CSAN PRONTO

CSAN® Pronto®
User Manual

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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, or maintenance procedures.

CSAN® Pronto® Test Strips are single-use strips.

Prior to operating the device, please read this User Manual carefully and undergo in-person training and user certification prior to use. If further explanations or support is required, please contact CSAN® staff at 1-800-267-2726.

CSAN® Pronto® is only to be used with CSAN® Pronto® consumables. 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. CSAN® Pronto® Test Strips are not to be reused or ingested. Please adhere to the expiration dates on the packaging. Consult with local regulations on proper disposal.

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 provided.

4.2 COMPONENTS

The following are included when you order CSAN® Pronto®:

Cat. #80301201

CSAN® Pronto®
(1 device)

Cat. #80301204

AC Power Adapter

4.3 MATERIALS REQUIRED BUT NOT PROVIDED

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

- CSAN® Pronto® Test Strips (Box of 50 strips, Cat#80301202)
- Lancets for capillary draw (spring-loaded lancets with a puncture depth of 2 mm are recommended)
- Alcohol wipes for cleaning fingerprick site prior to sample collection
- CSAN® Pronto® App for tablet, smartphone, or computer
- Ethernet cable (optional)
- Protective gloves
- Suggested disinfectant and cleaning wipes (Clorox Healthcare Bleach Germicidal Wipes® [DIN 02465671])

If CSAN® Pronto® is used to test collected venous whole blood, these additional supplies are required:

- Blood must be preserved in K_2EDTA Tubes
- Pipette for transferring whole blood to CSAN® Pronto® Test Strip
- Venous phlebotomy supplies

5.0 CSAN® PRONTO® SET UP

Important: Always move and handle the device 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 dust-free surface, free from movements and any potential vibrations, which can support the device weight
- Avoid placing the device in a location with excessive sunlight exposure or temperature and humidity fluctuations
- Protect device against water to prevent damage

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

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 with a mobile device or computer based on user preference.

1. Plug 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® Application onto an authorized[1] smartphone, computer, or tablet from the Apple App Store for iOS or Google Play for Android. Optional: provide internet access using the Ethernet port on the top of the device.

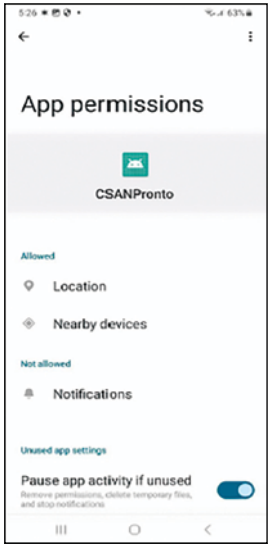
1. A tablet, computer, or smartphone is specifically provisioned for use with CSAN® Pronto®. It is recommended that the given tablet/smartphone has anti-malware software and is permission locked to only allow access to authorized personnel.

6.0 CONNECT CSAN® PRONTO® TO THE INTERNET

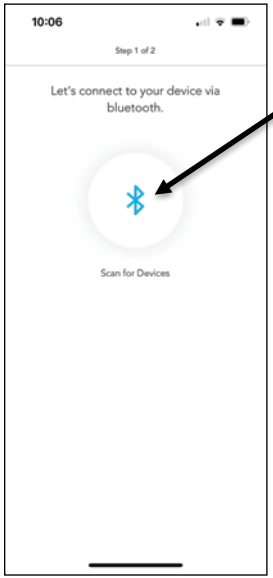
1. Open App

After installation of the CSAN® Pronto® Application, press “Next”.

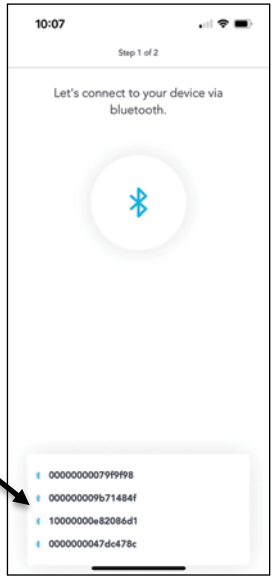
2. Enable Bluetooth and location services. On Android, enable these services in App permissions or by pop up notifications.



