerun the test.

Error Codes and Messages (point-of-care settings only)

Athelas Home generates the following Error Codes & Flags:

Error	Potential Cause	Recommended Action
The test strip has not been filled correctly	Error in the test strip, blank, or incomplete fill	Dispose the test strip and fill another one.
The test strip does not contain a uniform distribution of cells	Blood sample was not properly collected	Dispose the test strip and fill another one.
Optical/Test-Strip Error	Dust, debris or imager focus issue	Dispose the test strip and fill another one.
Hardware System Error	Actuator, processing board or WiFi module issue	Reboot the system and try again.
Test Strip Reverse Insertion	Test strip was inserted in the wrong orientation	Insert the strip with magnetic strip upwards towards the device and rerun the test.
LL!	WBC below reportable range of device	Repeat the test. If the retest confirms the error, send the sample to a reference lab.
HH!	WBC above reportable range of device	Repeat the test. If the retest confirms the error, send the sample to a reference lab.

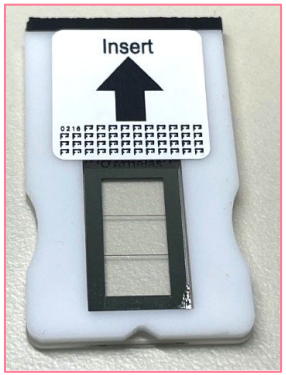
Error Codes and Messages (point-of-care settings only)

Flag	Potential Cause	Recommended Action
Abnormal Cells Detected Manual Review Recommended	Abnormal blood cells detected. This flag covers: presence of nucleated red blood cells, platelet clumps, abnormal lymphocytes, blast cells, reticulocytes, left shift, immature granulocytes	Repeat the test. If the retest confirms the flag, send the sample to a reference lab for a manual review.
Leukocytosis	WBC > 18 x 10^3/µL	Repeat the test. If the flag remains, notify the healthcare provider.
Leukocytopenia	WBC < 2.5 x 10^3/µL	Repeat the test. If the flag remains, notify the healthcare provider.

Athelas Home does not generate distributional flags for Neutropenia and Neutrophilia. Athelas Home may not detect or flag all morphological abnormalities.

Quality Control: Athelas AUTO-CHECK strip

Athelas Home is fully factory-calibrated and does not require ongoing calibration.
For Quality Control use Athelas AUTO-CHECK 3-level strip.



The Athelas AUTO-CHECK 3-level strip is a reusable strip that includes white blood cell and neutrophil graphic depictions in the appropriate aspect ratio and size. It includes three levels of WBC and NEUT% for different concentration counts.

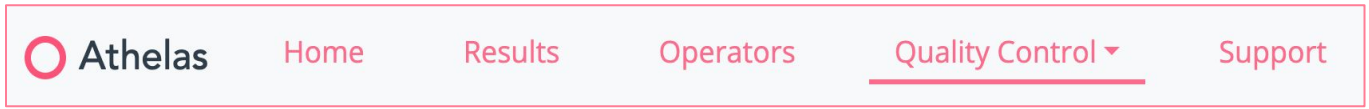
By placing AUTO-CHECK strip into Athelas Home device and pressing "Run Quality Control", an automated quality check will be run ensuring that the system optics, image processing, and analysis are working accurately.

It is recommended to use Auto-CHECK on the Athelas Home at least once a month.

Running Auto-Check

1. Insert the auto-check strip in the device with the magnet facing upwards. Make sure the strip is clean and free of fingerprints and contaminants.

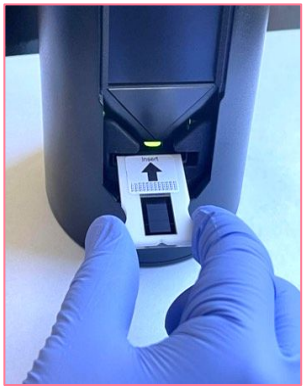
2. Log-in into clinic.athelas.com and select "Quality Control" from the toolbar on the top. Select "Run Quality Control" and follow the instructions on the page. Click on the "Start Quality Control" tab to start the test.



3. Athelas Home will analyze the strip and ensure that the internal target values for WBC and NEUT% are recovered per-region.

