TESTING OF A NOVEL SAMPLE COLLECTION DEVICE THAT INCREASES USABILITY OF AN AT-HOME MEDICAL DIAGNOSTIC TEST
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Healthcare economists argue that the most likely means of lowering healthcare costs is lower-cost venues of care becoming more capable. Emerging smartphone-linked diagnostic technologies are providing users with new access to health information, which is transforming the smartphone into a low-cost venue of care. However, the quality of this health data depends upon a layperson’s ability to reliably use these technologies. To render an in vitro diagnostic device usable by a layperson, a novel sample collection and delivery device, iTest, was designed. In this study, the technical feasibility of iTest was evaluated through side-by-side testing against direct pipette sample delivery, and a limit-of-detection (LOD) analysis. We hypothesized that there would be no significant difference in performance when measured against pipetting, and that the LOD would be at least comparable to an FDA-cleared diagnostic testing system. Our results show that the sample collection and delivery mechanisms employed in iTest perform as well as a pipette, and that the LOD was better than an FDA-cleared creatinine diagnostic test. These results provide the basis for further development of iTest, and lay the foundation for eventual implementation in an at-home diagnostic testing system intended for use by a layperson with no medical training.