INVITED PAPER

Advances in Smartphone-Based Point-of-Care Diagnostics

This paper reviews the state-of-the-art advances in smartphone-based point-of-care diagnostic technologies and their applications in medicine and biology.

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ABSTRACT | Point-of-care (POC) diagnostics is playing an increasingly important role in public health, environmental monitoring, and food safety analysis. Smartphones, alone or in conjunction with add-on devices, have shown great capability of data collection, analysis, display, and transmission, making them popular in POC diagnostics. In this article, the state-of-the-art advances in smartphone-based POC diagnostic technologies and their applications in the past few years are outlined, ranging from *in vivo* tests that use smartphone's built-in/external sensors to detect biological signals to *in vitro* tests that involves complicated biochemical reactions. Novel techniques are illustrated by a number of attractive examples, followed by a brief discussion of the smartphone's role in telemedicine. The challenges and perspectives of smartphone-based POC diagnostics are also provided.

KEYWORDS | Mobile medicine; point-of-care (POC) diagnostics; public health; smartphone

I. INTRODUCTION

As a form of test performed at or near the test site, point-of-care (POC) diagnostics has received increasing attention in recent years [1]–[9]. POC diagnostics offers several advantages compared with laboratory-based tests in that the former is normally portable, inexpensive, rapid, and easy-to-use [10]. These features have provided POC diagnostics with an indispensable role in global and public health, such as in the control and treatment of infectious and chronic diseases [11]–[13]. For example, it can provide timely diagnostics for tuberculosis (TB) and human immunodeficiency virus (HIV), effectively preventing the spread of these diseases, and provide continuous, long-term monitoring services for diabetes mellitus and cardiovascular diseases [14]–[17]. Besides, POC diagnostics has shown great potential in environmental monitoring and food safety analysis [18], [19]. Therefore, the development of POC diagnostic technologies becomes increasingly urgent.

The three phases of a POC test are preanalytical, analytical, and postanalytical [20]. Preanalytical phase includes selection of proper test methods and specimen collection. Analytical phase is the process of detecting targeted biological signals and transforming them into measurable signals. Postanalytical phase includes data analysis, result display, storage and transmission, and decision-making. Early POC technologies usually require extra peripheral devices for analytical and postanalytical evaluation (e.g., electronic sphygmomanometer), thus significantly increasing the cost and complexity in performance and limiting

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Table 1 Categories of Smartphone-Based Diagnostics

Category	Explanation	Examples	
***In vivo* test**	Tests that do not require sample consumption; biological signals are converted to electrical signals by various sensors.	Test with built-in sensor	Use the built-in sensors, such as the camera, to collect human body or environmental signals.
		Test with extra sensor	Use extra sensors, such as an ultrasound probe, to collect human body or environmental signals.
***In vitro* test**	Tests that require sample consumption; biological components or organisms are detected from samples, such as blood, sweat, *etc*.	Tube, strip, and specimen inspection	Take a specimen of bodily fluid and directly inspect the result using the built-in camera or a microscope connected to a smartphone.
		Microfluidic testing	Take a specimen of bodily fluid and use microfluidic technique to perform complicated biochemical tests, and visualize the result using a smartphone.

their widespread applications in global and public health. Developing cost-effective and easy-to-operate POC technologies is therefore desirable.

Recent advances in smartphone technologies hold great potential to solve these problems. Smartphones, equipped with a computer-like platform and various types of sensors, have several properties promoting their uses in POC diagnostics [21]. The global market has witnessed a rapid growth of smartphones in recent years. Reports from International Data Corporation (IDC) and Canalys state that the number of smartphone subscriptions worldwide has reached up to 1.0 billion in 2013, and the number is expected to surpass 1.2 billion in 2014, driven by rapid growth in developing countries (e.g., India and China) [22], [23]. This means that smartphones are becoming widely accessible even in resource-limited areas lacking adequate healthcare facilities. Furthermore, a rich set of built-in sensors (e.g., camera and microphone) can be used for the detection of biological signals, powerful processors and memories for the analysis and storage of diagnostic results, and high resolution screens for result display [24], [25]. Finally, smartphones are generally equipped with powerful data transmission capabilities, such as Global System for Mobile Communication (GSM), wireless fidelity (Wi-Fi), Bluetooth, and universal serial bus (USB), allowing short-distance and long-distance communication between a remote test site and centralized laboratory for professional guidance.

