



CoaguChek XS PT Test

REF	▽	SYSTEM
07797826160	24	CoaguChek® XS Plus
04625315160	2 x 24	

This insert is for healthcare professional use. These test strips are to be used with the CoaguChek XS Plus System. This is a CLIA Waived test system. A Certificate of CLIA Waiver (or higher) is required to perform the test. Information on obtaining CLIA certificates can be found at www.cms.hhs.gov/clia. Facilities performing testing must have a CLIA Certificate of Waiver. 42 USC 263a(c)(2). Any modifications and/or failure to follow test system instructions, including those for limitations/intended use and performance of QC testing as a failure alert mechanism, results in use that is considered high complexity and subject to all applicable CLIA requirements. All applicable state and local laws must be met. Laboratories with a certificate of waiver must follow the manufacturer's instructions for performing a test. 42 CFR 493.15 (e) (1).

Intended use The CoaguChek XS Plus System is intended for use by professional healthcare providers for quantitative prothrombin time testing for the monitoring of warfarin therapy. The system uses fresh capillary or non-anticoagulated venous whole blood. **Caution** For in vitro diagnostic use. For prescription use only.

Before you start testing If you are new to the CoaguChek XS Plus System, watch the *System Training DVD* and read the *System Getting Started Guide, System User Manual*, *CoaguChek XS Pro PT Controls* method sheet and this entire method sheet.

Storing the test strips Store the test strips in their original container, with the cap tightly closed. You can store the test strips at room temperature or in the refrigerator (2-30 °C or 36-86 °F). When stored properly, the test strips can be used until the expiration date printed on the test strip container.

Discard the test strips if they are past the expiration date on the container.

Handling the test strips When you are ready to test, open the test strip container and remove 1 test strip. **Immediately close the container. Make sure it seals tightly.** *IMPORTANT:* Do not open a container of test strips or touch a test strip with wet hands or wet gloves. This may damage the test strips. You must use the test strip within 10 minutes of removing it from the container. Otherwise, you may get an error message, and you will have to repeat the test.

Sample collection and preparation The steps that follow apply to collecting a blood sample from a fingerstick. Optionally, you may use a non-anticoagulated plastic capillary tube to collect the fingerstick blood sample. You may also use the CoaguChek XS Plus System to test venous blood. See the *CoaguChek XS Plus System User Manual* for more information. When collecting any type of sample, follow universal blood collection precautions and guidelines.

Step 1: Getting ready to test Gather supplies:
 -CoaguChek XS Plus Meter
 -CoaguChek XS PT Test strip and test strip code chip
 -Lancing device (e.g., CoaguChek Lancet [REF] 04348150001 Follow the manufacturer's instructions for use.)

If you are using test strips from a new, unopened container, you must change the test strip code chip. The three-number code on the test strip container must match the three-number code on the code chip. To install the code chip, follow the instructions in the *Code Chip* section of the *CoaguChek XS Plus System User Manual*. Place the meter on a flat surface (like a table or countertop) or hold it roughly horizontal so that it will not vibrate or move during testing. Vibrations or other movement can result in an error message.

Step 2: Getting a good drop of blood Increasing the blood flow in the finger will help you get a good drop of blood. Before you lance the finger, try the following techniques until you see that the fingertip has increased color:

- Warm the hand by having the patient hold it under his or her arm, use a hand warmer, and/or wash the hand with warm water.
- Have the patient hold his or her arm down to the side, so the hand is below waist.
- Massage the finger from its base.
- If needed, immediately after lancing, gently squeeze the finger from its base to encourage blood flow.

