



The importance of precision in anticoagulation management

CLIA-Waived

CoaguChek[®] XS System

The CoaguChek[®] XS System
A smart way to test

The CoaguChek XS System from Roche Diagnostics delivers excellent precision

Precision of PT/INR results can influence therapy decisions and patient outcomes. Clinicians should therefore select a point-of-care anticoagulation monitoring device that provides precise results. Since 1994, CoaguChek Systems have provided precise point-of-care PT/INR testing.

Precision refers to the reproducibility of patient results obtained under the same conditions over a period of time.

Precision is largely determined by statistical analysis of how much a given result is likely to deviate from the mean (average) of all results. The amount of variation—referred to as the standard deviation (SD)—is often expressed as a

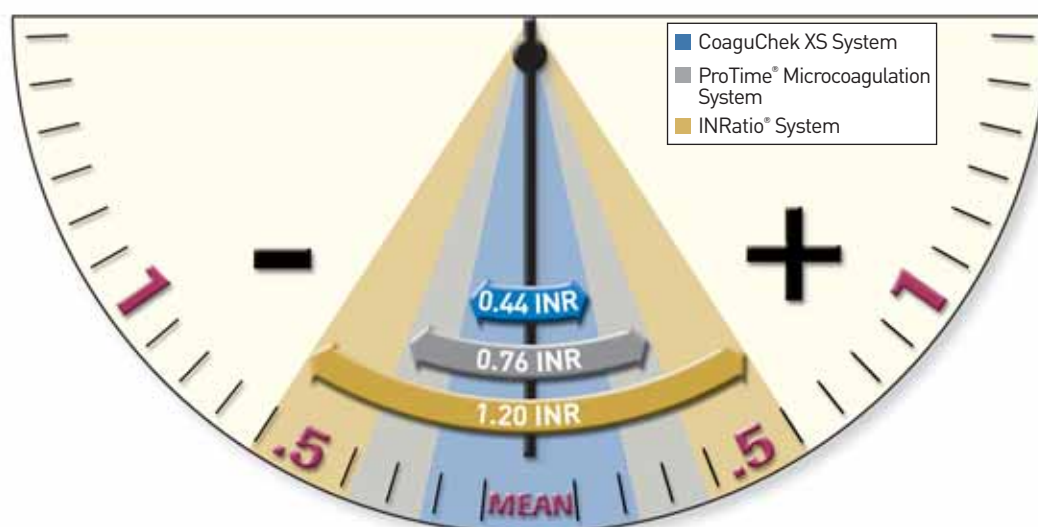
coefficient of variation (CV), which is calculated by dividing the standard deviation by the mean and multiplying by 100.

The CV is particularly useful for comparing the variability of data sets with different units of measurement because it is expressed as a percentage rather than in the units measured.¹

Assuming a normal distribution of all test results, 95% of those results should fall within 2 standard deviations of the mean.¹

Hence, the higher the CV, the wider the confidence interval (CI). Conversely, a smaller CV yields a narrower CI, which according to the American College of Physicians (ACP), indicates greater precision.¹

At a 95% confidence interval, results from the CoaguChek XS System are precise to within 0.44 INR, while the ITC ProTime® Microcoagulation System and HemoSense INRatio® System package inserts state that they are precise to within 0.76 INR and 1.20 INR, respectively.^{2,3,4}



Precision ranges

(Based on comparison of studies with different variables. INR mean, standard deviation and CV data for ProTime and INRatio Systems are from product package inserts.)

The CoaguChek XS System reports results with a narrower range of precision.

	Mean (PT/INR)	CV (%) (PT/INR)	SD	CI Values (Mean ± 2SD)*	Range of Precision*
CoaguChek XS System ²	2.6	4.4	0.11	2.38 – 2.82	0.44 INR
ProTime Microcoagulation System ³	3.2	6.0	0.19	2.82 – 3.58	0.76 INR
HemoSense INRatio System ⁴	3.1	10.0	0.30	2.50 – 3.70	1.20 INR

* Calculated based on the CV (SD/mean x 100)

¹ Lang T and Secic M. How to Report Statistical Information in Medicine: Annotated Guidelines for Authors, Editors, and Reviewers. Philadelphia, Pa: American College of Physicians; 1997.

