

## Low-cost flexible POC optical quantitative reader using self-metered lateral flow strips

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A K-C Corporate Research team has developed a low cost, broadly applicable lateral flow test strip reader. This reader possesses a transmission based optical path suitable for both immunogenic & colorimetric assays. The total cost of goods is projected to be less than five dollars for production volumes greater than one million. This fully-disposable, hand-held instrument automatically collects, processes, meters, and quantifies a sample. Additionally, this instrument can quantify a three standard absorbance unit change at one milliabsorbance resolution. On board memory and firmware allows for kinetic analysis spanning from minutes to hours. Finally, this technology is applicable for single or multi-analyte quantitation and is amenable to alternate site testing.

Kimberly-Clark has implemented an hsCRP diagnostic single use hand-held C-reactive protein immunological test system. It is a single parameter instrument (CRP only), with the ability to measure CRP on whole blood and serum samples *in vitro* using as little as three microliters of sample. Visual feedback guides the patient's to collect a small sample of blood via a finger stick and then press a button which precisely meters the requisite quantity of serum and performs a traditional lateral flow immunological assay which is subsequently quantified. The precision of this test (intra and inter-assay variability) has been demonstrated to be excellent ( $CV \leq 3\%$ ). Pre-clinical data established a strong correlation between the K-C hsCRP and two different clinical methods ( $R^2=0.93$ ). Data also established an accuracy range of 0-10 mg/L with the ability to flag samples that lie outside this range.

### Biography

Shawn Sullivan is a scientist employed in Kimberly-Clark's Corporate Research and Engineering division. Kimberly-Clark is a leading manufacturer of personal care, professional, and medical products.

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