Step 3: Performing the test

1. Wash the patient's hands with warm, soapy water or wipe the finger with alcohol. Dry the patient's hands completely. Make sure your hands and gloves are dry before proceeding.
2. When you are ready to test, remove 1 test strip from the container and **immediately close the container. Make sure it seals tightly.** Do not open a container of test strips or touch a test strip with wet hands or wet gloves. This may damage the test strips.
3. Insert test strip as far as you can into the meter. This powers the meter ON.
4. Press Patient Test on the meter display. The meter warms the test strip. Then the meter begins a countdown. You have 180 seconds to apply a blood sample to the test strip. If your facility procedures require use of the Operator ID and Patient ID, refer to the *CoaguChek XS Plus User Manual*.
5. The meter automatically checks to see if you have the right test strip code chip. The three-number code on the test strip container must match the three-number

code on the code chip before the test can be run. If using test strips from a new, unopened container, you must change the test strip code chip.

6. Use a CoaguChek lancet to perform a fingerstick.
7. Hold the finger very close to the target area (clear area of the test strip). Apply 1 drop of blood to the top or side of the target area and wait until you hear the beep (if the beeper is enabled). **You must apply blood to the test strip within 15 seconds of lancing the finger** and within 30 seconds when using venous blood. Applying blood later than that may produce an inaccurate result as the coagulation process will have begun.
8. Do not add more blood. Do not touch or remove the test strip while the test is in progress. The flashing blood drop symbol changes to an hourglass symbol when the meter detects sufficient sample.
9. The result appears in approximately 1 minute. Record the result.
10. Properly dispose of the used lancet and test strip.
11. Power the meter OFF. **NOTE: If you need to repeat a test, use a new test strip and lancet, and a different finger.**

Technical information: how the test works The CoaguChek XS PT Test, used as directed with the CoaguChek XS Plus Meter, will provide an electrochemical measurement of prothrombin time following activation of blood coagulation with human recombinant thromboplastin. In simple terms, blood works with the chemicals in the test strip to produce a small electric current in the test strip that measures blood-clotting time.

Contents of the test strip The test strip contains reagent (human recombinant thromboplastin 1.5 U), as well as stabilizers, preservatives, and additives.

Limitations of procedure

CoaguChek XS Plus System should not be used for patients being treated with any direct thrombin inhibitors, including Hirudin, Lepirudin, Bivalirudin, and Argatroban.

CoaguChek XS PT Test uses only fresh capillary or non-anticoagulated venous whole blood. Plasma or serum cannot be used.

Use only plastic syringes without anticoagulants or additives. Glass tubes or syringes must not be used.

The blood drop must be a minimum of 8 µL in volume. Low sample volume will cause an error message.

Never add more blood to the test strip after the test has begun or perform another test using the same fingerstick.

When a patient is on intravenous infusion therapy, do not collect the sample from the arm receiving the infusion line.

Hematocrit values between 25-55 % do not significantly affect test results.

Testing performed with the following in vitro spiked samples or native blood samples (triglycerides) indicated no significant effect on test results:

- Bilirubin up to 30 mg/dL
- Lipemic samples containing up to 500 mg/dL of triglycerides
- Hemolysis up to 1000 mg/dL
- Heparin concentrations up to 0.8 U/mL
- Low molecular weight heparins (LMWH) up to 2 IU anti-factor Xa activity/mL
- Clopidogrel up to 20 mg/dL
- Fondaparinux up to 5 mg/L

The presence of anti-phospholipid antibodies (APAs) such as Lupus antibodies (LA) can potentially lead to prolonged clotting times, i.e., elevated INR values. A comparison to an APA-insensitive laboratory method is recommended if the presence of APAs is known or suspected. ¹

Is the meter displaying "ERROR 6"? Sporadically occurring "ERROR 6" are generally due to an activation of the system fail safe mechanisms that are designed to prevent the release of wrong measurement results. However, in rare cases, "ERROR 6" may be received by patients under clinical conditions leading to extremely high coagulation times (>10 INR, <5 % Quick), e.g. treatment with warfarin (vitamin K antagonists) in combination with antibiotics and/or chemotherapeutics. If "ERROR 6" is displayed repeatedly, the result must be checked immediately using another method.

In rare cases, patients with long clotting times (> 8 INR) may receive an "ERROR 7" message on the meter display. If this error message appears again when the test is repeated, check the result using another method.

The results obtained cannot be used for the determination or the assessment of a therapy with factor II and factor X antagonists.

