CSAN PRONTO

CSAN® Pronto™ User Manual

1.0 Table of Contents

2.0 Intended Use

CSAN® Pronto™ is for use as a point-of-care device indicated for quantitative determination of white blood cells (WBC) and neutrophil percentages (NEUT%) in capillary or K_2EDTA venous whole blood. CSAN® Pronto™ is only to be used with CSAN® Pronto™ Test Strips.

CSAN® Pronto™ is indicated for *in vitro* diagnostic use only in clinical laboratory and point-of-care settings by trained healthcare professionals in adult populations. Please note that pediatric claims have not been established.

3.0 Warnings

CSAN® Pronto™ is a whole blood analyzer, which involves the collection of a blood specimen. All patient samples should be treated as potentially infectious and handled appropriately. Standard precautions should be employed. Personal Protective Equipment should be worn when processing samples, quality control testing, or maintenance procedures.

Test strips are single-use strips.

Prior to operating the device, please read this User Manual carefully and undergo in-person training prior to use. If further explanations or support is required, please contact CSAN® staff.

CSAN® Pronto™ is only to be used with CSAN® Pronto™ Test Strips (Cat. #80301200). All device materials provided are manufactured and designed to provide maximum operator safety. Altered use of the equipment, other than indicated, may result in safety impairment.

During use, CSAN® Pronto™ should be placed on a stable surface, free from movements and any potential vibrations. Operators are not to move the device from one location to another while in operation.

4.0 Device Description

4.1 PRINCIPLES OF METHOD AND PROCEDURE

CSAN® Pronto™ generates white blood cell (WBC) and neutrophil percent (NEUT%) counts through image analysis.

The microfluidic CSAN® Pronto™ 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 image analysis. The calculation of indices is based on international principles in hematology. Once these images are thoroughly analyzed, the white blood cell counts and neutrophil percent are displayed.

4.2 COMPONENTS

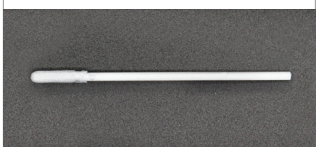
The following are required when you order CSAN® Pronto™:

Cat. #80301201

CSAN® Pronto™
(1 device)

Cat. #80301204

AC power adapter



Cat. #80301205

CSAN® Pronto™ Optical Swab
(to clean the optical parts of
CSAN® Pronto™)

* To order additional swabs, please contact CSAN® at 1 (800) 267-2726

Cat. #80301200

CSAN® Pronto™ Test Strip

Box of 50 strips

* To order strips, please contact CSAN® Order Desk at 1 (866) 669-2313

4.3 MATERIALS REQUIRED BUT NOT PROVIDED

The following are required for the operation of CSAN® Pronto™ and should be ordered separately:

- Lancets for capillary draw (spring-loaded lancets with a puncture depth of 2 mm are recommended)
- Venous phlebotomy supplies
- Alcohol wipes for cleaning finger/venous draw site prior to sample collection
- K_2EDTA tubes
- CSAN® Pronto™ App for tablet, smartphone, or computer
- Ethernet cable (optional)
- Pipette (for venous blood samples)
- Protective gloves
- Suggested disinfectant and cleaning wipes (Clorox Healthcare Bleach Germicidal Wipes® [DIN 02465671])

5.0 CSAN® Pronto™ Set Up

Important: Always move and handle carefully.

Prerequisites for installation:

- Make sure that an AC power outlet is available
- Ensure access to a reliable network connection
- Place the device on a stable surface, free from movements and any potential vibrations
- Avoid placing the device in a location with sunlight exposure and temperature fluctuations
- Protect device against water to prevent damage

To set up CSAN® Pronto™, open the packaging and set the device on a stable surface. When the device is plugged in and powered on, a light under the slide tray will turn orange.

[1] A tablet, computer, or smartphone is specifically provisioned for use with CSAN® Pronto™. CSAN® recommends that the given tablet/smartphone has anti-malware software and is permission locked to only allow access to authorized personnel. Compatible tablet/smartphone models include devices supporting iOS 9, 10, and 11, or Android 7, 8, and 9.

Prior to use, the device must be connected to the Internet. The Internet connection can be established by either plugging the device directly into an Ethernet port located on the top of the device, or via a wireless connection. If using Ethernet connection, proceed to Step 5 of **Section 6.0**. For connecting CSAN® Pronto™ to wireless Internet, please refer to **Section 6.0**.

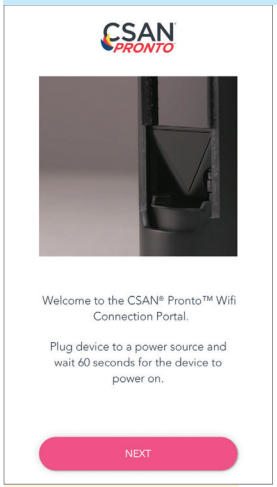
After the device is connected to the Internet, proceed with testing. When the device is connected to the Internet, a light under the slide tray will turn green, indicating the device is ready. The device may be used either through the mobile application or computer application based on user preference.