Over the past few years, there has been a significant increase in smartphone-based healthcare technologies, as reflected by over 40,000 mobile health applications available in 2012 [26]. A number of articles have reviewed these advances: Patrick *et al.* and Wang *et al.* reviewed the application of smartphone in healthcare respectively in 2008 and 2009 [27], [28]. Xie *et al.* reviewed the development of biomedical imaging techniques combined with smartphones in 2010 [29]. With the rapid development of smartphone, many novel features are available now, and many new healthcare technologies have been introduced. A more recent review by Agu *et al.* focused on the usage of smartphone in medical condition diagnostics that takes advantage of the smartphone's built-in camera or microphone [30]. Another recent review by Ozcan *et al.* focused on the uses of smartphone for imaging/microscopy and optoelectronic/electronic sensing, such as smartphone-based microscopy that can detect single virus, as well as smartphone-based cytometry [31]. These existing reviews have not focused on the combination of smartphone and POC diagnostics or only focused on a single area of smartphone-based POC diagnostics. Here, we review the latest developments in smartphone-based POC diagnostics, ranging from *in vivo* tests that use smartphone's built-in/external sensors to detect biological signals to *in vitro* tests that are combined with complicated biochemical reactions (Table 1). Novel techniques are introduced and illustrated by a number of attractive examples, followed by a brief discussion of the smartphone's role in telemedicine. Last, we present the challenges and perspectives in smartphone-based POC diagnostics.

II. *IN VIVO* TESTING

In vivo tests capture health information from the target without sample consumption. Some biological signals, such as two-dimensional (2D) color images and sounds, can be directly captured using a smartphone. Furthermore, more sophisticated diagnostic information can be obtained by connecting smartphone with add-on devices [32], [33].

A. Smartphone-Based POC Diagnostics With Built-in Sensors

Although a variety of sensors have been imbedded in smartphone, the widely used sensors in POC diagnostics are still limited to camera and microphone. A large amount

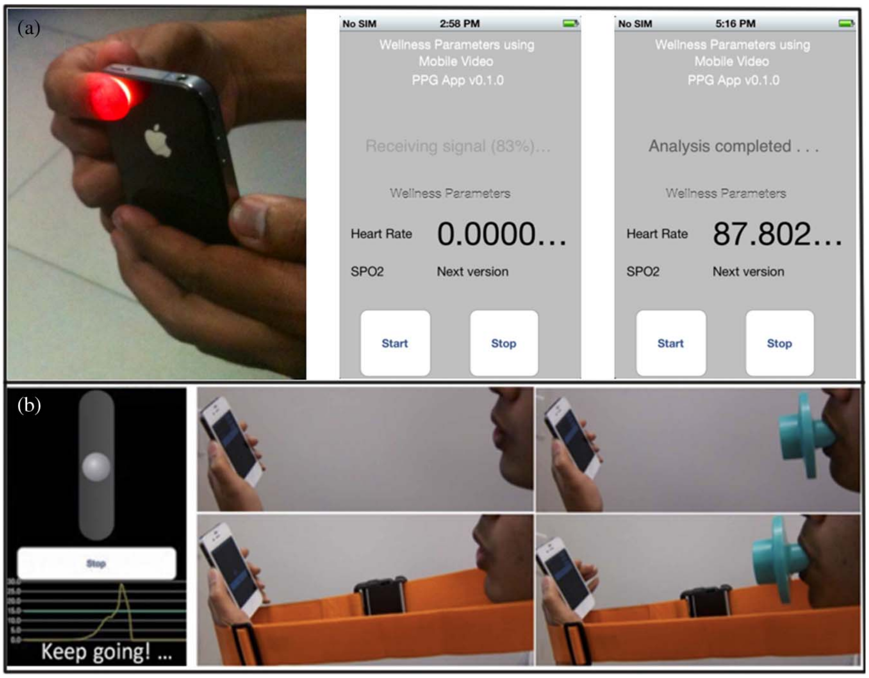

Fig. 1. ***Examples of in vivo POC diagnostics with smartphone's built-in sensors. (a) Heart rate detection from a fingertip [35]. (b) POC spirometer by recording the sound of exhalation using smartphone's built-in microphone [41].***

of diagnostic information can be extracted from the raw audio or video data when combined with signal or image processing algorithms.