Expected results The CoaguChek XS Plus meter displays test results in units equivalent to laboratory plasma measurements. Results may be displayed in:

- the International Normalized Ratio (INR= $(PT/Mean\ Normal\ PT)^{ISI}$)^{ISI})
 - seconds
 - % Quick (a unit used mainly by healthcare professionals in Europe).
- Each lot of test strips is calibrated to a reference lot that is traceable to the WHO International Reference Preparations. Normal INR levels vary from person to person. For the purpose of providing universal INR results, the Mean Normal Prothrombin Time (MNPT) has been established as 12 seconds and the International Sensitivity Index (ISI) for the system has been established as 1. The physician must determine the best INR level depending on the reason for anticoagulant treatment and how each individual responds to treatment (based on Prothrombin Time). Each physician should establish expected values for his or her patient population or individual patients. Differences in reagents, instruments, and

pre-analytical variables can affect prothrombin time results. These factors should be considered when comparing different prothrombin time test methods.² Experience comparing results obtained using the CoaguChek XS Plus System to those obtained using common clinical laboratory reagents shows that the System correlates well with the following clinical laboratory reagent: Dade Innovin. Other clinical laboratory reagents may not consistently correlate with the CoaguChek XS Plus System.

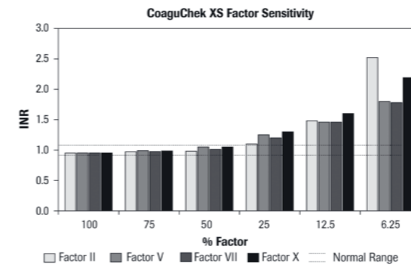
Unusual results If the meter displays an error message, refer to the *Error Messages* section of the *CoaguChek XS Plus System User Manual*. If the meter displays an unusual test result (other than an error message), check the following:
 -Certain drugs may affect results by interfering with warfarin pharmacology. The potential effect of a drug interaction with warfarin or the effect of underlying diseases (e.g., liver disease, congestive heart failure) must be considered when interpreting a result.

-Changes in the patient's diet can cause unusually low or high results.
 -Any unusual result should always be followed up with inquiries to define the cause of the unusual result. If the result does not match the clinical symptoms, repeat the patient test to rule out procedural error.

Performance characteristics

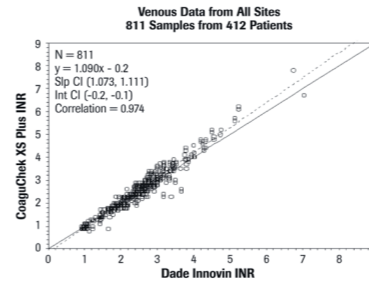
Measuring range: The CoaguChek XS Plus System has a reportable range of 0.8 to 8.0 INR.

Sensitivity: The CoaguChek XS PT Test is sensitive to various clotting factors as determined by in vitro tests. Single factor depleted plasma was combined with a normal plasma pool to produce a series of diluted plasma samples. These plasma samples were then tested using 3 representative lots of CoaguChek XS PT Test across 16 CoaguChek XS meters. The results, shown in the graph, represent the typical CoaguChek XS PT Test sensitivity to Factors II, V, VII, and X.



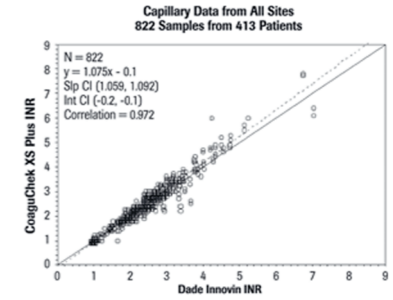
Accuracy: 811 venous samples were collected from 412 outpatients at three external sites. The INR of each sample was compared to the INR of a venous plasma sample measured on a Dade Sysmex 560 Analyzer using Dade Innovin (ISI = 1.02). The patient clinical conditions included (number of patients): not on warfarin (61), atrial fibrillation (163), valve repair/replacement (44), stroke/TIA (5), DVT (75), pulmonary embolism (22), cardiovascular accident (15), other heart-related disorders (9), other clotting disorders (13), other (5). The results are:

