# CoaguChek XS PT Test

REF **04625374160** Σ 6 SYSTEM CoaguChek® Vantus

*PERSONAL USE*

**English**

**Purpose**

The CoaguChek Vantus System measures an INR (International Normalized Ratio) based on a prothrombin time (PT) response to monitor the effect of a therapy with vitamin K antagonists by using the CoaguChek XS PT Test strips. The CoaguChek Vantus System uses fresh capillary whole blood from a fingerstick.

The system is intended for properly selected and suitably trained users on the prescription of the treating doctor.

Users should be stabilized on anticoagulation with vitamin K antagonists for at least 6 weeks prior to single patient self-testing with the CoaguChek Vantus System.

The CoaguChek Vantus System is intended for single patient self-testing only for adults, age 22 years and older.

**For USA: Caution: Federal law restricts this device to sale by or on the order of a physician.**
**Caution: These test strips are for use outside the body only.**

**Before you start testing**

If you are new to the CoaguChek Vantus System, read the *CoaguChek Vantus System Getting Started Guide* and the *CoaguChek Vantus System User Manual* before you start testing.

**Storing the test strips**

Store the test strips in the container with the cap tightly closed. You can store test strips at room temperature or in the refrigerator (2-30 °C or 36-86 °F).

The test strips can be used until the expiration date, which is printed on the test strip container. The meter will not accept expired test strips.

When transporting the test strips, the container can be exposed to 45 °C or 113 °F for up to 5 days.

**Handling the test strips**

When you are ready to test, remove 1 test strip from the container and **immediately close the container. Make sure it seals tightly.**

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.

**Materials provided**

- Container of CoaguChek XS PT Test strips REF 04625374160
- Test strip code chip

**Materials required (but not provided)**

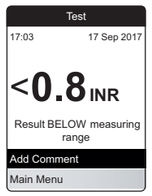
- CoaguChek Vantus Meter
- Lancing device and lancets (Follow the manufacturer's instructions for use.)

**Limitations of procedure**
**Information for you and your physician**

- The CoaguChek Vantus System for patient self-testing should not be used for patients being treated with any direct thrombin inhibitors, including Hirudin, Lepirudin, Bivalirudin and Argatroban.
- The CoaguChek XS PT Test for patient self-testing uses only fresh capillary blood from a fingerstick.
- 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 test strip after test has begun or perform another test using the same fingerstick.
- When a patient is on intravenous infusion therapy, do not collect fingerstick sample from arm receiving the infusion line.
- Hematocrit ranges between 25-55 % do not significantly affect results.
- Testing has confirmed that PT/INR test results are *not* affected by:
  - Bilirubin up to 30 mg/dL
  - Lipemic samples containing up to 500 mg/dL of triglycerides
  - Hemolysis up to 1000 mg/dL
  - Clopidogrel (Plavix®) up to 20 mg/dL
  - Fondaparinux (Arixtra®) up to 0.5 mg/L
  - Heparin concentrations up to 0.8 U/mL
  - Low molecular weight heparins (LMWH) up to 2 IU anti-factor Xa activity/mL
- Patients treated with protamine sulfate, oritavancin, and calcium dobesilate cannot be tested with this system.
- Patients who currently use Direct Oral Anticoagulant drugs (DOACs) listed below cannot be tested with this system.
  - Rivaroxaban
  - Apixaban
  - Dabigatran
  - Edoxaban
- The presence of anti-phospholipid antibodies (APAs) such as Lupus antibodies (LA) can potentially lead to prolonged clotting times, i.e., elevated INR values. If you have or suspect that you have APAs, contact your doctor.
- 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. Results obtained with the CoaguChek Vantus System for patient self-testing may not consistently correlate with clinical laboratory results, particularly for certain types of laboratory reagents. Your doctor can provide additional information regarding results comparison.
- The results obtained cannot be used for the determination or the assessment of a therapy with factor II or factor X antagonists.
- If you receive a discrepant INR result from another device, please contact your health care professional.

**Very low or very high test results**

The CoaguChek XS PT Test strips provide test results if the INR value is 0.8 to 6.0. If the meter displays < (less than) **0.8** or > (greater than) **6.0**, repeat the test. If, when you repeat the test, you get the same display (either < **0.8** or > **6.0**), call your doctor.

