An Autonomous Robotic System for Rapid Blood Draws and Analysis

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Introduction:
Diagnostic blood testing is the cornerstone of modern medicine with over 2B tests performed annually in the United States. However, diagnostic results are obtained almost exclusively in centralized labs, where blood samples withdrawn from manual venipuncture techniques, are run on benchtop analyzers. Recently, technology advancements have led to the development of point-of-care devices to move diagnostic testing away from the central lab. Yet, no such technology exists that can provide an end-to-end solution from venous blood draw to sample analysis in a single, automated step. To address these limitations, we have developed a blood draw and analysis device that robotically performs the venipuncture and then transfers the sample to a centrifuge-based analysis system to obtain a 4-part CBC. Namely, a 2-part white blood cell (WBC) count, as well as hemoglobin (Hgb) and hematocrit (Hct) measurements. In this paper, we present the design of the system, and proof-of-concept data demonstrating the efficacy of the 4-part CBC assay.

Methods: As seen in Fig. 1, the device consists of a venipuncture robot, pumping system, and blood analysis unit. The venipuncture robot operates by first scanning the peripheral forearm vasculature of the patient under near-infrared light. After processing the images, the device selects an injection site and lowers an ultrasound probe to obtain a zoomed-in view of the vessel and confirm blood flow. Finally, the needle is robotically guided into the center of the vein. The dual-mode imaging modality allows the device to operate across all demographics including notoriously difficult patients such as pediatrics and geriatrics, as well as obese and dark-skinned populations. Furthermore, the robotics track the injection site based on image feedback, and make fine adjustments to the needle pose to account for rolling veins. Once the needle perforates the vein, a peristaltic pump withdraws 2 ml of blood at 5 ml/min into the analysis unit. It consists of disposable, laser-cut hard plastic chips pre-loaded with nuclear stain to enhance the detection of WBCs, a miniaturized centrifuge to fractionate the sample, and an optics unit to fluoresce the sample and analyze the separated layers. The thickness of these layers is correlated to WBC counts, whereas Hgb and Hct are measured from the packed red cell volume.

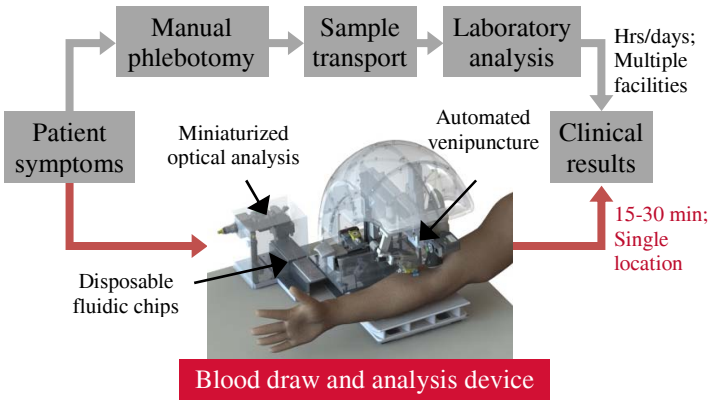

Figure 1. An automated device that performs venipuncture and provides quantitative blood measurements at the point of care.

Results and Discussion:
The venipuncture robot has been evaluated in numerous *in vitro* studies where the device has demonstrated >95% first-success in a phlebotomy training arm and customized skin tissue phantoms. To validate the accuracy of the centrifugal CBC assay, we have generated standard curves using blood sample controls with high, medium, and low values for each analyte (i.e. mono-nuclear WBCs, poly-nuclear WBCs, and Hgb, and Hct). In all cases, we have obtained a coefficient of determination >0.9, indicating proof-of-concept results in the diagnostic assays. We plan on generating at least 10 data points for each standard curve before moving on to *in vitro* testing using skin tissue phantoms infused with human blood, combining the robot, pumping, and blood diagnostics.

Conclusions: With the ability to rapidly draw blood and perform diagnostics at the point of care, this device can provide clinicians with key physiological data to guide patient treatment plans in time sensitive settings. In the future, we would like to incorporate the detection of other critical blood parameters in the device, such as cardiac markers, blood chemistry, and metabolic analytes. Additionally, we would like perform a human study where we evaluate the fully integrated system *in vivo,* from blood draw to sample analysis in a single automated step.