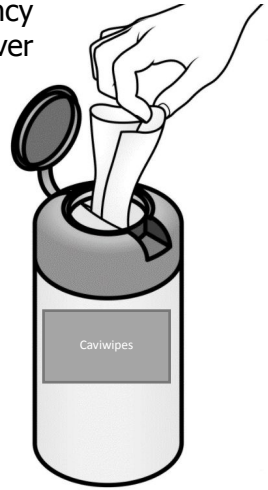
4. Scroll down to the Results section of the page. If the value of each level is within the corresponding range, then WBC, Neut% will read PASSED on the screen.

5. Once all 3 levels have passed QC, click 'Certify QC' tab to certify results. If QC test has not passed, contact your healthcare provider or designated Athelas representative.



Cleaning and disinfection instructions

The device uses a disposable test strip, therefore it will not have direct patient contact. In POC settings, to remove dust, dirt or debris and to clean and disinfect the surface of the device, the recommended frequency of cleaning is between each patient. For home users, regular cleaning/maintenance is not required. However if the device becomes dirty, the following procedure is recommended.



1. Before cleaning the device, ensure that it is turned off and unplugged from the power source. Do not use any acid, organic solvent, or alkaline agents, as they may cause discoloration, corrosion, or alter the device's surface.

2. Take a ready-to-use CaviWipes and follow the Directions of Use on the Caviwipe's labeling:

- Use a Caviwipe wipe to completely preclean surfaces of all visible debris.
- Use a separate Caviwipe wipe to thoroughly wet the surface by running the wipe three times horizontally and three times vertically. Take care to run the wipe along the stage of the device, the ports, the front reflective surface, as well as the device lid.
- Ensure the device surface remains visibly wet for at least 2 minutes.
- Discard the wipe and gloves after use, and clean hands.

3. Wait 5 minutes after cleaning the device to plug it back in and power it on.

If you have any questions, please contact your healthcare provider or designated Athelas representative at 877-324-4332.

Specifications

Indication(s) for Use

The Athelas Home is indicated for the quantitative determination of white blood cells (WBC) and Neutrophil percentages (NEUT%) in capillary whole blood from fingerstick for patient self-testing with results viewable by healthcare professionals, and in capillary or K2EDTA venous whole blood for multiple-patient use in point-of-care settings. For self-testing, the Athelas Home is intended to be used by a single person and should not be shared. The Athelas Home is only to be used with Athelas Test Strips. The Athelas Home is intended for adult patients (aged 21 and older) at risk of neutropenia. For self-testing patients with psychiatric conditions, clinical judgment should be exercised when deciding the end-user and based on the instructions for use (IFU), the treating physician should determine which patients are competent to perform the test by themselves. Results obtained with the Athelas Home should not be the sole basis for patient diagnosis, treatment, or management of leukopenia and neutropenia, and all results should be evaluated by a healthcare provider. Prescription Use Only.

Principles of Method and Procedure

A microfluidic test strip channel creates a stained monolayer of white blood cells. Multiple images are taken of the monolayer and the cells are counted and classified by computer vision based image analysis.

Warning and Precaution

Athelas test strips are for In Vitro Diagnostics only. Please consult your local authorities for proper disposal. Always be extra careful and wear appropriate protective wear when handling human blood, as it may be infectious. Test strips are not to be reused or ingested. Please adhere to the expiration dates on the packaging.

Specifications

Quality Control
The Athelas Home device is factory calibrated and has an internal quality control self test which runs automatically every time it is powered on and also prior to every test. An Athelas Quality Control Strip (Athelas Auto-CHECK) is also provided through Athelas. The Athelas Auto-CHECK to verify device is returning counts accurately and precisely on the QC grid strip material with expected WBC and Neut% metrics. The recommended Auto-CHECK frequency is once a month.

Operational settings
Recommended to use in 15°C — 30 °C (59 °F — 86°F), under 60% humidity, and under 2000m of altitude. Athelas system should remain in a stationary location free from excessive movements and any potential vibrations.

Materials Needed For Analysis
Provided: Athelas Analyzer; Athelas Test Strip, Auto-Check Strip. Not Provided: lancet (for capillary samples), enzymatic wipes, disinfecting wipes, protective gloves.