3. Connect to Device



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

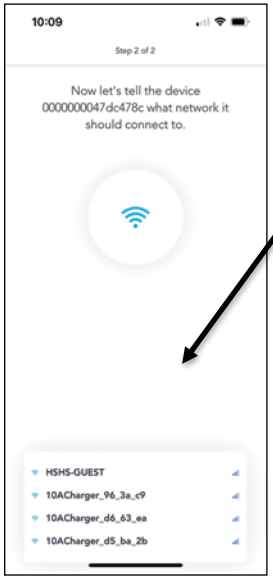


Once the device is found, the screen will prompt you to select 'Pair Device'.

4. Connect to Wi-Fi

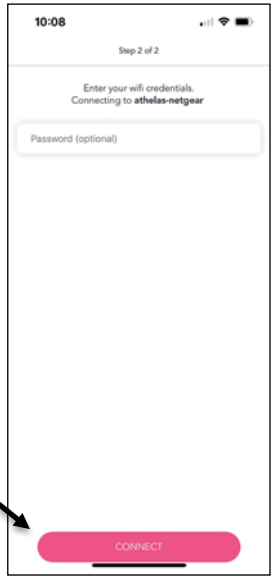
Tap the Wi-Fi button to search for Wi-Fi networks available.

5. Finish Connecting



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 “Connect” to finish pairing the device.



When the device has successfully connected, you will be prompted to continue to www.csan.ca to use the device.

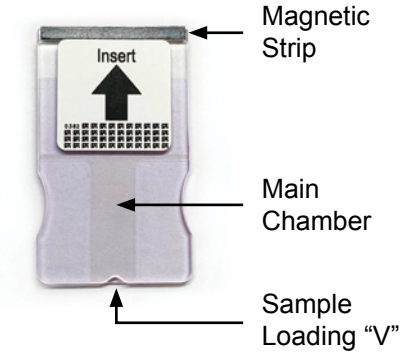
7.0 SAMPLE COLLECTION

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 CSAN® Pronto® Test Strip is for single use only and must be used immediately after opening the CSAN® Pronto® Test Strip package. Do not reuse CSAN® Pronto® Test Strips and dispose of lancets with care. Observe aseptic technique when handling the device, CSAN® Pronto® Test Strips, and lancets.

To collect blood for introduction into the CSAN® Pronto® Test Strip, utilize any capillary or venous blood collection method that conforms to hematology best practices. Blood should be filled in one continuous process until the main chamber of the CSAN® Pronto® Test Strip is completely filled (3-4 µL). If using a pipette to load sample, please aspirate a larger volume (~20 µL) to load the 3-4 µL. The blood source and strip should be angled at 45 degrees for proper flow. When filling the CSAN® Pronto® Test Strip, minor bubbles may appear that do not impact the process. However, pausing or otherwise failing to adhere to these instructions may cause larger air bubbles in the test strip that will impact the reading. The instrument will return an error message if this happens, and the test strip should be discarded and the test repeated. Do NOT reuse test strip.

NOTE:
Allow refrigerated blood samples to warm up to room temperature for at least 15 minutes prior to testing otherwise it may not yield accurate results. Refer to **Section 13.2**.

Process



Correct

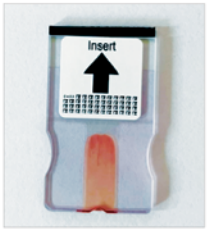
Good

Minimum

Incorrect

> 30 min

Under filled



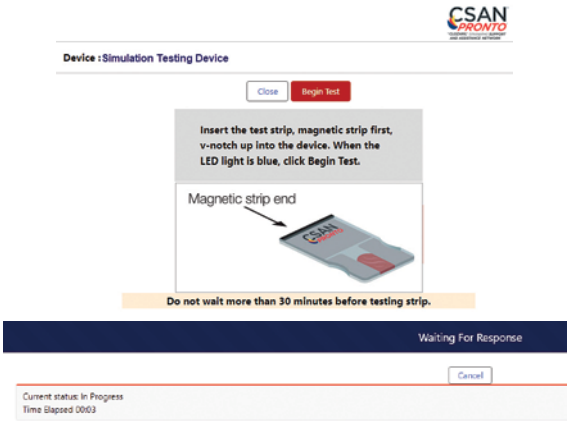
8.0 RUNNING A TEST

Once the CSAN® Pronto® Test Strip has been appropriately filled, wait at least 5 minutes before running the test. Do not wait more than 30 minutes before testing the strip.