Power outlet

1. Plug the power adapter into the power outlet on the device located on the lower back side (as pictured).
2. Download the CSAN® Pronto™ Application onto an authorized smartphone, computer, or tablet[1] from the Apple App Store for iOS or Google Play for Android.
3. Install the CSAN® Pronto™ Application on the smartphone, computer, or tablet.

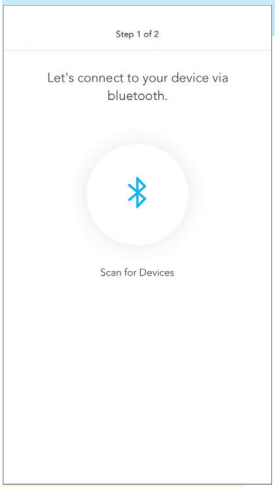
6.0 Connect CSAN® Pronto™ to the Internet

1. Login

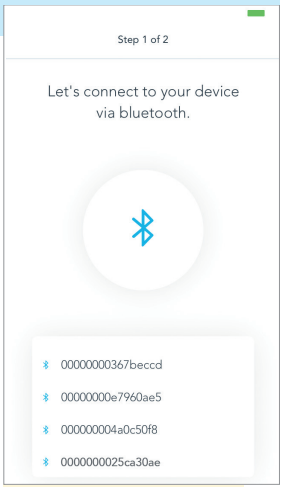


After installation of the CSAN® Pronto™ Application, press "Next".

2. Connect Device

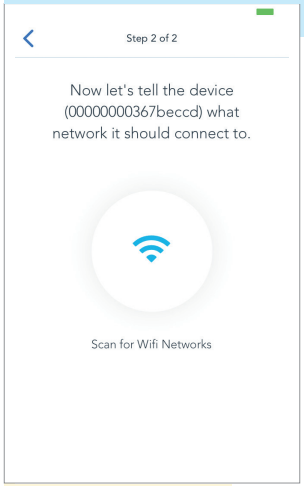


Press the Bluetooth button to scan for devices and connect to Bluetooth.

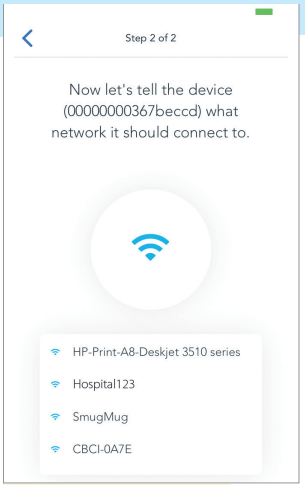


Once the device is selected, this will prompt the next screen.

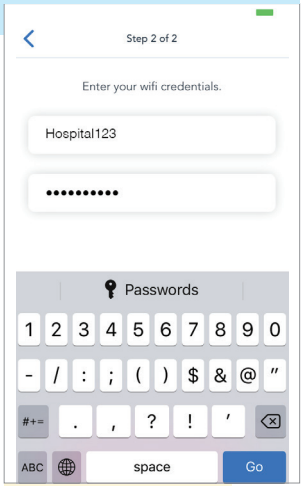
3. Connect to Wi-Fi



Tap the Wi-Fi button to search for available Wi-Fi networks.

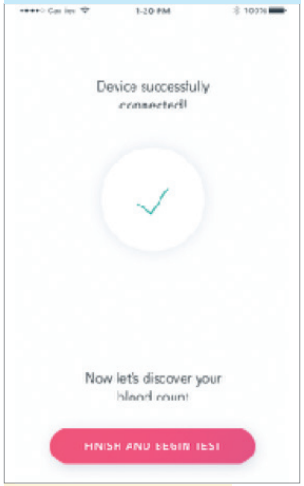


A list of all networks found will appear on the screen. Click on the network you wish to join.



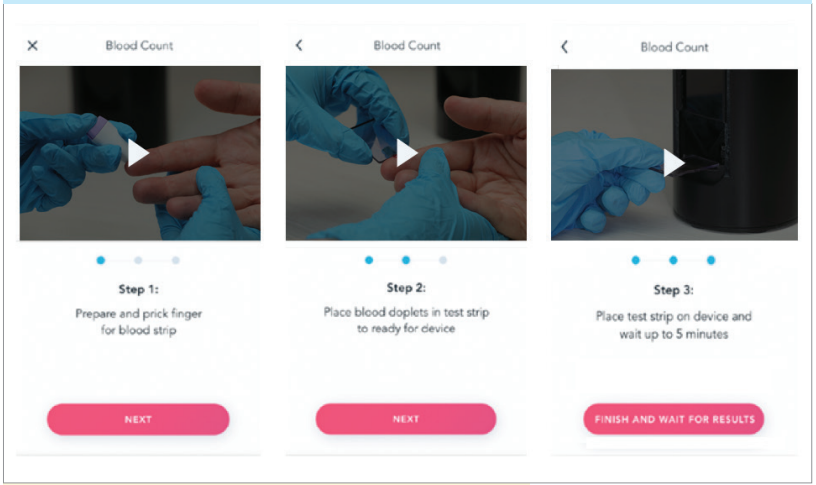
Type in the password for the Wi-Fi network and hit “Go” to finish pairing the device.