Storage, Shipping and Handling
The Athelas device and test strips should be stored at temperatures between -20°C and 40°C (-4°F and 104°F). Do not store in conditions with extreme humidity (> 60%). Keep the test strip package closed at all times and use before expiration date printed on test strip package insert. Device should be shipped within sealed original packaging to protect from damage during shipping. Device is ready to use upon unboxing. Device packaging does not contain any biohazardous reagents or lithium ion batteries that could cause damage throughout the shipping process. Handle with care when moving the device between different locations and avoid possible exposure to chemicals or extensive agitation during transportation.

Specifications

Sample Stability
Whole blood stability was evaluated by conducting a 24 hour stability study on nine different venous blood samples with low (0.5-3 x 10^3/µL, normal (4-10 x 10^3/µL), and high (>10 x 10^3 /µL) WBC levels. The samples were analyzed initially, after 12 hours, 24 hours, and 48 hours. Overall, all samples tested within 24 hours of collection time were found to meet the pre-set acceptance criteria of ±7.5% Bias for WBC, 5% SD (or 15% CV) for Neut% and ±10% Bias across the whole study.

Expected Values (Pekelharing et. al (2010))
Note, normal values may vary from one laboratory to the next depending on reagents and instrumentation.
Each laboratory should independently determine their own expected values.
Values on the table are just provided for reference.

Gender	WBC Range (10^3/µL)	Neutrophil Range (%)
Male	3.91 – 10.90	41.0 – 70.7
Female	4.49 – 12.68	42.9 – 74.3

Measuring Range
The display range for WBC is 1.0 – 25.0 x 10^3/µL
Results that exceed the measuring display range
will render results of **HH!** if above range and **LL!** if below range.

Limits of Detection
The LoD for WBC is 0.079 x 10^3/µL.

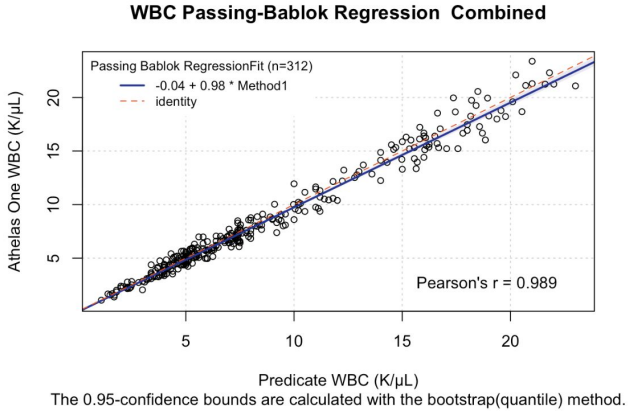
Limitations of Method/Procedure
Do NOT mix the sample for more than recommended period, as it may affect results.
System does not directly generate Absolute Neutrophil Count (ANC). Rather, White Blood Cell (WBC) and NEUT% are generated.

Performance Characteristics

Validation Studies
(performed on Athelas One, identical device to Athelas Home)

After analyzing the performance of the Athelas Home and the Sysmex XE 5000 in clinical settings, it was determined that the r^2, slope, intercept, and bias values in Passing-Bablok regression adequately showcase equivalence between the two testing mechanisms as per CLSI method comparison analysis recommendations. The Athelas Home demonstrated a high level of statistical significance in all key parameters. The study was conducted at 3 point-of-care sites, using nurse and clinician operators with abnormal & normal patient samples.

Overall bias was analyzed as well as bias at medical decision levels ($3.9x10^3$/µL WBC, $10.4x10^3$/µL WBC and on Neut% 46.4 and 76.9). The site-by-site overall bias, combined overall bias, site-by-site bias at medical decision levels all met the predefined maximum criteria of 7.5% for WBC and 10% relative Neut% or 5% absolute (as did their 95% confidence intervals).