Venous Data	N	Slope	Intercept	Correlation
Site 1	287	1.071	-0.2	0.969
Site 2	286	1.091	-0.1	0.975
Site 3	238	1.111	-0.1	0.983
All	811	1.090	-0.2	0.974



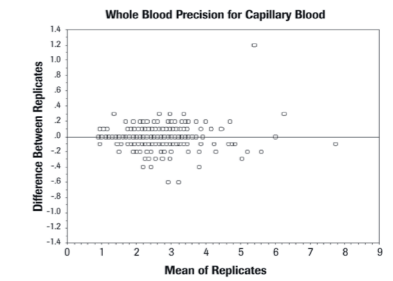
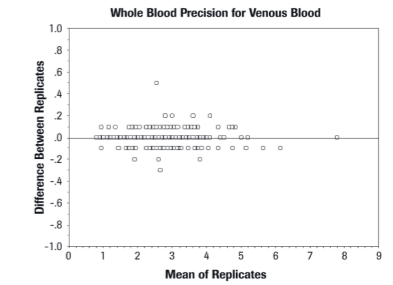
Accuracy: 822 capillary samples were collected from 413 outpatients at three external sites. Capillary blood samples were assayed on the CoaguChek XS Plus Meter with the CoaguChek XS PT Test and venous samples were measured on a Dade Sysmex 560 Analyzer with Dade Innovin (ISI = 1.02). The results are:

Capillary Data	N	Slope	Intercept	Correlation
Site 1	287	1.048	-0.1	0.959
Site 2	297	1.071	-0.1	0.974
Site 3	238	1.111	-0.1	0.988
All	822	1.075	-0.1	0.972



Precision: Whole blood precision was determined for venous and capillary blood from sample duplicates collected at three sites. The following results represent whole blood precision for venous and capillary blood.

Sample	N	Mean INR	SD	CV
Venous	399	2.32	0.046	2.00
Capillary	399	2.26	0.077	3.39



Built-in controls and diagnostics The CoaguChek XS Plus System has quality control functions integrated into the meter and test strips, so you do not have to run quality control tests with liquid quality controls. A two-level, on-board quality control test is performed within the test chamber as part of every blood test. For more information about the built-in quality control functions, see the *CoaguChek XS Plus System User Manual*. Roche Diagnostics has available optional liquid quality controls [REF] 04625382160 for the CoaguChek XS Plus System. These controls are provided to assist with meeting regulatory compliance requirements, as applicable to your facility. Frequency and necessity of liquid quality control tests are at the discretion of each individual facility.

Additional information The user manuals for *CoaguChek XS Plus System* and *CoaguChek XS Pro System* contain more information. If you need technical help, call Roche Diagnostics Technical Service Center at 1-800-428-4674, 24 hours a day, 7 days a week, 365 days a year. Any adverse reactions experienced with the use of this product, and/or quality problems should also be reported to FDA's Med Watch Adverse Event Reporting program online [at www.fda.gov/MedWatch/report.htm], by phone (1-800-FDA-1088), or by returning the postage-paid FDA form 3500 (which may be downloaded from www.fda.gov/MedWatch/getforms.htm) by mail to (MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787) or fax (1-800-FDA-0178).

If there are any problems with the CoaguChek XS Plus meter, notify CMS at <http://www.cms.hhs.gov/clia/ro-map.aps>.

For symbols, return policy, and limited warranty, refer to the other side of this method sheet.

References

- 1 Moll S and Ortel TL Monitoring Warfarin Therapy in Patients with Lupus Anticoagulants. *Annals of Internal Medicine* 1997;127:177-185.
- 2 Loeliger EA, van den Besselaar AMHP, Lewis SM. Reliability and Clinical Impact of the Normalization of the Prothrombin Times in Oral Anticoagulant Control. *Thromb Haemostas*. 1985;53:148-154.

Distribution in USA by:
 Roche Diagnostics, Indianapolis, IN
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