

# Assure® PT Care Prothrombin Time (PT)/INR Monitoring System

This is a CLIA Waived Test System. Please read the Assure PT Care Prothrombin Time (PT)/INR Monitoring System User's Manual for complete instructions.

## Intended Use

The Assure PT Care Prothrombin Time (PT)/INR Monitoring System is intended for Professional Use.

The Assure PT Care Prothrombin Time (PT)/INR Monitoring System is an in vitro diagnostic device that provides quantitative Prothrombin Time (PT) results, expressed in seconds and INR units. It uses fresh capillary whole blood.

It is intended for use by healthcare professionals at the point of care to monitor patients who are on Warfarin-type (Coumarin) anticoagulation therapy.

This device is not intended to be used for screening purposes (to detect a potential health problem or disease).

## Warnings and Precautions

CAUTION - The Test Strips are for use outside the body only.

CAUTION - Possible infectious risk.

- Patient samples, Control, and used Test Strips are potentially infectious. Dispose strips and blood collection devices using universal precautions.
- The Control Strips contain human source material. Though the strips have been tested negative for Hepatitis B, Hepatitis C, and HIV, no known test method can offer complete guarantee that the human source material will not transmit infectious disease. Hence, handle as if potentially infectious.

## Precautions

- Assure PT Care Test Strips are designed for use only with the Assure PT Care Meter.
- Avoid using substitute Transfer Tube(s) when performing test to prevent possible error(s).
- Do not use the Test Strip, Control Strip, and Control Activation Solution past its expiration date.
- Keep sealed strips in the original sealed pouches until ready to use.
- Use only fresh capillary whole blood from the fingertip for testing.
- Use only 21-gauge auto lancets for the finger-stick.
- Apply the blood sample to the Test Strip immediately after lancing the finger.
- Never add more blood to the Test Strip after the test has begun or perform another test using the same finger-stick.
- A minimum of 10-12 µL in volume of the blood sample must be transferred to the Test Strip. Low sample volume or air bubbles may cause an error message.
- Poor finger-stick and sample transfer technique may affect results.
- Weekly monitoring of oral anticoagulation therapy using a home PT/INR device, significantly improves time in therapeutic range and improves clinical outcomes.

## Storing the Testing Supplies

Store the Test Strips, the Control Strips and Control Activation Solution in their box at room temperature or in the refrigerator (2-27°C, 35-80°F). Equilibrate Strips to room temperature before performing a test, else erroneous results can occur. When stored properly, an unopened Test Strip, Control Strip or Control Activation Solution can be used until the printed expiration date. DO NOT USE supplies past the expiration "Exp." date stated on their label. Once a Test Strip or Control Strip pouch has been opened, the strip should be used within 10 minutes.

## Preparing for Testing

Read the Assure PT Care PT/INR User Manual before use. The manual contains information about product use. Quick Reference Guide, testing tips, and instructional videos are also available.

### Step 1: Getting Ready to Test

1. Refer to the recommended products available and reordering information in the user's manual.
2. Gather supplies:
  - a. Assure PT Care Meter
  - b. Assure PT Care PT Test Strip
  - c. Sample Transfer Tube (as provided by ARKRAY USA)
  - d. Single Use 21-gauge Auto Lancet
3. Place the Meter on a flat surface. Turn the Meter on by pressing the POWER button on the top of the Meter.
4. Warm hands to increase circulation.
5. Clean finger with alcohol swab and wipe with gauze to dry it completely.
6. If using a Test Strip from a new lot, the Low and High Control Strips must first be run following the instructions below or in the Performing a Control Test section of the Assure PT Care User's Manual.

### Step 2: Performing a Control Test

*Note - This step is only required if using a Test Strip from a new lot. Otherwise, skip to step 3, Performing a Test.*

Control testing confirms the performance of both the Meter and Test Strips and should be completed for each new lot of Test Strips. The plasma present on the Control Strip has a limited shelf life; perform the test as soon as each lot is received.

1. Turn the Meter on. Follow prompt to complete test. Make selection for either Control or Patient Test Strip test.
2. Using the NFC Tag provided in the kit, place the NFC Tag in contact with the NFC Tag scanner on the Meter. The Lot number will auto populate and must be verified. If the Lot number matches the strip, proceed.
3. Insert a Low Control Strip and the Meter will detect the Control Strip.
4. With the Control Strip in place, the Meter will indicate that it is warming up and will display blinking icon when it is ready for the Control Activation Solution Drop.
5. Using only the Sample Transfer Tube supplied by ARKRAY USA, apply a drop of Control Activation Solution to the sample well in the Control Strip.
6. In less than a minute, the test will be complete, and the Meter will display the clotting time results in seconds.
7. Repeat steps 3 through 6 using High Control Strip.

