

## **Next generation CLIA waived** point of care PT/INR analyzer



## High performance across the therapeutic range

Data obtained from independent FDA 510(k) equivalence study. CLIA waiver approved for POC use without requirement for specialist training.1

Laboratory Reference INR Range	Allowable Difference	Percentage within allowable difference	
		UBI: Xprecia Prime2Roche Coaguchek3	
0 to 1.9	± 0.4 INR	98.30%	97.13%
2 to 3.5	± 20% INR	97.70%	82.31%
3.6 to 4.5	± 20% INR	91.80%	85.71%
Total	-	97.18%	90.09%

- 1 FDA 510 (k) CLIA waiver https://www.accessdata.fda.gov/cdrh\_docs/clia\_waivers/CW230004.pdf. date of access 19.07.2024
  2 Xprecia Prime Allowable Difference Acceptance Criteria for all Evaluable Subjects (including outliers) all study sites N = 355 patients
  3 Roche Coaguchek Allowable Difference Acceptance Criteria for all Evaluable Subjects (including outliers) all study sites N = 353 patients
- Easy finger-to-strip application
- No calibration chips required
- Accurate testing in 5 steps
- Strip eject button for safer waste disposal

Register vour interest



Trust Xprecia Prime™ to provide reliable results every time. Request a demo and see the difference!



XpreciaSales@universalbiosensors.com Phone: +1 302 366 2723

## Results in less than 1 minute





**Scan patient ID** 



Scan test strip



**Insert test strip** 



Apply sample



Results shown

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## Xprecia Prime