The megapixel count of the smartphone's built-in camera has been doubled in every two years in recent decades and is now as high as 41 megapixels (Nokia 808 PureView). Researchers are able to extract various types of health information from images of the human body, such as fingertips, eyes, and skin using image and/or video postprocessing techniques performed either in a smartphone or computer. Widely used image processing algorithms include Fourier transform [34], [35], color signal analysis [36], region segmentation [37], and pattern recognition [38], [39]. For example, fingertips contain abundant information about blood circulation. Jonathan *et al.* [34] and Pal *et al.* [35] obtained changes in heart rate by capturing photoplethysmographic (PPG) signals from a fingertip using a reflection PPG imaging technique [Fig. 1(a)]. To collect PPG signals from a fingertip, a smartphone was used to detect, record, and process the reemitted signals of a white light emitting diode (LED) illumination source. Similarly, Scully *et al.* achieved monitoring of various physiological signals, including cardiac R-R intervals, breathing rate, and blood oxygen saturation [36].

In addition to obtaining blood circulation status from fingertips, a bunch of other smartphone-based technologies have been developed. For example, a simple smartphone-based pupilloeter was developed to measure the diameter of pupil, providing information on the function of autonomic nervous system [37]. By comparing tongue images acquired using a smartphone with an image database, Samsung Electronics Company developed a method to determine the overall health status of a person (e.g., fatigue status) [38]. Similarly, Wadhawan *et al.* developed a smartphone-based melanoma detection technology [39].

Audio information taken by the smartphone's built-in microphone, combined with digital signal processing algorithms, is also used to acquire health information. Yoshimine *et al.* reported the use of a voice-recording function to diagnose the overall health status of individuals by comparing to the voice database from healthy individuals [40]. Larson *et al.* reported a smartphone-based spirometer, in which the sound of exhalation is recorded and analyzed for lung function [see Fig. 1(b)] [41]. Thus, smartphone-based POC technologies have been rapidly developed to collect and monitor basic health information in nonclinical settings.

B. Smartphone-Based POC Diagnostics With External Sensors

So far, the information extracted by smartphone's built-in sensors is mainly limited to images and sounds. Many external sensor systems have been designed and integrated into the smartphone to extend its capability to extract more sophisticated diagnostic information, such as body temperature and functional images of organs and tissues. This allows previously unattainable health information to be extracted using external sensors and processed or