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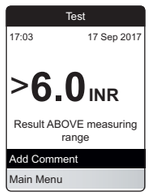


**Built-in controls**

The CoaguChek Vantus System has built-in quality control functions in the meter and test strips. The meter automatically runs its own quality control test as part of every blood test, so you never have to run quality control tests with liquid quality control solutions. For more information about the built-in quality control functions, see the *CoaguChek Vantus System User Manual.*

**Performance Characteristics**

**Measuring range:** The CoaguChek Vantus System has a PT measuring range of 0.8-6.0 INR.

**Accuracy:** Method comparisons were conducted at 4 US study sites comparing test results obtained by self-trained users with the CoaguChek Vantus System to those obtained by healthcare providers using the CoaguChek Vantus System (Figure 1) as well as the predicate device CoaguChek XS System (Figure 2). In addition, the test results obtained by the self-trained users were compared to a laboratory reference, Siemens Innovin measured on Sysmex CA-1500 instruments (Figure 3). Overall, the comparison results show slopes between 0.98 and 1.00, intercepts between 0.00 and 0.13 and correlation coefficients ≥ 0.91. These study results indicate that self-trained users are able to obtain results that are as accurate as those obtained by healthcare providers trained in the use of the CoaguChek Vantus System.

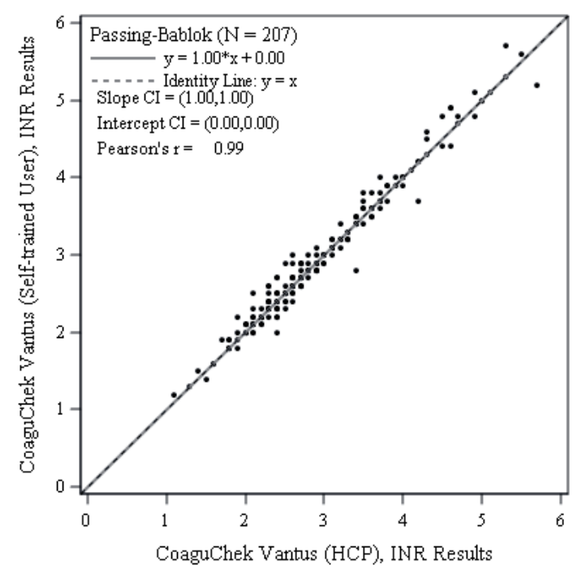


**Figure 1.** Results comparison between the CoaguChek Vantus System conducted by self-trained users vs. the CoaguChek Vantus System conducted by health care providers (HCP). All measurements used capillary blood.

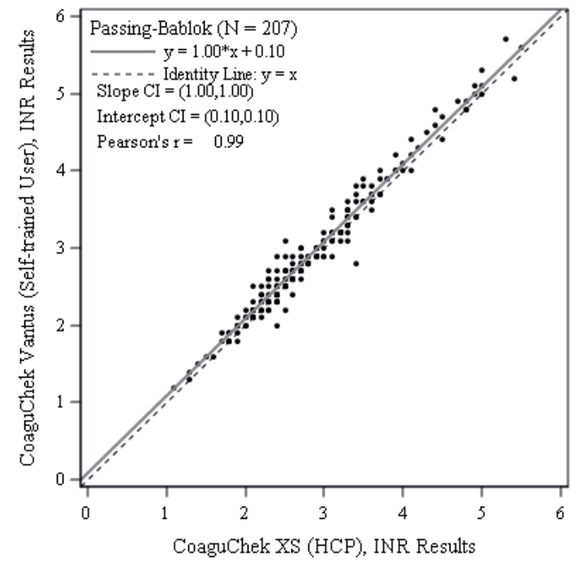


**Figure 2.** Results comparison between the CoaguChek Vantus System conducted by self-trained users vs. the predicate device CoaguChek XS System conducted by health care providers (HCP). All measurements used capillary blood.

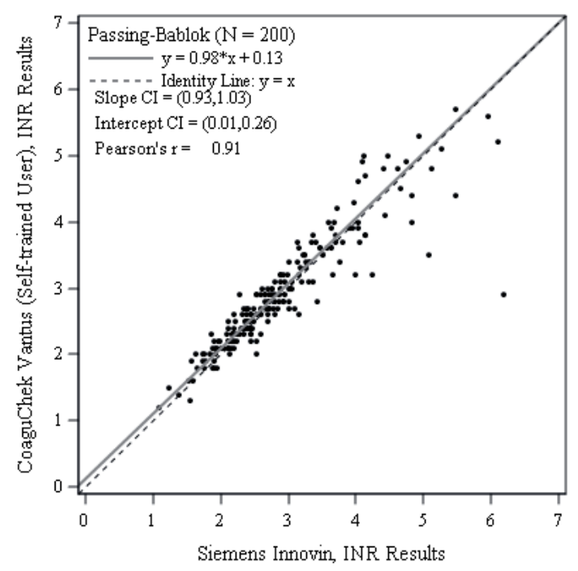


**Figure 3.** Results comparison between the CoaguChek Vantus System conducted by self-trained users vs. the laboratory reference Siemens Innovin conducted by lab personnel. Measurements with the CoaguChek Vantus System used capillary blood and Siemens Innovin measurements used venous citrate plasma.