The Assure PT Care Meter will display a fail message if the control results are outside of the range for that level of control. If this occurs, repeat the test with a new Control Strip. If it is still outside the recommended range, refer to the Assure PT Care User's Manual for further troubleshooting information or contact Technical Service at: 800.818.8877.

### Step 3: Performing a Test

1. Open an Assure PT Care Test Strip pouch and remove the Test Strip.
  2. Using the NFC Tag provided in the Strip Kit place the NFC Tag in contact with the NFC Tag scanner on the Meter. The Lot number will auto populate and must be verified.
  3. Holding the round end, gently push the strip completely into the Meter. When properly in place, the Meter will start the warming process. The time for completion of the warming process will be displayed in seconds.
  4. The Meter will display a blinking drop icon to indicate it is ready for the blood sample. The blood sample must be applied to the strip within 2.5 minutes.
  5. Use the single use 21-gauge auto lancet to lance the finger; following instructions in the User Manual or brochures.
  6. If required to encourage blood flow, gently squeeze the finger from its base. After collection in tube, the blood must be transferred to the Test Strip within 15 seconds. If it takes longer to form a good drop of blood, lance a different finger, and repeat.
  7. Using a Sample Transfer Tube provided, collect blood and fill to green line and apply the blood sample to the sample well with green blinking light. Avoid introducing air bubbles into the sample. Follow the appropriate Sample Transfer Tube instructions in the Assure PT Care PT/INR User's Manual. The Meter will detect that a blood sample has been applied.
  8. When testing is complete, the results appear on the screen.
  9. Remove the Test Strip and throw it away in a sharps container.
  10. Turn off the Meter.
- If a repeat test is needed, use a new lancet, a new Test Strip, a new Sample Transfer Tube, and a different finger.

### Very Low or Very High Test Results

The Assure PT Care Test Strips provide test results if the INR value is between 0.8 and 8.0. If the Meter displays an error message, repeat the test ensuring that the sample does not contain any air bubbles. When the test is repeated and the same error is received, call technical service at 800.818.8877.

### Test Principle

The Assure PT Care PT/INR system uses direct clot detection technology to directly determine Prothrombin Time. Each Test Strip contains a rotating spoked wheel which draws samples into a reaction well containing thromboplastin. The wheel spokes mix the sample with the reagent and rotate across a light beam. As the sample transforms into a solid clot, it is picked up by the spokes interrupting the light beam. This elapsed time from when the sample is applied to the Test Strip to when the clot is detected is the actual Prothrombin Time. No curve fitting algorithms or look-up tables are used.

Elements of the Assure PT Care System (Meter and Test Strips) and its use are covered by the following U.S. Patent: 7,235,213. Additional Patents pending.  
All other product names and trademarks are the property of their respective owners.  
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## Quality Control

Quality control is an important part of PT/INR testing to verify the integrity of the performance characteristics of the testing system. The Assure PT Care Meter has been designed with multiple internal systems to ensure proper system function. When turned on, the Meter runs an extensive self-check protocol to assure that room temperature, timing functions, battery level and optical and mechanical functions are within specification. Each Test Strip kit is shipped with two Low Control Strips, two High Control Strips and Control Activation Solution. The plasma is generated from a pool of normal donors where the Vitamin K dependent proteins are removed and added back at different levels to represent the 'Low' and 'High' level ranges. Real plasma allows for a fully functional liquid quality control test of both the reagent's ability to generate a clot and the analyzer's ability to detect a clot. When done correctly, control testing confirms the performance of both the Meter and Test Strips and should be completed for each new lot of Test Strips, as soon as each lot is received, within the stated shelf life.