5-30 min

1. Place the CSAN® Pronto® Test Strip into the base of CSAN® Pronto® within the rail-guided regions, as pictured, with the **magnetic strip (black stripe) inserted first and the insert sticker facing up**.

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



2. Sign in to www.csan.ca portal with the CSAN® provided login. Once the CSAN® Pronto® Test Strip is correctly inserted, the device LED will turn blue, choose the appropriate patient identifier, and follow the steps on each screen. Once done, hit “Begin Test”.

3. While the test is running, a counter will show the steps to 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 CSAN® Pronto® Test Strip to its original position and you may remove the CSAN® Pronto® Test Strip from the device. Properly discard the CSAN® Pronto® Test Strip after results are generated.

6. The results will be displayed in the CSAN® Patient Care Portal along with the patient identifier. These results are not diagnostic or prescriptive. 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
This flag covers:

- WBC >18 x 10^3/µL

Leukocytopenia
This flag covers:

- WBC <2.5 x 10^3/µL

Error Codes

The CSAN® Pronto® Test Strip has not been filled correctly
Suggestion to resolve:

- Please dispose of the CSAN® Pronto® Test Strip and fill another one

The CSAN® Pronto® Test Strip does not contain a uniform distribution of cells
This error covers:

- Error in the CSAN® Pronto® Test Strip
- CSAN® Pronto® Test Strip blank
- Uneven distribution

Suggestion to resolve:

- Please dispose of strip and try another

Device lens is Dirty
This error covers:

- Dust, debris present
- Imager focus issue

Suggestion to resolve:

- Please dispose of strip and try another

2. CSAN® Pronto® may not detect or flag all morphological abnormalities.
3. CSAN® Pronto® does not generate distributional flags for neutropenia and neutrophilia.

Hardware System Error
- Please reboot system (unplug system for 30 seconds) and try again
This error covers:

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

Suggestion to resolve:

- Verify the device's network connection

The determined WBC value is above the reportable range
This error covers:

- The determined WBC value is above the reportable range

Suggestion to resolve:

- Please repeat a CSAN® Pronto® test or have the patient go to the laboratory for a venous blood sample

The determined WBC value is below the reportable range
This error covers:

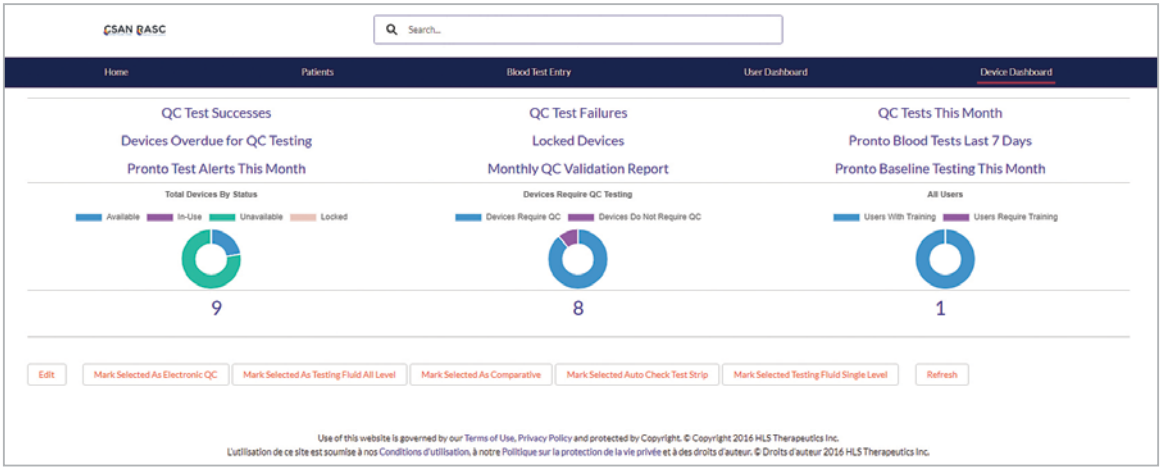
- The determined WBC value is below the reportable range

