



COAGUCHEK® XS SYSTEMS

Recalibrating for the future

A new standard. A renewed commitment to transparency.

In 2016, the Expert Committee on Biological Standardization established rTF/16, the WHO Fifth International Standard for Thromboplastin Human, Recombinant, Plain.¹ Some laboratories have adopted rTF/16, but some diagnostic test manufacturers are still calibrating to an array of different standards. Roche is committed to adhering to the latest reference standards — and we're proactively informing our customers of this change as part of our commitment to transparency.

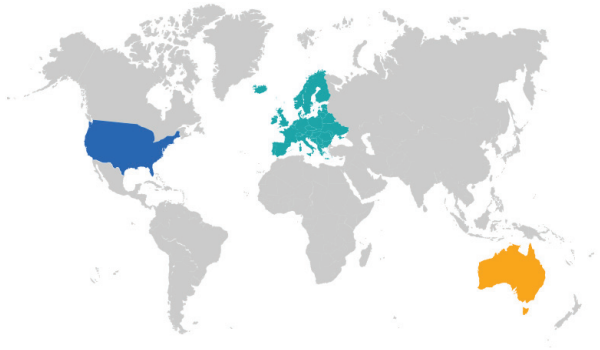
Consistent results you've counted on for decades.

Roche has been a trusted provider of INR testing systems for more than 20 years. Our newly calibrated strips will continue to deliver high-quality, accurate results.

Here's what we're doing to ensure the quality and accuracy you expect:

Performing first-customer monitoring that provides global, real-world data and feedback

Participating regions for testing



To help ensure accuracy, newly calibrated rTF/16 test strips were directly compared to:

- Laboratory results (both human and rabbit)
- rTF/09 calibrated strips

Ensuring the right results

The following steps are included in our calibration process:

<p>Raw materials/reagents screened for adherence to performance specifications</p>	<p>Strict criteria at defined medical decision points and sampling across the measurement range</p>	<p>Calibration vs. Innovin to confirm high correlation with human recombinant</p>	<p>Additional QC process certifies each lot prior to release</p>

*The National Institute for Biological Standards and Control. Medicines & Healthcare products Regulatory Agency. "WHO International Standard 5th International Standard 2016 Thromboplastin, Human, Recombinant, Plain NIBSC code: rTF/16 Instructions for Use." October 24, 2016. <https://www.nibsc.org/documents/ifu/rTF-16.pdf>.

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