

Design and development of point-of-care test kit for early diagnosis of chronic kidney disease

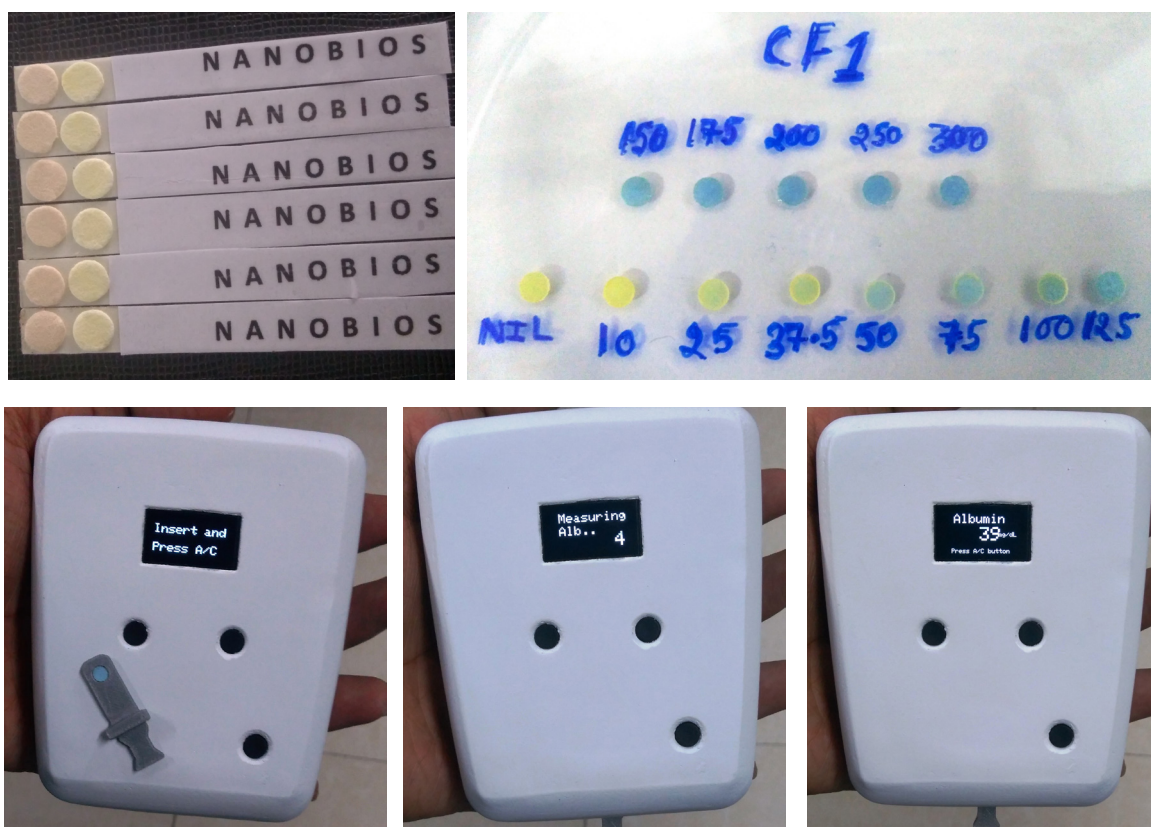
The risk of chronic kidney disorder, preeclampsia and other diseases which affect the albumin and creatinine level can be detected at an earlier stage by estimating the albumin and creatinine ratio. According to many reports including WHO 2014, 8-10% of the world population is affected by kidney related diseases. In India, there are more than 10 million cases every year for chronic kidney disease (CKD). Preeclampsia is another life-threatening disorder that occurs during pregnancy (affecting 1 in 20 pregnancies), childbirth and postpartum period. It causes high blood pressure and a significant amount of protein in the urine. Proteinuria is one of the major features of preeclampsia, which is one of the most common and potentially severe complications of pregnancy. According to WHO, pre-eclampsia accounts for 12% of mortality in India and more than 50% in the case of pregnant women. Persistent proteinuria greater than 50 mg/dL indicates a strong possibility of renal disease and protein level greater than 300 mg/dL suggest the higher amount of albumin is secreting from the kidney to the urine and need immediate clinical attention. Urine albumin and creatinine level and their ratio are one of the most important biomarkers for the diagnosis of a renal disorder.

A point-of-care test kit has been developed which includes colorimetric paper based assay for analysis of albumin, creatinine level and their ratio along with a colorimetric reader for early stage diagnosis of chronic kidney disease and pre-eclampsia. The developed colorimetric assay strips are much cheaper when compared to currently available such products in the market. The



colorimetric reader gives results in 30 seconds for each test and can be used as a personal diagnostic device.

Herein, we have developed two separate paper based assays for albumin and creatinine. Regents and dyes are immobilised onto the paper which changes the color according to the concentration of the albumin and creatinine present in urine. We have also developed a portable reader which detects the change in color of the strips. The reader has a photo sensor which converts the RGB values of the colored strip into light intensity. If there is any change in the color due to the concentration of albumin or urine, it changes the light intensity value. Values of the light intensities are calibrated for different values of albumin and creatinine from the standard bovine serum albumin and creatinine standard. We are currently testing our developed device at KEM hospital, Mumbai. Our developed assay and reader can detect the range of albumin from 10 mg/dL to 300 mg/dL and the range of creatinine from 20 mg/dL to 400 mg/dL.



Developed reader and the colorimetric assays for albumin and creatinine