

LabPad[®] INR

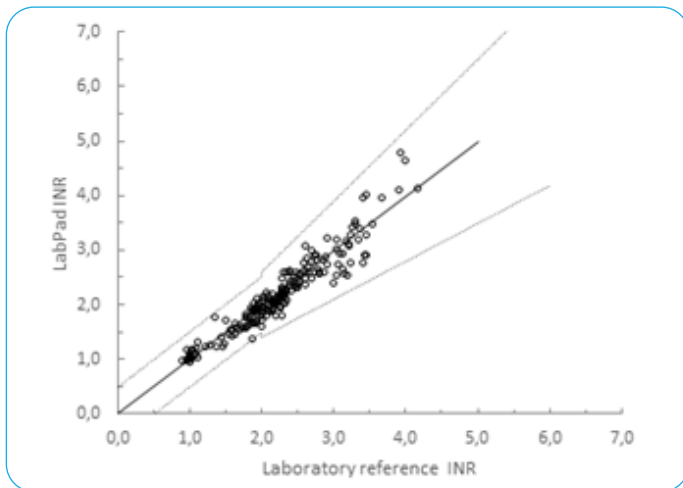
Point-of-care for PT/INR



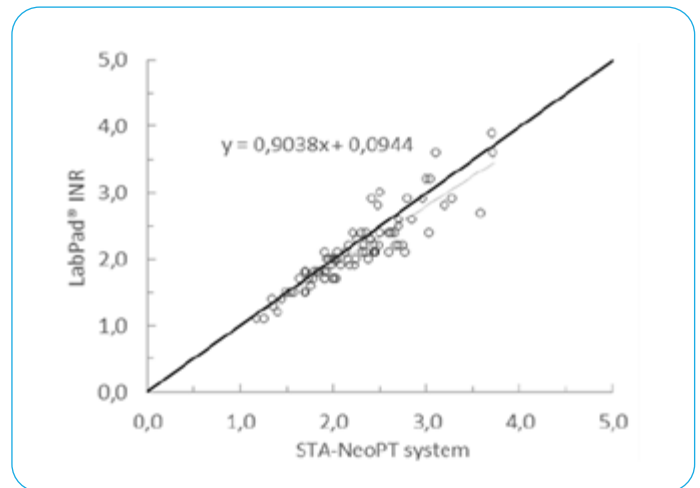
- ▶ Handheld device
- ▶ 3 simple steps:
 - ▶ insert Tsmart[®]
 - ▶ drop blood
 - ▶ discard Tsmart[®]
- ▶ Comfortable handling, silicone band and shape to fit human hands
- ▶ Touchless release preventing from contamination
- ▶ Unique microcuvette
- ▶ 3µL ▶ small blood sample
- ▶ 3D-shaped ▶ easy to grab
- ▶ Datamatrix for built-in QC
- ▶ No need for code chip
- ▶ Single packed to ensure reagent stability
- ▶ Room temperature storage



Accuracy



The study was performed in Grenoble University Hospital using capillary blood from 200 subjects on two Tsmart® INR lots and two LabPad® analysers. Laboratory testing was performed using corresponding venous blood with the core-lab STA-R Evolution® analyzer using CI Plus reagent from Diagnostica Stago. INR results were compared according to the ISO 17593:2007 standard.



The study was conducted in real-life laboratory routine conditions in the French biology lab Oriade-Noviale. A total of 84 subjects receiving VKA drugs were enrolled. Five different LabPad® INR devices and two different lots of Tsmart® INR consumables were used. Laboratory testing was performed using corresponding venous blood with the core-lab STANeoPTimal® reagent from Diagnostica Stago.

Quality control

3 built-in QC

1. Reading Datamatrix for quick-load of ISI, reference time, lot number and expiration date
2. Checking the proper filling of the Tsmart® micro channel
3. Embedded algorithm to verify dynamics of coagulation process

External QC

2 INR levels available to perform liquid control

Features

✓ Consumable	⇒ 3D-shaped microcuvette
✓ Sample size	⇒ 3µL
✓ Sample type	⇒ Capillary whole blood
✓ Measuring time	⇒ <1min.
✓ Test shelf-life	⇒ 18 months
✓ Bluetooth	⇒ Low Energy
✓ Device interface	⇒ USB B port
✓ Battery	⇒ Built-in
✓ Memory	⇒ 1,000 results
✓ Discarding consumable	⇒ Automatic ejection