4. Finish Connecting



When the device has successfully connected, you will be prompted to “Begin Test”.

5. Instructions For Use

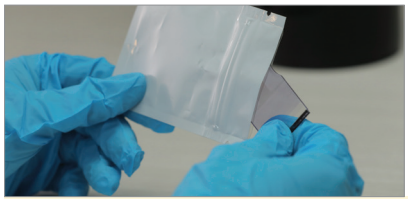


Once you begin the test, the application will guide you through steps on various screens. Each screen will show you instructional videos. Hit “Next” as you move along the process.

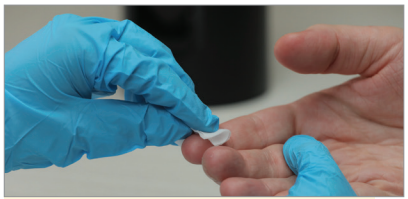
7.0 Sample Collection

Important: Always handle human blood specimens carefully, as they may be infectious. Protective gloves are to be worn at all times when handling blood specimens. Please note that each test strip is for single use only and must be used immediately after opening the test strip package. Do not reuse test strips and dispose of lancets with care. Observe aseptic technique when handling the device, test strips, and lancets.

7.1 SAMPLE COLLECTION: CAPILLARY



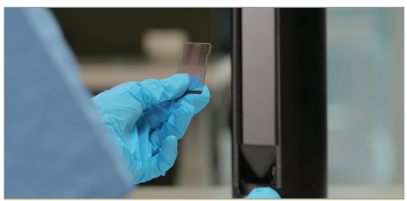
1. Take one test strip package labelled "CSAN® Pronto™ Test Strip". Open the package, take the test strip out. Do not use if the test strip is damaged (i.e., cracked, visibly dirty).



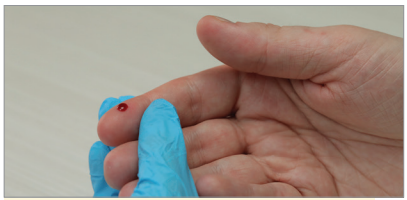
2. Clean the selected fingertip with an alcohol wipe and allow to dry completely before puncturing.

3. Lightly hold pressure at the fingertip and puncture a non-callused area on the side of the fingertip using a lancet.

4. Wipe away the first two drops using a cotton wipe.

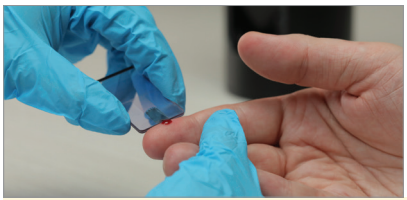


7. Observe the test strip for proper fill. The device will not complete testing if air bubbles are present or if the test strip is less than about 75% filled. Wipe off excess blood from the edge of the test strip with a cotton wipe and proceed with testing. When the slide is inserted properly and ready to start the test, the light will turn light blue.



5. Re-apply pressure until a third drop of blood appears. **Do not** "milk" the finger or apply too much pressure.

8. The test strip must be read within **30 minutes** of loading the sample.

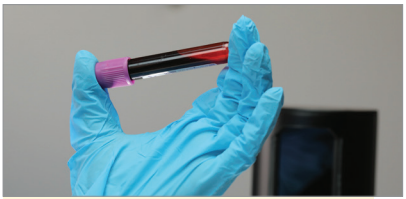


6. Place the third drop on the test strip and fill in one continuous process. **Note:** Place the test strip at about a 45° angle towards the blood drop and do not detach the finger from the test strip until the test strip is completely filled. Improper filling may cause air bubbles in the test strip.

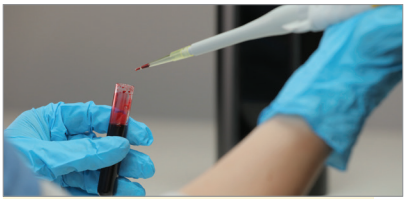
Make sure the patient is relaxed and his or her hand is warm to increase blood circulation (middle finger or ring finger are recommended sites for sampling).

