Abstract

Abnormally low or high blood iron levels are common health conditions worldwide and can seriously affect an individual’s overall well-being. A low-cost point-of-care technology that measures blood iron markers with a goal of both preventing and treating iron-related disorders represents a significant advancement in medical care delivery systems. Methods A novel assay equipped with an accurate, storable, and robust dry sensor strip, as well as a smartphone mount and (iPhone) app is used to measure total iron in human serum. The sensor strip has a vertical flow design and is based on an optimized chemical reaction. The reaction strips iron ions from blood-transport proteins, reduces Fe(III) to Fe(II), and chelates Fe(II) with ferene, with the change indicated by a blue color on the strip. The smartphone mount is robust and controls the light source of the color reading App, which is calibrated to obtain output iron concentration results. The real serum samples are then used to assess iron concentrations from the new assay, and validated through intra-laboratory and inter-laboratory experiments. The intra-laboratory validation uses an optimized iron detection assay with multi-well plate spectrophotometry. The inter-laboratory validation method is performed in a commercial testing facility (LabCorp). Results: The novel assay with the dry sensor strip and smartphone mount, and App is seen to be sensitive to iron detection with a dynamic range of 50 - 300 ug/dL, sensitivity of 0.00049 a.u/ug/dL, coefficient of variation (CV) of 10.5%, and an estimated detection limit of ~15 ug/dL. These analytical specifications are useful for predicting iron deficiency and overloads. The optimized reference method has a sensitivity of 0.00093 au/ug/dL and CV of 2.2%. The correlation of serum iron concentrations (N=20) between the optimized reference method and the novel assay renders a slope of 0.95, and a regression coefficient of 0.98, suggesting that the new assay is accurate. Last, a spectrophotometric study of the iron detection reaction kinetics is seen to reveal the reaction order for iron and chelating agent. Conclusion: The new assay is able to provide accurate results in intra- and inter-laboratory validations, and has promising features of both mobility and low-cost.