Bias at Medical Decision Levels

WBC Level (K/µL)	Bias (K/µL)			Bias (%)			Limits (%)	Full CI within Limits?
	Estimate	LCI (2.5%)	UCI (97.5%)	Estimate	LCI (2.5%)	UCI (97.5%)		
3.9	-0.126	-0.185	-0.043	-3.238	-4.733	-1.100	± 7.5 %	Yes
10.4	-0.266	-0.387	-0.122	-2.559	-3.722	-1.174	± 7.5 %	Yes

Neutrophil Level (%)	Bias (Percentage Points)			Limits (Percentage Points)	Full CI within Limits?
	Estimate	LCI (2.5%)	UCI (97.5%)		
46.4	0.936	-0.764	1.851	± 5	Yes
76.9	0.333	-1.150	1.321	± 5	Yes

Performance Characteristics

Within Run and Total Precision
(performed on Athelas One and Athelas Home)

Precision studies on Athelas Home were performed using residual K2EDTA whole blood samples around medical decision levels and the upper and lower limit of the analytical measuring range. The study was conducted with nine whole blood samples, three different operators and three different test strip lots.

In total 90 tests were run per sample level, with 810 tests run in total. The mean, standard deviation (SD), and coefficient of variation (CV) were calculated for each sample. The results met the predefined specifications (CV%) for precision.

A 48-run in-home precision study with Athelas Home users was also conducted, and successfully met evaluation criteria for WBC and NEUT%.

Athelas One Study

WBC Summarized

Sample	Mean Value (K/µL)	N	Repeatability		Between-Lot		Between-Instrument		Between-Operator		Total		Target Evaluation		
			SD (K/µL)	CV (%)	SD (K/µL)	CV (%)	SD (K/µL)	CV (%)	SD (K/µL)	CV (%)	SD (K/µL)	CV (%)	Target Metric	Experiment Value	Target Value
1	2.20	90	0.12	5.62	0.00	0.00	0.00	0.00	0.04	1.70	0.13	5.87	CV	5.87%	7.50%
2	3.75	90	0.20	5.42	0.00	0.00	0.01	0.36	0.02	0.60	0.20	5.46	CV	5.46%	7.50%
3	4.12	90	0.20	4.78	0.00	0.00	0.06	1.43	0.04	1.02	0.21	5.09	CV	5.09%	7.50%
4	5.11	90	0.25	4.96	0.00	0.00	0.14	2.73	0.10	1.87	0.30	5.96	CV	5.96%	7.50%
5	7.89	90	0.33	4.18	0.06	0.78	0.09	1.14	0.15	1.94	0.38	4.82	CV	4.82%	7.50%
6	10.01	90	0.50	5.01	0.00	0.00	0.10	0.98	0.19	1.91	0.55	5.45	CV	5.45%	7.50%
7	14.64	90	0.66	4.51	0.19	1.27	0.00	0.00	0.00	0.00	0.69	4.69	CV	4.69%	7.50%
8	17.52	90	0.70	3.97	0.00	0.00	0.17	0.95	0.26	1.49	0.76	4.34	CV	4.34%	7.50%
9	23.33	90	1.01	4.33	0.77	3.31	0.20	0.87	0.43	1.82	1.36	5.81	CV	5.81%	7.50%

Athelas Home Study

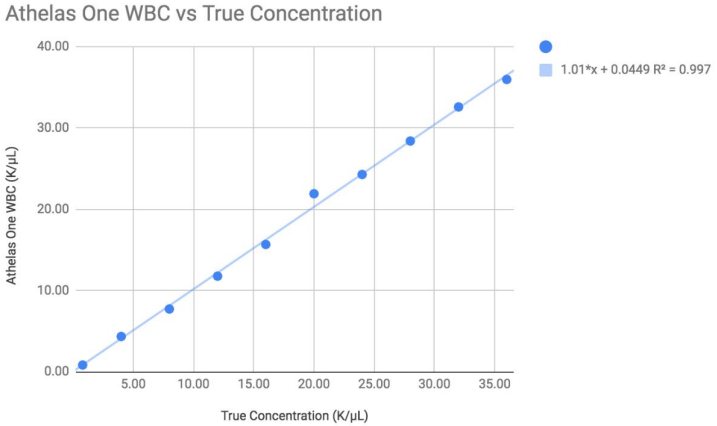
	Value	Eval Criteria	Pass/Fail
WBC CV%	5.4% CV	7.5% CV	Pass
NEUT% SD	1.2% SD	5% SD or 15% CV	Pass

