

Low-Cost Smartphone-based PT/INR Testing

Regular testing of blood coagulation is necessary for millions of people on blood-thinning medications such as warfarin, yet existing testing methods are either done in a laboratory or are prohibitively expensive for many. This innovation uses hardware built into common smartphones along with inexpensive attachments to realize high accuracy testing for a fraction of this cost.

What is the Problem?

For millions of people with a variety of medical conditions suffer from increased risk of morbidity or mortality from blood clotting, requiring anticoagulation drugs such as warfarin. This medication must be closely monitored to prevent adverse effects, using prothrombin time (PT) or international normalized ratio (INR) tests to assess the coagulation of the blood under the influence of the medication. PT/INR tests are typically performed in a laboratory, requiring plasma to be separated from the whole blood followed by analysis on expensive equipment. While at-home PT/INR monitors that directly use whole blood exist and have been shown to improve patient quality of life and decrease risk of adverse drug effects, these testing modules typically cost hundreds of US dollars. This cost presents an accessibility challenge for resource-constrained environments, resulting in US patients being in the therapeutic range only 64% of the time, and 40% in developing countries. There is a need for more accessible, cost-effective at-home PT/INR testing for regularly monitoring the efficacy of blood thinning medications.

What is the Solution?

This innovation presents a low-cost PT/INR testing system without custom electronics or expensive hardware. Using the vibration motor and camera available on any common smartphone, vibrations from the phone that are transmitted to a cup containing a drop of the blood to be tested. A copper particle attached within the cup will vibrate in response to the applied vibrations from the smartphone motor, its motion tracked by the camera. As the blood coagulates in the cup, the vibrations of the copper particle will slow, and eventually stop as the viscosity of the blood surrounding it increases. From analyzing smartphone video data of the vibration of the copper particle, the software is capable of measuring PT and INR with inter-class correlation coefficients of 0.963 and 0.966 respectively compared to a clinical-grade coagulation analyzer.

What is the Competitive Advantage?

Accessibility is the greatest strength of this new method for PT/INR testing. The total materials cost of the smartphone attachment, plastic disposable cup, and copper particle is around \$0.03.

Technology ID

BDP 8419

Category

Selection of Available
Technologies
Diagnostic

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On-board vibration motors and cameras are not only ubiquitous on modern smartphones, but also smartphones that are over a decade old available secondhand for \$35.

In addition, as custom electronics and custom hardware is not necessary for this device to function, regulatory approval is streamlined, as smartphone hardware is not regulated under the FDA's Mobile Medical Applications and Software as a Medical Device guidance.

Altogether, despite the extremely low materials cost, 99.6% of all blood plasma measurements and 100% of whole-blood measurements fall within allowable differences for INR testing set by the International Organization of Standards for this type of device. This unprecedented accessibility for the PT/INR testing has the potential to impact millions around the world that require this regular testing because of their blood thinning medication.

Patent Information:

[US20240369582A1](#)

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References

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