7.2 SAMPLE COLLECTION: VENOUS

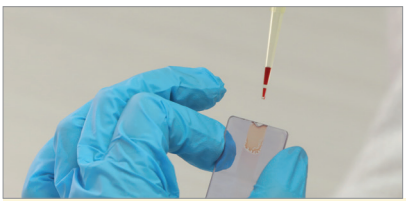
1. If the venous blood sample has been stored at refrigerated temperature, allow it to reach room temperature (18–26°C or 64–79°F) before testing.



2. Mix the tube of blood thoroughly by using a mechanical mixer or by manually inverting the tube 10–15 times.



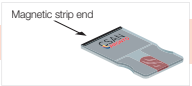
3. Use a pipette or syringe to retrieve the specimen from the container. An aspiration volume of 3–4 µL is recommended.



4. Angle the pipette tip at about a 45° angle from the test strip for proper flow. Place a drop of blood (about 3.5 µL) or control fluid on the test strip and allow it to fill in throughout one continuous process. **Do NOT** refill if the initial drop is insufficient, use a new test strip and repeat the measurement.

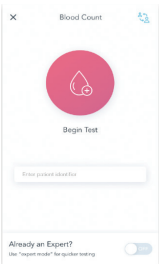
8.0 Running a test

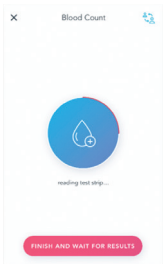
Do not wait more than 30 minutes before testing the strip.



Make sure the magnetic end of the test strip is inserted first into CSAN® Pronto™.

1. Place the test strip into the base of CSAN® Pronto™ within the rail-guided regions, as pictured, with the magnetic strip (black stripe) inserted first. **Note:** If the test strip is improperly inserted (i.e., not fully in), the system will detect this and render a warning.





2. Once the test strip is correctly inserted, enter the patient identifier. Once done, hit “Begin Test”.

The test will not begin until a patient identifier is inputted.

3. While the test is running, a red circle around the droplet button will show the estimated time left for completion.

4. CSAN® Pronto™ will now take multiple images of the test sample and render a result on the screen after a few minutes.

5. When CSAN® Pronto™ is done testing, it will return the test strip to its original position and you may remove the test strip. Properly discard the test strip after results are generated.

6. The results will be displayed on the application screen along with the patient identifier. If a quantitative measurement is not displayed on the screen, one of the error flags or error codes listed in **Section 9.0 Errors and Flagging** may appear.

9.0 Errors and Flagging

CSAN® Pronto™ generates the following flags and error codes:[2]

Flags[3]

Abnormal Cells Detected - Manual Review Recommended
This flag covers:

- Presence of nucleated red blood cells
- Presence of platelet clumps
- Presence of abnormal lymphocytes
- Presence of blast cells
- Presence of reticulocytes
- Left shift
- Presence of immature granulocytes

Leukocytosis

- WBC >18 x 10^3/µL

Leukocytopenia

- WBC <2.5 x 10^3/µL

Error Codes

Optical/Test Strip Error - Please dispose of strip and try another.

- Dust, debris, imager focus issue, error in the test strip, blank, unfilled, or uneven distribution

Hardware System Error - Please reboot system and try again.

- Actuator, processing board, or Wi-Fi module issue

HH!

- WBC above reportable range

LL!

- WBC below reportable range

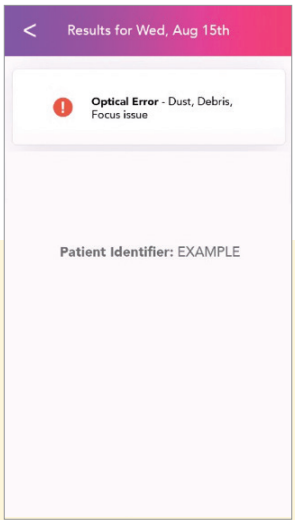
[2] CSAN® Pronto™ may not detect or flag all morphological abnormalities.

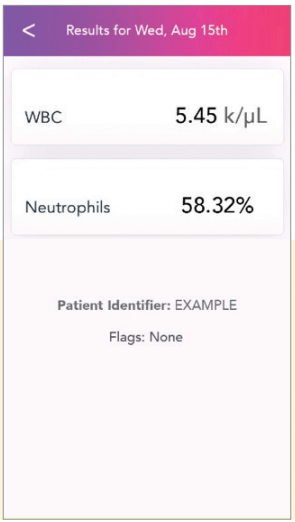
[3] CSAN® Pronto™ does not generate distributional flags for neutropenia and neutrophilia.

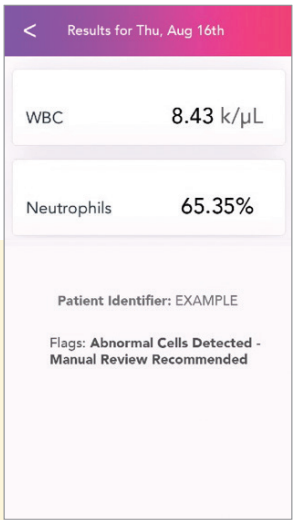
9.1 RESULTS AND ERRORS/FLAGGING

The screenshots on the right serve as examples of how the application returns error codes, flags, and results.