Performance Characteristics

Linearity
(performed on Athelas One, identical device to Athelas Home)

A linearity study was conducted to assess the linear correlation of the Athelas Home WBC concentration across reported ranges. Ten samples across the reporting range were run in 4 replicates across 4 devices and one test strip lot. Linearity is maintained at high counts well beyond $10x10^3$ WBC/µL (evaluated up to $35x10^3$/µL) thanks to detection designed to handle crowded imaging and cell clumping (avoiding the hook effect), as shown in Figure on right from a $12x10^3$ WBC/µL sample. The samples were obtained by pooling together one low WBC concentration fresh whole blood sample one high WBC concentration sample in different volumes which is a recommended option in CLSI EP6-A.
The method has been demonstrated to be linear from lower limit to upper limit and within measured allowable max % diff for each interval.

Parameter	N	R^2	Slope	Intercept	CVr
WBC	10	0.997	1.013	0.0449	5.08%



Performance Characteristics

Interference Studies

Interference studies were performed taking sample abnormalities, drugs, metabolites, sample additives and dietary substances into consideration. A list of substances were tested and found not to interfere. Substances tested: Bilirubin C, Bilirubin F, Hemolytic Hemoglobin, Lipid, Chyle, nRBCs, Giant Platelets, Platelet Clumps, Platelet Aggregates, Reticulocytes. None of the substances were found to interfere with the measurements of the Athelas Home. Although it should be noted that such interferons can have impact on hematology results. As such, the Athelas Home analyzer has flagging capabilities to notify the user when abnormal cell types are present. See 'Errors and Flagging' section for more information.

Reference Intervals

A reference interval study was conducted to validate the reference intervals of the Sysmex XE-5000 in context of the Athelas Home data. The transferring approach was utilized to confirm the manufacturer's reference interval given in the table on the right.

Parameter	Male (N = 60)		Female (N = 60)	
	Lower Limit	Upper Limit	Lower Limit	Upper Limit
WBC	3.91 10^3/μL	10.90 10^3/μL	4.49 10^3/μL	12.68 10^3/μL
NEUT%	41.0 %	70.7 %	42.9 %	74.3 %

Reportable Range

The reportable range for WBC is 1.0 - 25.0 x 10^3/μL.

Technical Specifications

Dimensions: 90 mm diameter x 220 mm height; **Weight**: 0.79 kg
Pollution degree: 2
Overvoltage category: II
Device Electrical Specification: 12V DC, 2.2A
Atmospheric Pressure: 870 hPa to 1080 hPa
Equipment not suitable for use in the presence of flammable mixtures.

Power Adapter
Part Number: Friwo FW8030M/12
Type: 1898521
Input: 100V~ – 240 V~, 50–60 Hz, 300-600 m
Output: 12V, 2.5A

Electromagnetic Compatibility and Electrical Safety

Guidance and manufacturer's declaration – electromagnetic immunity. The Athelas Home WBS system is compatible with its electromagnetic (EM) environment and does not emit levels of EM energy that cause electromagnetic interference (EMI) in other devices in the vicinity. The Athelas Home WBC System underwent Electromagnetic Compatibility (EMC) testing by an independent laboratory, Bay Area Compliance Laboratories Corp at 1274 Anvilwood Ave, Sunnyvale, CA 94089, USA (Tel: 408-732-9162).
The test results indicated that the device is compliant with the relevant standard (IEC 60601-1-2 Edition 4.0 2014-02, Medical Electrical Equipment - Part1-2: General Requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests). The tests conducted include Conducted Emissions, Radiated Emissions, Harmonic Current Emissions, Voltage Fluctuations and Flicker, Electrostatic Discharge Immunity, Electrical Fast Transients Immunity, Surges Immunity, Conducted Disturbances Induced by RF Fields Immunity, Power Frequency Magnetic Fields Immunity, and Voltage Dips and Interrupts Immunity.

The Athelas Home WBC System is also certified for the following standards: ANSI/AAMI ES60601-1:2005/(R)2012: Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance (IEC 60601-1:2005, Mod) and FCC Part 15 Subpart B Class B.