² Fuller J and Miller E. Evaluation of the Accuracy and Precision of the CoaguChek® XS System. Roche Diagnostics Corporation. 2006. Precision testing was conducted using capillary therapeutic whole blood samples. N=344.

³ ProTime Microcoagulation System package insert. Edison, NJ. International Technidyne Corporation; 2001. Precision testing was conducted using only a Level III control. N=19.

⁴ INRatio System package insert. Milpitas, Ca. HemoSense Inc; 2003. Precision testing was conducted using capillary therapeutic whole blood samples. N=20.

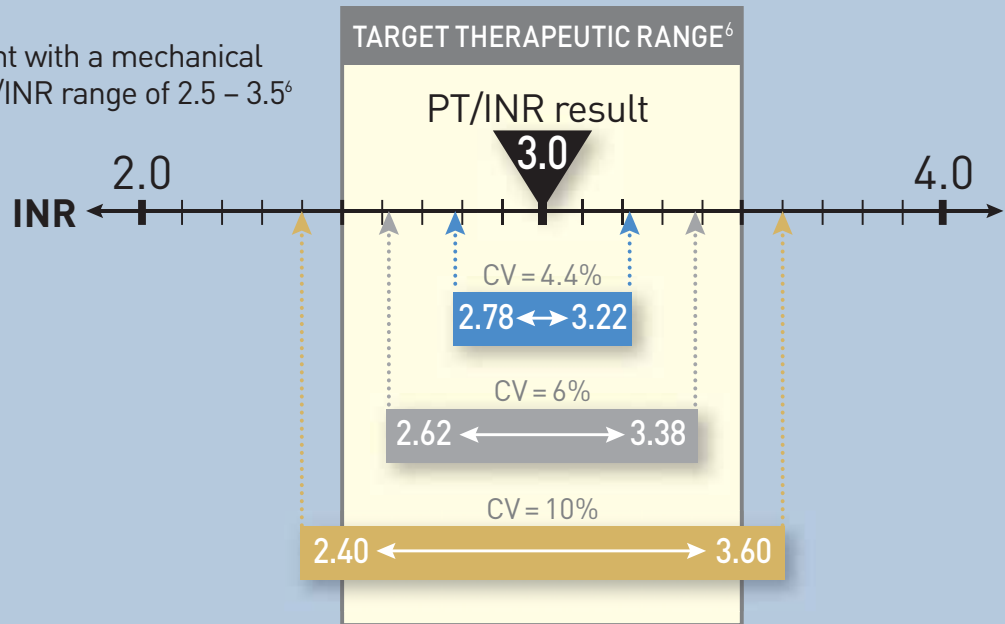
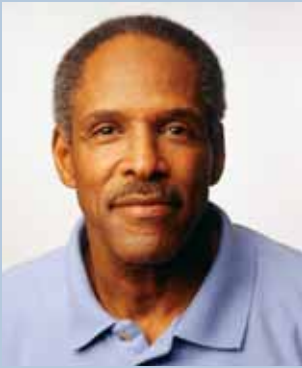
According to *CHEST* guidelines, patients on warfarin therapy should be managed within a narrow therapeutic range⁵

Because of its lower CV for test results, the CoaguChek XS System is likely to produce results that can help physicians make accurate therapy decisions based on a patient's target PT/INR range, as shown below.

Systematic imprecision may increase the likelihood that a patient's PT/INR value could inaccurately indicate a need for a dosage adjustment, thus increasing the risk of an adverse event.

Example:

52-year-old male patient with a mechanical heart valve, a target PT/INR range of 2.5 – 3.5⁶ and target value of 3.0

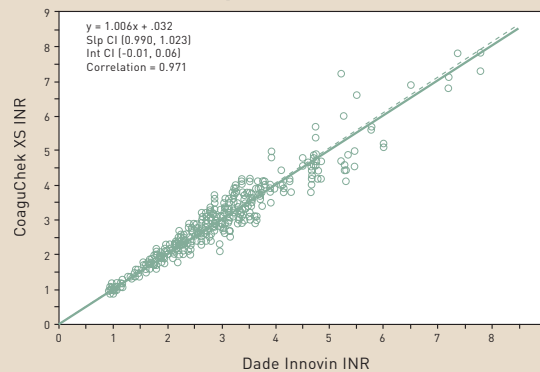


Confidence from accurate results at the point of care.