Note: WBC units "k/µL" represent 10^3/µL within the CSAN® Pronto™ App.



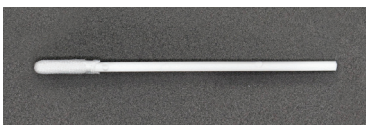




10.0 Maintenance and Cleaning

1. Before cleaning the device and performing maintenance, ensure the device is unplugged from the power source. Do not use any acid, organic solvent, or alkaline agents as they might cause discolouration or corrosion and alter the device's surface.
2. To remove dirt, blood, and other fluids off the device, and to clean and disinfect the surface of the device, take a ready-to-use enzymatic wipe (Clorox Healthcare Bleach Germicidal Wipes® [DIN 02465671] are recommended) and gently wipe the outside surface areas of the device.
3. To prevent the transmission of blood-borne pathogens, disinfect the device by wiping it 3 times horizontally and vertically with the Clorox Healthcare Bleach Germicidal Wipes®, and allow the disinfectant solution to soak for 5 minutes.
4. If the device renders an Optical Error code, the optical parts are likely dirty and the optical lens should be cleaned. To clean the optical parts, insert the CSAN® Pronto™ Optical Swab provided into the test strip insertion area. Use the optical swab to wipe the top end of the test strip insertion area. Move the optical swab forward and backward about 5–10 times. If it is dirty, repeat with a new cleaning swab.
5. Wait 5 minutes after cleaning CSAN® Pronto™ to plug it back in and to power it back on. A single CSAN® Pronto™ Optical Swab is provided with your CSAN® Pronto™. Please contact CSAN® at 1 (800) 267-2726 to order more.

The recommended cleaning cycle for CSAN® Pronto™ is twice a week.



11.0 Troubleshooting Guide

Note: Please contact CSAN® at 1 (800) 267-2726 if your device problem is not solved by this guide. Before sending it back for service, clean and disinfect the device and request a Return Authorization form from CSAN® at 1 (800) 267-2726.

12.0 Specifications

12.1 CALIBRATION AND QUALITY CONTROL

CSAN® Pronto™ is factory calibrated and has an internal diagnostic quality control (QC) self-test, which runs automatically every time it is powered on and also prior to every test. Once the self-test has completed measuring equipment performance and passes, the device will flash the LED light three times as it connects to the application. The built-in QC self-test also includes error codes, which measure performance of the operator's ability to handle and insert test strips into the device correctly.

A hematology QC test fluid can be used with CSAN® Pronto™. The recommended QC fluid, "CP WBC Quality Control Fluid", may be obtained by contacting CSAN® Order Desk at 1 (866) 669-2313.

12.2 SPECIMEN COLLECTION AND PREPARATION

Both capillary blood and K_2EDTA venous whole blood may be analyzed with CSAN® Pronto™. Before using a K_2EDTA sample, thoroughly mix by using a mechanical mixer or manually inverting the tube 10–15 times. The sample may be stored at room temperature (18–26°C, 64–79°F), or in a refrigerator (2–8°C, 35–46°F) for 24 hours. However, if the sample is stored in a refrigerator, allow it to warm up to room temperature before collecting and mixing.

12.3 SAMPLE STABILITY

Whole blood stability was evaluated on CSAN® Pronto™ 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 concentrations. The samples were analyzed initially, after 12 hours, 24 hours, and 48 hours. Overall, samples were found to meet Measurand Drift Criteria regarding sample stability across a 24-hour duration.

12.4 EXPECTED VALUES (Pekelharing, *et al.*, 2010)

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

Note: The above values are provided for reference purposes only. Normal values may vary from one laboratory to the next depending on reagents and instrumentation. As such, each laboratory should independently determine their own expected values.

12.5 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.

12.6 LIMITS OF DETECTION (LoD)

The LoD for WBC is 0.079 x 10^3/µL.

12.7 LIMITATIONS OF METHOD/ PROCEDURE

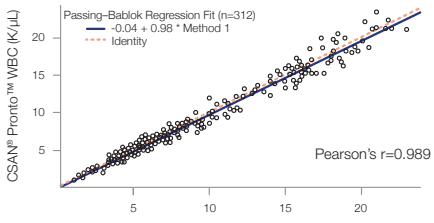
1. Use the test strips immediately after opening the package—do not open in advance.
2. Measurement should be made within 30 minutes after the blood has been drawn into the test strip.
3. Do NOT reuse test strips.
4. Do NOT mix the venous sample for more than the recommended period, as it may affect results.
5. Results above the measuring range will render **HH!** on the display. Results below measuring range will render **LL!** on the display.
6. See the results of the **Interference Study** (see summary results in **Section 13.5**) for interference-related limitations. This also reviews the process by which flagged interfering cells by CSAN® Pronto™ should be handled.
7. CSAN® Pronto™ may not detect or flag all morphological abnormalities.
8. CSAN® Pronto™ does not generate distributional flags for neutropenia and neutrophilia.

