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A Smartphone-based Point-of-Care Quantitative Urinalysis Device for Chronic Kidney Disease Patients

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Abstract

This paper presents the design and development of a smartphone-based urinalysis device that has the ability for chronic kidney disease (CKD) patients themselves to conduct rapid and reliable quantitative urinalysis of human serum albumin (HSA) using an aggregation-induced emission (AIE) nanomaterial bioprobe with their own smartphones. The focus of this paper is a novel solution to the device agnosticism issue as a wide diversity of smartphones co-exist in the market. The solution comprises: a) custom-design and fabrication of an imaging housing that provides a consistent imaging condition regardless of the physical dimensions and the camera position of the smartphone used, b) orchestration of an image processing and analysis process that produces consistent image colour intensity values regardless of the camera sensor and imaging software used by the smartphone, and c) special design and development of an intuitive cross-platform mobile application that is scalable to growth, adaptable to changes, resilient to loss of data, and has an extremely low requirement for smartphone hardware. Preliminary evaluation of the device has confirmed the effectiveness of the proposed solution and the viability of such a smartphone-based device for people who have already developed or are prone to CKD to regularly perform point-of-care (POC) urine testing in order to self monitor their own health conditions without the burden of frequent visits to their doctors.

Keywords: chronic kidney disease, urinalysis, microalbuminuria, smartphone, device agnosticism, point-of-care

1. Introduction

The kidney is one of the most vital organs in the human body, with its primary function of filtering the blood to remove wastes and toxins. In addition, the kidney is responsible for regulating blood pressure, water balance in the body and vitamin D activation. Chronic kidney disease (CKD) is a major health issue worldwide. More than 500 million people - 7% of the world's population - have some form of CKD, causing millions of deaths every year [1]. In Australia alone, over 1/3 of the population aged over 65 is at risk of CKD and yet many of them are unaware of that [2]. Early and regular testing of high-risk groups - such as people with diabetes, hypertension, cardiovascular disease, and family history of kidney failure - can prevent from progressing to end-stage kidney disease (ESKD) that may result in dialysis, transplantation, and renal replacement therapy outcomes [3, 4]. In Australia, age-standardised incidence of ESKD is significantly higher in Aboriginal and Torres Strait Islander people compared with other Australians mainly due to limited access to early detection facilities [5], which if available, treatment with medication, dietary and appropriate changes to their lifestyle would be more effective [6].

Urinalysis - urine diagnosis - is a standard method for the identification of people at earlier time points in the trajectory of CKD when it does not necessarily produce signs or symptoms. One urinalysis method is to measure the amount of Human Serum Albumin (HSA) [7], a serum protein that would normally be present at high concentration levels in blood and should not appear in urine more than a clinically normal threshold value of 30 mg/dL. Early stage of kidney damage would allow a small amount of albumin to leak into urine, leading to the condition of microalbuminuria that exhibits albumin levels of more than 30 mg/dL in urine [8, 9]. Microalbuminuria urinalysis measures albumin concentration levels in various urine specimens, every few hours within a 24-hour window in order to produce a reliable result [10]. It relies on bulky and costly bench-top urine analysers and trained skills only available in laboratory settings, thereby requiring successive patient visits to clinics or hospitals and long turnaround times [11].

Point-of-care (POC) testing is preferred to laboratory urinalysis as it can provide rapid results on the site, partic-

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