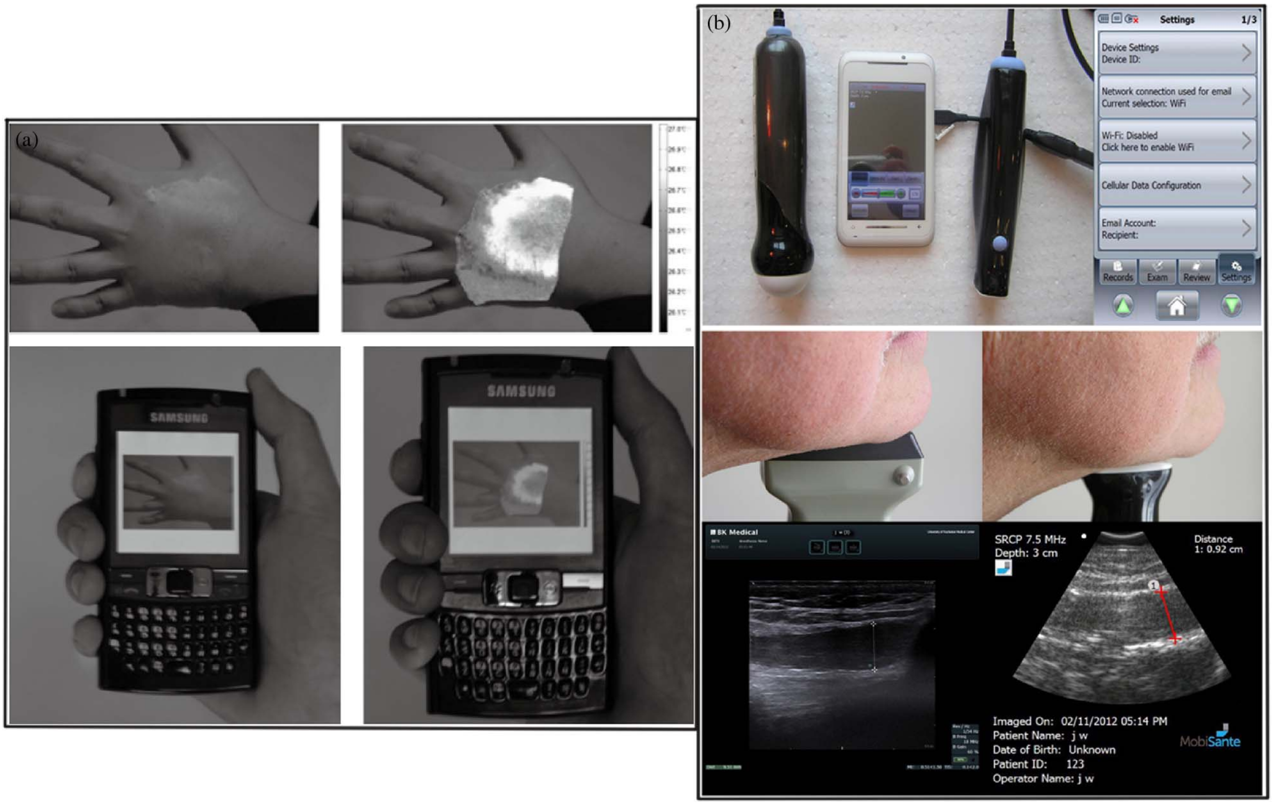

Fig. 2. ***Examples of in vivo POC diagnostics with extra sensors. (a) Skin temperature detection by mapping skin temperature changes to TLC color changes [42]. (b) POC ultrasound imaging system (Mobisante MobiUS SP1 system) with two mechanical sector USB probes [44].***

transmitted using a smartphone in the form of one-dimensional (e.g., body temperature and pulse rate), two-dimensional (e.g., ultrasound image), or three-dimensional (e.g., time-sequence ultrasound images) signals.

Huang *et al.* developed a smartphone-based thermal imaging technology to quantitatively measure the temperature of human skin [42]. In this method, liquid crystal thermal (TLC), showing temperature changes in different color, was prepainted on human skin. The color changes were then captured as two-dimensional images using a smartphone's built-in camera and analyzed in a personal computer to measure the final temperature [see Fig. 2(a)] [42]. Khandoker *et al.* developed a smartphone-based low-cost oximeter photoplethysmo-graphy [43], in which the desired information, including blood oxygen saturation and pulse rate, was collected using a hardware system that can detect the absorption of red and infrared signals through a fingertip. The digital signals were then transmitted to a smartphone through USB for diagnostic result display and data communication between on-site patients and off-site clinicians.

Smartphone-based medical imaging is an important emerging area in POC diagnostics. Medical imaging, different from smartphone-based microscopy introduced in Section III-A, is the technique applied to create images of the human body (or function and parts) for clinical purposes, such as X-ray, computed tomography (CT), optical coherent tomography (OCT) and ultrasound. With the capability of providing high-resolution images of internal structure of human body, medical imaging has been widely used in the evaluation and diagnosis of many diseases. However, the high cost and need for highly trained skill to operate these clinical devices prohibit such imaging technologies from many remote regions. With significant advances in smartphone's display and processing capabilities, medical imaging combined with smartphone has become a research area with great potential [29]. MobiSante developed an ultrasound probe that is able to be plugged into a smartphone [Fig. 2(b)] [44]. With an ultrasonic transducer, the smartphone can acquire and display ultrasound images, which can then be transmitted to an off-site health center for further interpretation. Using this system, they obtained images of the suprahyoid airway and muscular architecture of mouth floor.

