Hand-Held X-ray Fluorescence (XRF) Analysis for Fast, Accurate, Comprehensive Small Volume Blood Diagnostics using Blood Drops Rapidly Solidified into Homogeneous Thin Solid Films

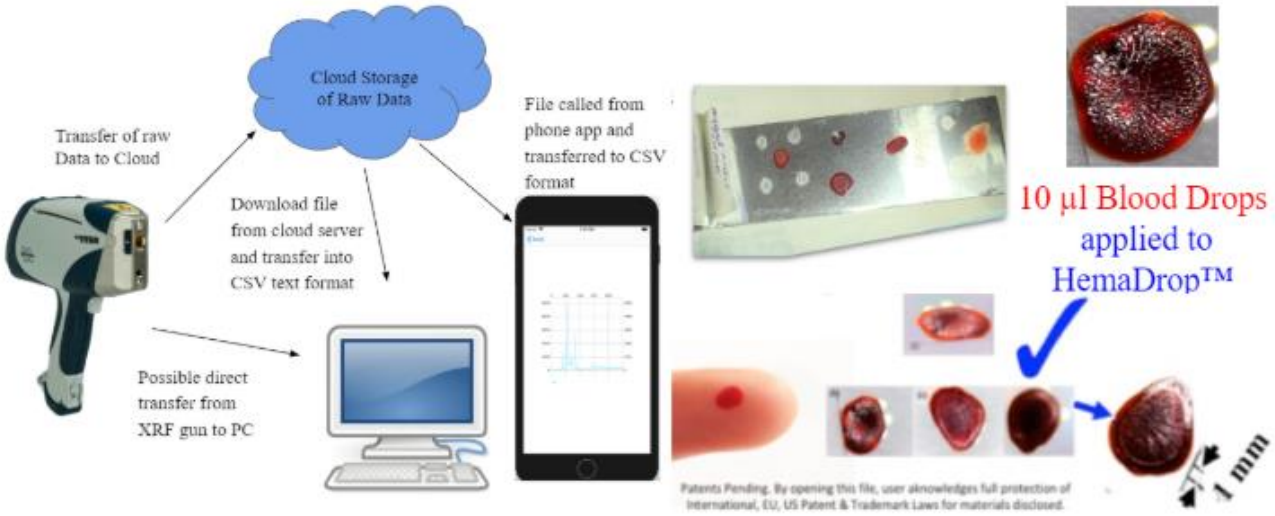


Figure 1: Data pathway summary showing the blood analysis process can be expedited by computing the analysis algorithm, can be applied in many places. HemaDrop™ coatings transforms liquid µL-sized drops into planar, smooth, uniform Homogenous Thin Solid Films (HTSFs) [1,2]. These HTSF can be analyzed in air or in vacuo via XRF, Ion Beam Analysis, and any solid state analytical UHV spectroscopy, such as XPS.

How Previous Research/Technologies Tried To Reduce Blood Volume Used For Tests But Failed:

Reducing the volume extracted for blood tests in infants or the chronically ill reduces anemia, pain, and other issues. In 2016, Theranos claimed to use nL-sized samples for blood diagnostics but failed to meet lab standards with relative errors > 10%, sometimes > 300%. It hid these inaccuracies from the FDA and physicians and resorted to secret, risky blood dilution to generate volumes in the mL range and used HPLC standards. It has been banned from the blood testing market by the FDA for three years.

Design For Blood Collection Strip Coated With Hyper-Hydrophilic Hemadrop™ [1, 2]:

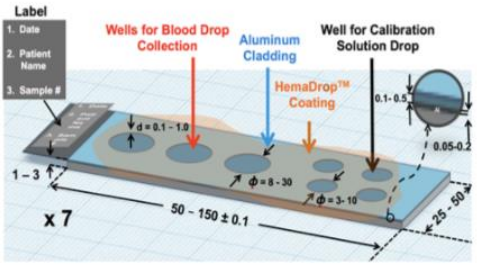
InnovaStrip™ Collection Substrate:

- Novel design that is small and portable needed to optimize blood collection
- Ten different designs were tested sequentially

Benefits of InnovaStrip™ Design:

- Multiple collection wells for **reliability & accuracy**
  - 4 wells for calibration solution
  - 3 blood drop collection wells
- **Small and Portable** for use in remote/unserved locations
- Extremely **inexpensive** (est. 40 cents per slide)
- Aluminum cladding optimizes **charge evacuation** (decreases interference with solid-state analysis techniques)

Picture of Blood Drop Collection Strip

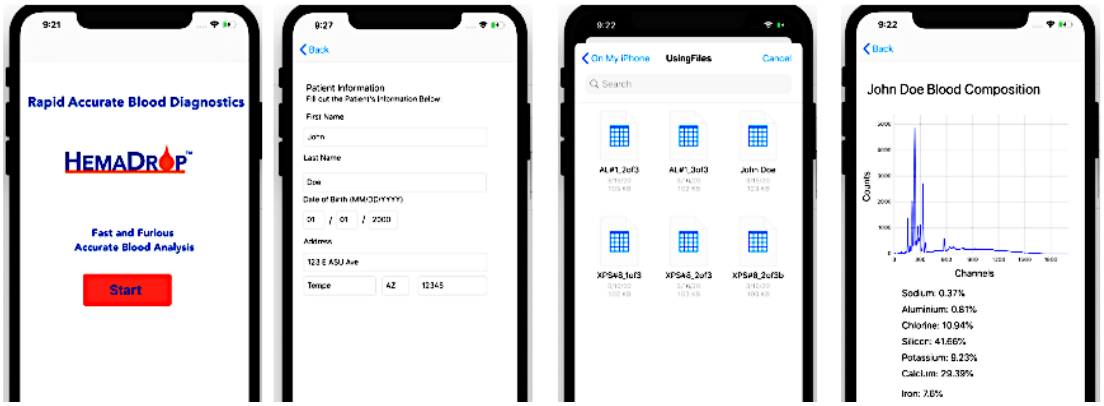


Blood Collection Strip Design

Elements Detected Using Hand-Held XRF In Rapidly Solidified Blood Drops:

Blood electrolytes such as ^{23}Na, ^{24}Mg, Ca, ^{35}Cl, ^{39}K, ^{40}Ca, etc., metals such as ^{56}Fe, trace elements such as ^{63}Cu, ^{79}Se, ^{126}I, heavy metals such as ^{75}As, ^{112}Cd, ^{200}Hg, ^{207}Pb, and radio-nuclides such as ^{87}Sr, ^{131}I, ^{235}U, ^{239} Pu are detected and analyzed

FHAX App Implementation of FABA Algorithm and Example of XRF analysis on Blood HSTF:



(a) *(b)* *(c)* *(d)*

Figure 2: Screenshots of the prototyped FHAX app for iPhone. (a) Welcome screen, (b) Standardized patient data input screen in the EPIC digital format used by most hospitals (HIPPA protected),(c) Data file selection for the specified patient, and (d) Actual XRF data collected with composition results screen to be converted into mg/dL. The following is a YouTube link to a video demonstration of the app: https://youtu.be/F5Y-_Djk6hQ

Schematic Of The Hand-Held InnovaStrip Device Showing Its Three Components:

(a) ***(b)*** ***(c)***

Figure 3: (a) HemaDrop™ coated Blood Collection Strip With 2 wells and 4 calibration HTSF (b) Hand-Held Analyzer where HemaDrop Strip™ is inserted(c) XRF spectrum collected in this work on blood HTSF

How The InnovaStrip™ Devices Saves Money & Time For Patients & Doctors And Saves Lives:

Since blood tests target specific components, e.g. Na, S, K, Mg, Cl, Cu, As, Zn, and Fe, specific elements can be selected for a specific diagnostic and measured more accurately with an order of magnitude greater speed, e.g 1-2 min at most for about ten to fifteen blood trace elements (electrolytes and metals) to within $\leq \pm$ 10% accuracy ,instead of 15-20 min for 117 elements with less than 50-100∞ accuracy, and hours and days for

[1] Herbots, Suresh, *et al*. (2019). MRS Adv.. 1-25. 10.1557/adv.2019.398.

[2] Herbots, Balasootiya, Peng, *et al.* US & Intl. Pat. Pend. (2016-20)