13.0 Performance Characteristics

13.1 VALIDATION STUDIES

After analyzing the performance of CSAN® Pronto™ and a commercially available laboratory reference method, 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 (**Figure 1**). CSAN® Pronto™ 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 and normal patient samples.

Figure 1: WBC Passing–Bablok Regression Combined



The 0.95-confidence bounds are calculated with the bootstrap (quantile) method.

Overall bias was analyzed (**Table 1**) as well as bias at medical decision levels (WBC counts of 3.9 x 10^3/µL and 10.4 x 10^3/µL, and NEUT% of 46.4% and 76.9%). The site-by-site overall bias, combined overall bias, site-by-site bias at medical decision levels, and combined bias at medical decision levels all met the predefined maximum criteria of 7.5% for WBC and 10% NEUT % (as did their 95% confidence intervals).

Table 1: 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

CI=confidence interval; LCI=lower confidence interval; UCI=upper confidence interval.

13.2 WITHIN-RUN AND TOTAL PRECISION

Precision studies were performed using residual K_2EDTA 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 (targets shown in **Table 2**).

Table 2: 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%

13.3 PRECISION AND REPRODUCIBILITY

A 20-day reproducibility study was conducted to assess potential sources of imprecision of CSAN® Pronto™ including sites, runs, devices, operators, and test strip lots. Testing was performed using the standard hematology control fluid at the 3 levels (high, normal, and low). The fluid includes human leukocytes (neutrophils, lymphocytes, basophils, eosinophils, monocytes) preserved along with red blood cells (RBCs).

The study was conducted in accordance with recommendations from CLSI EP05-A3. Results were analyzed for repeatability, between-run, between-day, between-site, and overall precision using a 3-level Nested ANOVA analysis. Overall reproducibility levels were found to meet the acceptance criteria of 7.5% CV for WBC and 5% SD or 15% CV for neutrophils (results shown in **Table 3**).

Table 3: Precision and reproducibility analysis for CSAN® Pronto™ assessing sources of imprecision

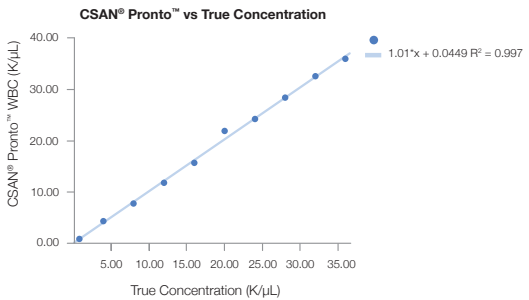
Precision/Reproducibility	WBC	NEUT%
Within-run		
Low Panel Member (%CV ± SD)	5.097 ± 0.140	5.278 ± 2.680
Normal (Medium) (%CV ± SD)	4.492 ± 0.339	6.030 ± 3.015
High (%CV ± SD)	4.300 ± 0.656	5.838 ± 2.967
Between-run		
Low Panel Member (%CV ± SD)	0.000 ± 0.000	2.440 ± 1.239
Normal (Medium) (%CV ± SD)	1.479 ± 0.112	1.865 ± 0.932
High (%CV ± SD)	0.000 ± 0.000	0.000 ± 0.000
Total		
Low Panel Member (%CV ± SD)	5.583 ± 0.153	6.780 ± 3.443
Normal (Medium) (%CV ± SD)	5.726 ± 0.432	6.689 ± 3.344
High (%CV ± SD)	6.305 ± 0.961	6.525 ± 3.316

13.4 LINEARITY

A linearity study was conducted to assess the linear correlation of CSAN® Pronto™ 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 10 x 10^3 WBC/µL (evaluated up to 35 x 10^3/µL) thanks to detection designed to handle crowded imaging and cell clumping (avoiding the hook effect), as shown in **Figure 2**. The samples were obtained by pooling together one low WBC concentration fresh whole blood sample and one high WBC concentration sample in different volumes, which is a recommended option in CLSI EP6-A.

Figure 2: CSAN® Pronto™ WBC vs True Concentration

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



The method has been demonstrated to be linear from lower limit to upper limit and within measured allowable max % diff for each interval.

