

A wireless, hand-held, Smartphone-based “assay agnostic” analyzer that delivers rapid, point-of-care, central laboratory quality diagnostic results using the iAssay™ platform.

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iAssay™ is designed for use at a patient’s home by home health care practitioners, at the primary care physician’s office, by paramedics/EMTs on-site and in transport, by ED staff for triage, and by veterinarians in the clinic and in the field. Any popular test format (e.g. Rapid Diagnostic Tests (RDT), electrochemical) can be used just by plugging in the appropriate “Personality Module” (adaptor). Once the Personality module is inserted, the iAssay System functions identically to the native reader, but at 10% of the price. The iAssay System also wirelessly and compliantly populates patient records as tests are completed due to the inherent wireless nature of the smartphone that runs the platform.

Embedded microcontroller-based systems have been on the market for decades. The iAssay embeds the whole smartphone in the system so that it can be used for image analysis, operator interface, “wireless everything.” In addition to adaptor-type Personality Modules that adapt existing POC test cartridges to the platform, functional Personality Modules (e.g. high speed microprocessor, satellite communications, imaging, and fluid control) allow for iAssay hardware functionality expansion.

In the case of a simple RDT, an adaptor Personality Modules accurately positions the test cartridge test line(s) in the field of view of the adjacent imaging functional Personality Module so that its image is captured and analyzed using stored calibration information. For more complex fluorescent-type assays, the adaptor Personality module would also include controllable light sources of specific wavelengths to enable analysis.

Electrochemical test cartridges plug into a mating connector inside of the adaptor Personality Module. The electrical capabilities of the native device sold by the Original Equipment Manufacturer (OEM) are under the control of the smartphone that runs iAssay, and in agreement with the protocols provided by the OEM partner. The capabilities of iAssay are essentially limitless from a Point of Care standpoint due to smartphone programmability / hardware native features and the Personality Modules. All Point of care assays can now be run on one inexpensive platform, eliminating the need for multiple readers.

Early testing using lateral flow rapid diagnostics kits for PSA (JAJ International, San Diego, CA Catalog #QC-001) and NT-pro-BNP (JAJ International, San Diego Catalog #QH-001) showed high reproducibility and linear responses in the ranges of 2-10 ng/mL (see attached Figure 1) and 90-850pg/mL (see attached Figure 2), respectively.