Accuracy is a measurement of how closely estimated results from a monitoring system correlate (agree) with reference values, such as those from a lab.

Results from the CoaguChek XS System demonstrate a correlation coefficient of 0.97 compared to this lab method.⁷

Capillary Data from All Sites
700 Samples from 357 Patients



The CoaguChek XS System for precise, accurate and *fast* PT/INR results at the point of care



Not only does the CoaguChek XS System provide precise, accurate results, but it delivers them quickly—in about a minute. That means you get immediate, actionable data so you can make dosage adjustments with confidence, which can help you deliver better patient care.

Take a minute to compare it to other systems available today.

	CoaguChek XS System ⁷	HemoSense INRatio [®] System ⁴	ITC ProTime [®] Microcoagulation System ^{†3}
Sample size	10 µL	15 µL	27 µL
Reading range	0.8 – 8.0 INR	0.7 – 7.5 INR	0.8 – 7.0 INR
Heparin insensitivity	Yes**	No	No
Hematocrit range	25 – 55%	30 – 55%	20 – 60%
Calibration input	Code Key	Manual Entry	Bar Code on Cartridge
ISI	1.0	1.0	1.0

** The CoaguChek XS PT Test is insensitive to low molecular weight heparins (LMWH) up to 2 IU anti-factor Xa activity/mL. In addition, results are unaffected by heparin concentrations up to 0.8 U/mL.⁷

† Using ProTime 3 cuvette.

The leader in point-of-care anticoagulation monitoring

Since 1994, Roche Diagnostics has helped healthcare professionals provide quality care to their patients with a PT/INR meter they trust. Find out why 4 out of 5 point-of-care PT/INR tests are performed with a CoaguChek system.⁸ Contact your Roche Diagnostics account manager to schedule an in-office demonstration, or call 1-800-852-8766.

- ¹ **Lang T and Secic M.** How to Report Statistical Information in Medicine: Annotated Guidelines for Authors, Editors, and Reviewers. Philadelphia, Pa: American College of Physicians; 1997.
- ² **Fuller J and Miller E.** Evaluation of the Accuracy and Precision of the CoaguChek[®] XS System. Roche Diagnostics Corporation. 2006. Precision testing was conducted using capillary therapeutic whole blood samples. N=344.
- ³ **ProTime Microcoagulation System package insert.** Edison, NJ. International Technidyne Corporation; 2001. Precision testing was conducted using only a Level III control. N=19.
- ⁴ **INRatio System package insert.** Milpitas, Ca. HemoSense Inc; 2003. Precision testing was conducted using capillary therapeutic whole blood samples. N=20.
- ⁵ **Ansell J, Hirsh J, Dalen J, et al.** Managing Oral Anticoagulation Therapy. *Chest.* 2001;119:25-38.
- ⁶ **Salem D, Stein P, Al-Ahmad A, et al.** Antithrombotic Therapy in Valvular Heart Disease—Native and Prosthetic: The Seventh ACCP Conference on Antithrombotic and Thrombolytic Therapy. *Chest.* 2004;126:457-482.
- ⁷ **CoaguChek XS System package insert.** Indianapolis, In. Roche Diagnostics Corporation; 2006. Precision testing was conducted using capillary therapeutic whole blood samples.
- ⁸ **Third quarter 2006 total market share of projected distributor unit sales of the Point of Care Testing Coagulation Reagents and Kits product class by HPIS Market Intelligence, a division of GHX Global Healthcare Exchange.** Total Market includes all market sectors as defined by HPIS: Physician, LongTerm Care, Treatment Centers, Clinical laboratory, Hospital, Home Healthcare and Other/Unspecified. Data on file.

POC anticoagulation testing with the CoaguChek XS System — a smart way to test.



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