Suggestion to resolve:

- Please repeat a CSAN® Pronto® test or have the patient go to the laboratory for a venous blood sample

10.0 ADMINISTRATION

Click the device dashboard tab to go to the administrator screen. The administrator can manage all devices and users that have access to running tests at a given clinic.



11.0 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 discoloration 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. Wait 5 minutes after cleaning CSAN® Pronto® to plug it back in and to power it back on.

The recommended cleaning cycle for the CSAN® Pronto® is twice a week. However, if the device becomes dirty, please follow the above instructions.

12.0 TROUBLESHOOTING GUIDE

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

The CSAN® Pronto® device LED light indicator will assist in determining the status of the device.

Orange LED light indicates CSAN® Pronto® is not connected to the internet.

Green LED light indicates CSAN® Pronto® is connected to the internet and ready to use.

Blue LED light indicates that the CSAN® Pronto® Test Strip has been inserted into the CSAN® Pronto® and the “Begin Test” can be clicked within the CSAN® Patient Care Portal.

White LED light indicates that the CSAN® Pronto® is running the test.

Red LED light indicates a test is in queue, and the CSAN® Pronto® is waiting to start testing.

13.0 SPECIFICATIONS

13.1 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. The built in QC self-test also includes error codes, which measure performance of the operator's ability to handle and insert CSAN® Pronto® Test Strips into the device correctly.

CSAN® Pronto® AUTO-CHECK Strip (MDL #103728) Cat# 80301207 may be ordered by contacting the HLS Customer Service at 1-866-669-2313. The AUTO-CHECK Strip can help ensure that the device is returning counts accurately and precisely on the QC grid strip material with expected WBC and Neut% metrics. The recommended AUTO-CHECK Strip testing frequency is at least once a month. A defined frequency can be set by the device manager and the end-user will be prompted to run the AUTO-CHECK Strip test at that time. If not run, the device will automatically lock out.

13.2 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 or 64–79°F), or in a refrigerator (2–8°C, 35–46°F) for 24 hours. However, if the sample was stored in a refrigerator, allow it to warm up to room temperature for 15 minutes prior to testing and mix before loading onto CSAN® Pronto® Test Strip.

13.3 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, 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 Neut% or 15% CV for Neut% on Whole Blood, and ± 10% Bias across the whole study.

13.4 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.

13.5 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 an error code if above or below the range.

13.6 LIMIT OF DETECTION (LoD)

The LoD for WBC is 0.079 x 10^3/µL.

13.7 LIMITATIONS OF METHOD / PROCEDURE

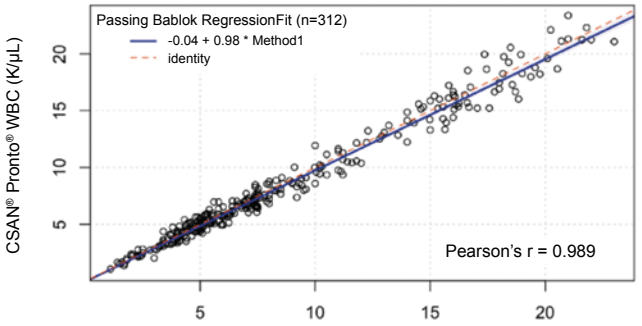
1. Use the CSAN® Pronto® Test Strips immediately after opening the package—do not open in advance.
2. Measurement should be made after 5 minutes but before 30 minutes after the blood sample has been loaded into the CSAN® Pronto® Test Strip.
3. Do NOT reuse CSAN® Pronto® Test Strips.
4. Do NOT mix the venous sample for more than the recommended period, as it may affect results.
5. Results that exceed the measuring display range will render an error code if above or below the range.
6. See the results of the **Interference Study** (see summary results in **Section 14.5**) 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.