## Limitations of Procedure

- The measuring range for the Assure PT Care system is between INR of 0.8 to 8.0. Results outside of this range must be confirmed using an alternative method.
- INR values above 4.5 should be verified or repeated by a laboratory method.
- The Assure PT Care system should not be used if the patient is on Heparin or Low Molecular Weight Heparin or any Direct Thrombin or Factor Xa Inhibitor.
- Hematocrit ranges between 15%-60% do not significantly affect results.
- Testing has confirmed that PT/INR test results are not affected by; Bilirubin up to 20 mg/dL, Lipemia up to 3000 mg/dL and Hemolysis up to 500 mg/dL.
- The Assure PT Care Meter is sensitive to deficiencies in Vitamin K-dependent Coagulation Factors known to influence the PT test (i.e., factors II, V, VII and X.) at the following levels; Factor II: <25%, Factor V: < 50%, Factor VII: < 50%, Factor X: < 50%.
- The Assure PT Care PT/INR Monitoring System has not been evaluated and tested clinically in pediatric patients or in patients with the following medical conditions; Anemia, Polycythemia, Cancer, Antiphospholipid Antibody Syndrome, Severe Liver disease, Scleroderma, Reynaud's Disease.
- The presence of Anti-phospholipid Antibodies (APAs), such as Lupus Antibodies (LA), can potentially lead to prolonged clotting times, i.e., elevated INR values.
- Differences in reagents, instruments, and pre-analytical variables can affect Prothrombin Time results. These factors should be considered when comparing results from different test methods.
- The patient or user should consult their healthcare provider when results are outside the specified range.

## Service and Support

If technical assistance is required, or unusual results are obtained, call Technical Service at 800.818.8877.

## Performance Characteristics for the Assure PT Care PT/INR System

### Reportable Range

The Assure PT Care PT/INR System has a reportable range of 0.8–8.0 INR. If the INR is outside the reportable range, 0.8 <INR> 8.0, an error message is displayed.

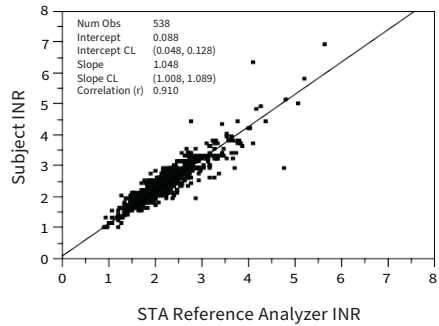
### Capillary Accuracy and Precision Data

A clinical study was conducted across three different point of care sites where the Assure PT Care PT/INR system was compared against a Diagnostica Stago STA Compact Analyzer using Dade Innovin. The results comparison is as follows:

	N	Slope	Intercept	Correlation
Site 1	88	1.060	0.143	0.946
Site 2	187	1.078	0.050	0.947
Site 3	266	0.958	0.286	0.900
All Sites	541	1.015	0.179	0.924

The test results obtained by trained subject users were compared to results obtained using a laboratory-based reference method. Results are shown in the plot below.

### Results Comparison: Subject vs. Reference Instrument

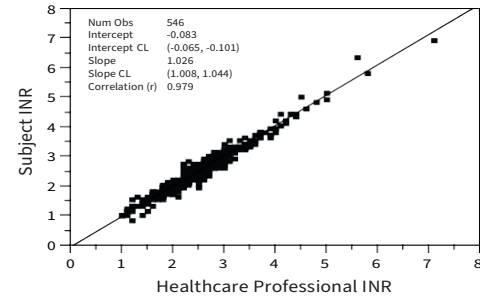


### Accuracy

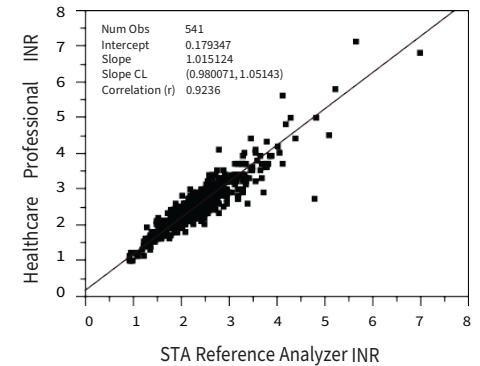
A study was conducted comparing test results obtained by trained subject users with those obtained by healthcare professionals when both were using the Assure PT Care System. The correlation was very high, as indicated by the following statistics:

N=546, Slope=1.026, Intercept=-0.083 and Correlation Coefficient=0.98. This study demonstrated that trained subject users obtain results that are comparable to those obtained by healthcare professionals trained in the use of the Assure PT Care System.

### Results Comparison: Subject vs. Healthcare Professional



The test results obtained by healthcare professionals were compared to results obtained using a laboratory-based reference method. Results are shown in the plot below.