13.5 INTERFERENCE STUDIES

Interference studies were performed taking sample abnormalities, drugs, metabolites, sample additives, and dietary substances into consideration. The interference study results demonstrated that the following interferents do not interfere with test results up to the following concentrations:

Table 4: List of interferents that do not interfere with CSAN® Pronto™ up to the concentration listed

Interferents	Concentration	Interferents	Concentration
Triglyceride rich lipoproteins	500 mg/dL	Rifampicin	78.1 µmol/L
Hemolysate	500 mg/dL	Cyclosporine	5 mg/L
Protein	8 g/dL	Acetaminophen	1324 µmol/L
Levodopa	20 mg/L	Heparin	3000 U/L
Methyldopa	71 µmol/L	Ibuprofen	2425 µmol/L
Metronidazole	701 µmol/L	Bilirubin C	5 mg/dL
Acetylsalicyclic acid	3.62 mmol/L	Bilirubin F	15 mg/dL
Phenylbutazone	400 mg/L		

As such, CSAN® Pronto™ has flagging capabilities to notify the user when abnormal cell types are present. See **Section 9.0 Errors and Flagging** for more information on the process by which CSAN® Pronto™ recommends samples for manual review due to potentially interfering cell types.

13.6 REFERENCE INTERVALS

A reference interval study was conducted to validate the reference intervals using a commercially-available laboratory reference method in the context of CSAN® Pronto™ data in a healthy adult population with a 95% confidence interval.

The transferring approach was utilized to confirm the manufacturer's reference interval in **Table 5**.

Table 5: Reference interval

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

13.7 REPORTABLE RANGE

The Reportable Range of CSAN® Pronto™ is **1 x 10^3 WBC/µL–20 x 10^3 WBC/µL**.

13.8 FLAGGING COMPARISON STUDY

This study was conducted to assess the flagging capabilities (distributional and morphological) of CSAN® Pronto™ compared to a comparator device utilizing patient samples covering a range of abnormal conditions. This study was performed with 312 patient samples from either capillary whole blood or venous whole blood collected in K_2EDTA anticoagulant. Summarized data is presented for both distributional flags (**Table 6**), as well as morphological flags (**Table 7**).

Distributional Flags

The results of CSAN® Pronto™'s distributional flagging (leukocytosis, leukocytopenia) compared to the comparator device were divided into two categories: 1) no flags, negative judgement and 2) patients with positive distributional abnormalities with flags present, positive judgement.

Table 6: Distributional Flagging Summary

		Comparator device		
		Positive (Abnormal)	**Negative (Normal)**	**Total**
CSAN® Pronto™	Positive (Abnormal)	34	4	38
	Negative (Normal)	5	269	274
	Total	39	273	312

% Positive Agreement (Sensitivity) = 87.2%; 95% CI: 72.57, 95.70

% Negative Agreement (Specificity) = 98.5%; 95% CI: 96.29, 99.60

% Overall Agreement = 97.12%; 95% CI: 94.59, 98.67

Morphological Flags

The results of CSAN® Pronto™'s morphological flagging (nucleated RBCs, platelet clumps, etc.) compared to the comparator device were divided into two categories: 1) no flags, negative judgement and 2) patients with positive distributional abnormalities with flags present, positive judgement.

Table 7: Morphological Flagging Summary

		Comparator device		
		Positive (Abnormal)	Negative (Normal)	Total
CSAN® Pronto™	Positive (Abnormal)	90	7	97
	Negative (Normal)	9	206	215
	Total	99	213	312

% Positive Agreement (Sensitivity) = 90.91%; 95% CI: 83.44, 95.76

% Negative Agreement (Specificity) = 96.71%; 95% CI: 93.35, 98.67

% Overall Agreement = 94.87%; 95% CI: 91.81, 97.04

The flagging study covered a variety of abnormal samples that were flagged by the comparator device, with a breakdown as follows:

Table 8: Abnormal Samples Flagged by Comparator Device

Predicate Flag	Count
PLT Clumps?	15
Abn Lympho/L_Blasts?	51
Blasts?	46
Immature Gran?	29
Left Shift?	14

CSAN® Pronto™ met the pre-defined acceptance criteria (specification of ≥90%) and accurately recommends samples for manual review that may contain Abnormal Cells, such as NRBCs, Platelet Aggregates, Abnormal Lymphocytes, Blast Cells, Immature Granulocytes, and Left Shift.

14.0 Cybersecurity

CSAN® Pronto™ devices should be kept in a safe place only for the access of authorized individuals. Additionally, care should be taken not to leak any login information related to a given device owner account. The password used should have at least 8 characters, include one special character, one capital letter, and one number. In case of account leaks, an account reset procedure should be initiated by contacting CSAN® staff.

All devices should be placed inside a protected network behind a firewall with appropriate anti-malware software installed. The firewall should only accept known incoming connections and specifically block unauthorized network access on port 22. The firewall should also provide access to api.athelas.com on port 443.

When not in use, the CSAN® Pronto™ device should remain online to obtain critical security patches as needed. In case of cybersecurity attacks to a given device that have been identified, your device may be temporarily deactivated by CSAN®. CSAN® staff should be contacted in case of known compromises in your network or environment.