14.0 PERFORMANCE CHARACTERISTICS

14.1 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.

14.2 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 CSAN® Pronto® 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%

14.3 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 CSAN® Pronto® 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

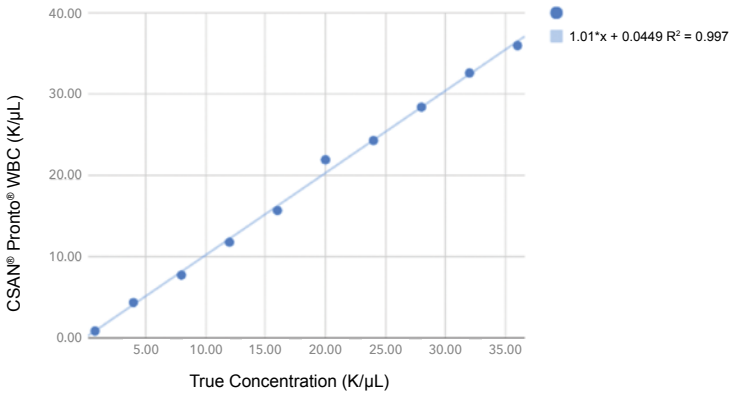
Precision/Reproducibility	WBC	Neut%
Within-run		
Low Panel Member (%CV ± SD)	5.097 ± 0.140	5.278 ± 2.680
Normal (Medium) (%CV ± SD)	4.492 ± 0.339	6.030 ± 3.015
High (%CV ± SD)	4.300 ± 0.656	5.838 ± 2.967
Between-run		
Low Panel Member (%CV ± SD)	0.000 ± 0.000	2.440 ± 1.239
Normal (Medium) (%CV ± SD)	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

14.4 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 CSAN® Pronto® 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 from a 12 x 10^3 WBC/µL sample.** 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.

14.5 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
Acetylsalicylic 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.

14.6 REFERENCE INTERVALS

A reference interval study was conducted to validate the reference intervals using a commercially-available laboratory reference method in the context of the 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%

14.7 REPORTABLE RANGE

The Reportable Range of CSAN® Pronto® is **1 x 10^3 WBC/µL–25 x 10^3 WBC/µL**.

14.8 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.

15.0 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 divulge login information related to a given device owner account. The password used should have at least 12 characters, including one special character, one capital letter, and one number. In case an account has been compromised, 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 80 and 443.

When not in use, if possible the CSAN® Pronto® device should remain online to obtain critical security patches as needed. If the device is off-line, then device start up may be longer than expected as such patches are downloaded and installed. 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 to assess any potential cybersecurity attacks.

CSAN® staff may be contacted at 1-800-267-2726.

16.0 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

16.1 WARRANTY

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

16.2 SERVICE AND DISPOSAL

CSAN® Pronto® has no customer service maintenance other than cleaning of the device. Prior to disposing of the device in accordance with local disposal requirements, please clean the surface as recommended in **Section 11.0 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.

16.3 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 CSAN® Pronto® Test Strip package closed at all times and use before the expiration date printed on the CSAN® Pronto® Test Strip package.

16.4 ACCESSORIES AND CONSUMABLES

The following CSAN® Pronto® accessories and consumables are available to order from HLS Customer service at 1-866-669-2313:

- CSAN® Pronto® AUTO-CHECK Strip (Cat. #80301207)
- Power adapter (Cat. #80301204)
- Box of 50 CSAN® Pronto® Test Strips (Cat. #80301202)

The following accessories and consumables are available to order from a local distributor:

- Lancets
- Suggested disinfectant and cleaning wipes (Clorox Healthcare Bleach Germicidal Wipes® [DIN 02465671])
- Pipette
- Alcohol wipes

17.0 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

18.0 GENERAL GUIDANCE

18.1 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.

18.2 PATENTS

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

18.3 SYMBOLS USED

	Warning
	Caution
	Attention, see instructions
	Consult instructions for use
REF	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	Lot number
IVD	For *in vitro* diagnostic use
	Biohazard
	Temperature limit

19.0 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.
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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