## Results Comparison: Healthcare vs. Reference Instrument Study User Demographics

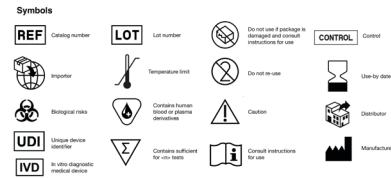
A patient home testing clinical study was conducted at three different sites, consisting of patients testing at home (trained subject users) for ten weeks and five visits to the clinical site. One hundred seventeen patients were enrolled in the study and one hundred eight patients completed all five visits.

The table below outlines the demographic information for the trained subject users who completed all five clinic visits.

Demographic	Number	Percent
Total number of users	108	100%
Caregivers	2	2%
Males	63	58%
Females	45	42%
Age Range	27-92	100%
Median Age	69 years	N/A
Less than 30 years	1	1%
Age 31 – 50 years	6	6%
Age 51 – 70 years	55	51%
Age 71 years and above	46	43%
Median Education	Some College	N/A
On warfarin 1 – 12 months	9	8%
On warfarin 1 – 3 years	20	19%
On warfarin 3 – 5 years	18	17%
On warfarin > 5 years	61	56%
Atrial fibrillation	49	45%
Valve replacement	21	19%
Pulmonary Embolism	11	10%
Deep Vein Thrombosis	10	9%
Stroke/stroke prevention	4	4%
Factor V Leiden	1	1%
Lipoprotein A	1	1%
Other	13	12%

The reasons for nine subject drop-outs were as follows:

Reason	# of Subjects
Personal Reasons	4
Illness	2
Physically incapable of performing tests	3



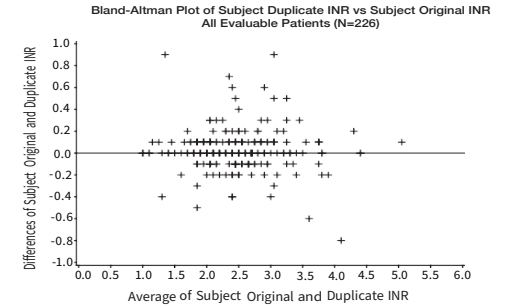
Note: See symbols glossary in the Assure PT Care PT/INR Monitoring System User's Manual.

## Precision

A study was conducted and the precision of duplicates for capillary blood results was calculated for both trained subject users and healthcare professionals. The following results were obtained:

	User Results	Professional Results
N	226	225
Ave. CV(%)	3.44	2.53
95% CI	2.79 - 4.10	2.12 - 2.94

Bland-Altman bias plots (or difference plot) are useful in analyzing the agreement between two different trained subject user duplicate results. Below is a Bland-Altman plot that compares the difference of the trained subject user original INR and duplicate INR to the average of the original and duplicate INR.



This study demonstrated that trained users obtain results that are comparable to those obtained by healthcare professionals trained in the use of the Assure PT Care System.

**MANUFACTURED BY:**  
CoaguSense, Inc.  
48377 Fremont Blvd. Ste 113  
Fremont, CA 94538 U.S.A.

**DISTRIBUTED BY:**  
ARKRAY USA  
5182 W 76th Street  
Minneapolis, MN 55439 U.S.A.  
800.818.8877  
www.arkrayusa.com

**Assure® PT Care®** | A COAGUSENSE PARTNER  
PT/INR Monitoring System

CSI PN 500011 Rev. AA  
PN 5699-01 Rev. 05/23

## Limited Warranty

ARKRAY USA, Inc. ("ARKRAY") warrants that the Assure PT Care meter ("Meter") is free from all defects in material and workmanship for a period of one (1) year from date of delivery. When the Meter is used for the intended purpose and in the appropriate manner, and after an attempt is made by you and ARKRAY to fix the issue by telephone, ARKRAY's only remedy is to replace the Meter. The warranty does not apply to a Meter damaged by misuse, alteration or tampering to either the hardware or software. Contact Technical Support at 800.818.8877 for instructions.

This warranty applies only to the Meter. ARKRAY USA's entire liability in connection with the Meter, regardless of the legal or equitable basis of any claim, is limited to the purchase price of the Meter. In no event shall ARKRAY USA, Inc. be liable to the purchaser for any incidental, consequential (including but not limited to loss of income or profits) special, indirect, or punitive damages arising from or in any way connected with the purchase or operation of the Meter or its parts. No warranty of merchantability or fitness for a particular purpose is implied from the sale of the Assure PT Care PT/INR System. No warranty, express or implied (if any) shall extend for a longer duration.

## References

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