In case of proof of physical tampering, CSAN® staff should be contacted at 1 (800) 267-2726 to assess any potential cybersecurity attacks.

15.0 Technical Specifications

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

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

15.1 WARRANTY

All CSAN® Pronto™ devices are warrantied against defective material for a period of one year.

15.2 SERVICE AND DISPOSAL

CSAN® Pronto™ has no customer service maintenance other then cleaning of the device or optical lens. Prior to disposing of the device in accordance with local disposal requirements, please clean the surface as recommended in **Section 10.0 Maintenance and Cleaning**. CSAN® Pronto™ does not contain any lithium ion batteries.

Decontaminate and dispose of all specimens, reagents, and other potentially biohazardous materials in accordance with local, provincial, and federal regulations. CSAN® Pronto™ is only considered a potential biohazard upon opening it from the package and after the first use.

15.3 SHIPPING AND HANDLING

Analyzer is ready to use upon unboxing. For best results, do not store package in conditions with extreme humidity (>60%) or high temperatures (>35°C, >95°F). Handle with care when moving the device between different locations and avoid possible exposure to chemicals or extensive agitation during transportation.

The entire CSAN® Pronto™ system should be operated at the temperature range of 15–30°C (59–86°F).

CSAN® Pronto™ Test Strips should be stored at room temperature and not frozen. Keep the test strip package closed at all times and use before the expiration date printed on the test strip package.

15.4 ACCESSORIES AND CONSUMABLES

The following CSAN® Pronto™ accessories and consumables are available to order from a local distributor:

- Power adapter (Cat. #80301204)
- Box of 50 CSAN® Pronto™ Test Strips (Cat. #80301202)
- Lancets
- Suggested disinfectant and cleaning wipes (Clorox Healthcare Bleach Germicidal Wipes® [DIN 02465671])
- Pipette
- Alcohol wipes

16.0 Electromagnetic Compatibility and Electrical Safety

Guidance and manufacturer's declaration—electromagnetic immunity.

The device is intended for use in the electromagnetic environment specified below. CSAN® Pronto™ 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.

CSAN® Pronto™ underwent Electromagnetic Compatibility (EMC) testing by an independent laboratory.

The test results indicated that the device is compliant with standards IEC 60601-1-2 Edition 4.0 2014-02, IEC 61326-1:2012-Ed.2.0 and IEC 61326-2-6:2012-Ed.2.0.

CSAN® Pronto™ is also certified for the following standards: ANSI/AAMI ES60601-1:2005/(R) 2012: IEC 60601-1:2005, Mod, IEC 61010-1:2010-Ed.3.0, IEC 61010-2-101:2015-Ed.2.0 and FCC Part 15 Subpart B Class B.

Rules	Description	Results
IEC 61326-1:2012 EMC Emissions	Conducted Emissions AC Mains, 120 V/60 Hz, 230 V/50 Hz	Compliant
	Radiated Emissions, 30-1000 MHz	Compliant
	Harmonic Distortion (IEC 61000-3-2)	Compliant
	Voltage Fluctuations and Flicker (IEC 61000-3-3)	Compliant
IEC 61326-1:2012 Immunity	Electrical Fast Transients (IEC 61000-4-4)	Compliant
	Radiated RF Immunity (IEC 61000-4-3)	Compliant
	Conducted RF Immunity (IEC 61000-4-8)	Compliant
	Surges (IEC 61000-4-5)	Compliant
	Voltage Dips and Interruptions (IEC 61000-4-11)	Compliant
	Electrostatic Discharge (IEC 61000-4-2)	Compliant

17.0 General Guidance

17.1 WARNING

Do NOT modify this equipment. 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. CSAN® Pronto™ is suitable for use in all establishments including those directly connected to a 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.

17.2 PATENTS

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

17.3 SYMBOLS USED

	Warning
	Caution
	Attention, see instructions
	Consult instructions for use
	Catalog number or part number
	“Use By” date (expiration date phrase)
	Do not re-use

	Manufacturer (legal entity) name and full address
	Date of manufacture
	Lot number
	For *in vitro* diagnostic use
	Biohazard
	Temperature limit

18.0 References

1. Test reports, on file with the manufacturer.

2. Pekelharing, et al. (2010). Haematology reference intervals for established and novel parameters in healthy adults. *Diagnostic Perspectives*. 1:1–11.

3. Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline CLSI Document EP05-A3. Third Edition, 2014.

4. Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach.

5. Approved Guideline CLSI Document EP06-A. Interference Testing in Clinical Chemistry.

6. Approved Guideline CLSI Document EP07-A2.

7. Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline Document CLSI EP09-A3. Third Edition, 2013.

8. Protocols for Determination of Limit of Detection and Limit of Quantification; Approved Guideline CLSI Document EP17-A.

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