Electromagnetic Compatibility and Electrical Safety

Rules	Description	Results
IEC 60601-1-2 §7.3, EMC Emissions	Conducted Emissions (CISPR 11)	Compliant with Class B Limits
	Radiated Emissions (CISPR 11)	Compliant
	Harmonic Current Emissions (IEC 61000-3-2)	Compliant
	Voltage Fluctuations and Flicker (IEC 61000-3-3)	Compliant
IEC 60601-1-2 §8.9, Immunity	Electrostatic Discharge (IEC 61000-4-2)	Compliant
	Electrical Fast Transients/Bursts (IEC 61000-4-4)	Compliant
	Radiated RF EM Fields (IEC 61000-4-3)	Compliant
	Conducted RF Disturbance (IEC 61000-4-6)	Compliant
	Power Frequency Magnetic Fields (IEC 61000-4-8)	Compliant
	Surges (IEC 61000-4-5)	Compliant
	Voltage Dips And Interruptions (IEC 61000-4-11)	Compliant
	Radiated Fields In Close Proximity (IEC 61000-4-39)	Compliant

General Guidance

Warning

Do not modify this equipment without authorization of the manufacturer. This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation.

The Athelas system is suitable for us in all establishments including those directly connected to low-voltage power supply network that supplies buildings used for domestic purposes. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures: reorient or relocate the receiving antenna, increase the separation between the equipment and receiver, connect the equipment into an outlet on a circuit different from that to which the receiver is connected, or consult the dealer or an experienced radio/TV technician for help.

Do not position the equipment in a way that makes it difficult to operate the disconnecting device.

Maintain minimum separation distance of 12 inches (30 cm) between any part of the Athelas Pro device and portable RF communications equipment. Performance of the device might degrade if proper distance is not maintained.

Patents

This product is protected by the following patents: No. 15/415,775 and No. 62/629,557.

References

1. Pekelharing et. al (2010). Haematology reference intervals for established and novel parameters in healthy adults. Diagnostic Perspectives 1: 1 – 11.
2. Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline CLSI Document EP05-A3. Third Edition, 2014
3. Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach;
4. Approved Guideline CLSI Document EP06-A. Interference Testing in Clinical Chemistry;
5. Approved Guideline CLSI Document EP07-A2.
6. Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline Document CLSI EP09-A3. Third Edition, 2013
7. Protocols for Determination of Limit of Detection and Limit of Quantification; Approved Guideline CLSI Document EP17-A.

Proficiency Quiz

This quiz and training session should be administered when evaluating if a user has properly learned how to operate the Athelas Home. All steps must be passed by the patient in order for them to be considered proficient on the system.

1. Ask the patient to identify the following components from the package: Athelas Home Device, Lancet, Athelas Test Strip, User Manual, Athelas Home Power Cable. Ensure all elements are successfully identified.
2. Ask the patient to plug in the device and ensure the indication light turns on. Ensure that the device successfully turns on and the patient understands the process to do so.
3. Ask the patient to install the Athelas application on a designated mobile phone or tablet. Ensure he/she is able to open the application and successfully pair to the device following the steps.
4. Ask the patient to review the pricking process with the lancet. Demo the process once to the patient on your own finger. Then ask the patient to prick their own finger following the appropriate steps in the manual. Ensure that the proper steps are followed (discarding first two drops, filling the test strip in full.). If the patient has trouble, guide them through the process once more. If after repeated attempts the patient still is making mistakes, note that they may not be a good candidate for the Athelas Home system.
5. Demonstrate how to insert the test strip into the device once for the patient. Then return the test strip to the patient and ask them to do it on their own. Ensure that the patient inserts the strip properly.
6. Ensure the patient presses ‘Run’ and knows how to initiate the test. Allow them to independently conduct this step at least once, and record observation.
7. While the test is running, walk the patient through the error codes that may show up if he/she makes a mistake in the process, and ensure the patient understands the next steps following each error (described in the error code section of this manual).
8. Take the user manual from the patient, and ask them what the correct resolving steps are for the patient-facing error codes. Ensure they answer correctly, else review and repeat process.
9. Once test has completed running, ensure the patient is familiar with how to parse a ‘success’ from an error code. And then ensure the patient is able to safely unplug the device clean up their sampling error (disposing of test strip, lancet, and wiping finger with a tissue if needed).


Athelas