**Patient demographics:** Table 1 outlines the demographic information for all self-trained users performing tests with the CoaguChek Vantus System.

**Table 1.** CoaguChek Vantus System self-trained demographic information (comparison to predicate device CoaguChek XS System).

| | | Number | Percent |
|---|---|---|---|
| All | | 207 | 100.0 |
| Gender | Female | 89 | 43.00 |
| | Male | 118 | 57.00 |
| Age | Range (years) | 27-90 | N/A |
| | Mean (years) | 66.30 | N/A |

**Precision:** Results of precision studies using 688 blood samples are shown in Table 2.

**Table 2.** Precision of the CoaguChek Vantus System

| Blood | < 2.0 INR | 2.0 - 3.5 INR | > 3.5 - 4.5 INR | > 4.5 - 6.0 INR |
|---|---|---|---|---|
| N | 200 | 394 | 70 | 24 |
| Mean (INR) | 1.1 | 2.6 | 4.0 | 4.9 |
| SD (INR) | 0.04 | 0.08 | 0.12 | 0.07 |
| CV (%) | 3.8 | 3.1 | 3.2 | 1.5 |

| Controls | Level 1 | Level 2 | Level 3 | Level 4 |
|---|---|---|---|---|
| N | 1040 | 1040 | 708 | 712 |
| Mean (INR) | 1.32 | 2.79 | 5.85 | 3.39 |
| SD (INR) | 0.03 | 0.07 | 0.17 | 0.09 |
| CV (%) | 2.3 | 2.7 | 2.9 | 2.7 |

**Usability:** 238 self-trained users participated in the study. Each received a survey after participation. The results summarized in Table 3 show that the acceptability, the handling and the functionality of the system rates as very good (overall 1.3).

**Table 3.** Usability rating of the CoaguChek Vantus System by self-trained users. The statements in the questionnaire were rated on a scale of 1 (strongly agree) to 5 (strongly disagree). Number of lay users in survey = 238

| Statement | Number of responses | Mean Rating |
|---|---|---|
| Overall, I liked the new CoaguChek Vantus System | 238 | 1.3 |
| Using the new CoaguChek Vantus system was easy | 238 | 1.4 |


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| Statement | Number of responses | Mean Rating |
|---|---|---|
| I liked the size of the meter and the meter buttons | 238 | 1.3 |
| Navigating the meter buttons and screens was easy | 238 | 1.4 |
| I was able to understand the instructions for testing the INR | 238 | 1.4 |
| I was able to successfully perform a test on the meter | 238 | 1.4 |
| I was able to easily read the INR result | 238 | 1.2 |
| I was able to insert the test strip easily | 238 | 1.3 |
| It was easy to apply the blood to the test strip | 238 | 1.4 |
| The amount of blood needed for the test strip was easy to obtain | 238 | 1.4 |
| The test strip was easy to handle | 238 | 1.3 |
| I was able to apply blood to the test strip within 15 seconds of lancing the finger | 238 | 1.3 |
| **Overall Rating** | | **1.3** |

## Symbols

Roche Diagnostics uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard (for USA: see https://usdiagnostics.roche.com for definition of symbols used):

| | |
|---|---|
| REF | Catalogue number |
| LOT | Batch code |
| IVD | In vitro diagnostic medical device |
|  | Manufacturer |
|  | Contains sufficient for <n> tests |
|  | Use-by date |
|  | Temperature limit |
|  | Consult instructions for use |
| SYSTEM | Analyzers/Instruments on which reagents can be used |
| GTIN | Global Trade Item Number |

## Additional information

The *CoaguChek® Vantus System User Manual* contains more information. If you need technical help, call the Roche Diagnostics Technical Service Center at 1-800-428-4674, 24 hours a day, 7 days a week, 365 days a year.

## LIMITED WARRANTY

Roche Diagnostics warrants that this product will meet the specifications stated in the labeling when used in accordance with such labeling and will be free from defects in material and workmanship until the expiration date printed on the label. THIS LIMITED WARRANTY IS IN LIEU OF ANY OTHER WARRANTY, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR PARTICULAR PURPOSE. IN NO EVENT SHALL ROCHE DIAGNOSTICS BE LIABLE FOR INCIDENTAL, INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES.



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