III. *IN VITRO* TESTING

In vitro tests are biochemical tests that detect/measure biological components (e.g., metabolites, proteins, and nuclei acids) and organisms (e.g., cells and microbes) from

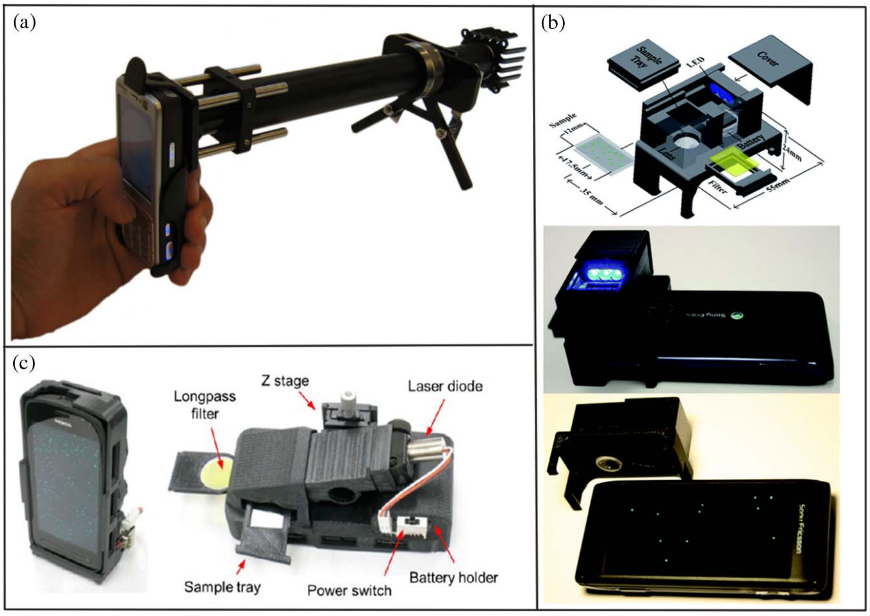

Fig. 3. ***Examples of smartphone-based microscopy systems. (a) Smartphone microscopy optical layout for fluorescence imaging [48]. (b) Schematic diagram and different views of the designed optical attachment for wide-field fluorescent imaging on a cell-phone [49]. (c) A cell phone-based fluorescence microscope [50].***

blood, sweat, saliva, urine, water, or food [11], including conventional microscopy, widely used lateral flow assays, and lately developed microfluidic devices.

A. Recent Developments of Smartphone-Based Microscopy

Microscopy, which allows the microscale investigation of biological specimens, is widely used in biochemical tests to identify objects (e.g., cells, bacterium, and parasites) that cannot be visualized directly by naked eyes [45], [46]. Microscopes can be used in specimen tests, microfluidic tests, or any other form of *in vitro* tests that need visualization in microscale. Conventional lab microscopy is relatively costly, bulky, and requires a highly trained staff, impeding its application to near-patient diagnosis. In response, researchers have developed accurate, cost-effective, and easy-to-perform microscopy, as a general tool suitable for POC applications using smartphones. Hence, before we delve into any specific smartphone-based biochemical diagnostic technique, we briefly review the recent development in smartphone-based microscopic imaging techniques.

Most smartphone-based microscopes are optical microscopes that consist of a visible light source and a system of lenses to magnify images of small objects. Image resolution and field-of-view (FOV) are two main parameters to evaluate the optical microscope's performance. Smith *et al.* developed a microscope attached to a smartphone that transformed the phone's integrated lens to a 350× microscope and visible-light spectrometer [47]. The microscope has a resolution of 1.5 μm and a usable FOV of 150 × 150 μm without image processing and approximately 350 × 350 μm with postprocessing. Breslauer *et al.* reported a smartphone-mounted light microscope and obtained a resolution of 1.2 μm and a usable FOV of 180 × 180 μm by adding a ball-lens to the system [see Fig. 3(a)] [48]. Zhu *et al.* demonstrated a wide-field fluorescent and dark-field imaging technique on a smartphone, in which a specimen was excited by a battery powered LED, after which the fluorescent emission from the sample was imaged using an additional lens positioned in front of the built-in camera [see Fig. 3(b)] [49]. This smartphone-based microscopy showed a large FOV of $\sim$81 mm^2 with a raw spatial resolution of $\sim$10 μm. Wei *et al.* reported a field-portable fluorescence microscopy platform installed on a smartphone with high spatial resolution that is able to image both individual nanoparticles (100 nm of fluorescent particles) and viruses (fluorescently labeled human cytomegaloviruses) [see Fig. 3(c)] [50].

A type of lens-free microscope has been recently developed that obviates the need for any lenses or other optical components [51]. Tseng *et al.* reported a lens-free holographic microscope attached to a cellphone with a spatial resolution of 1.5 $\sim$ 2 μm over a FOV of $\sim$24 mm^2 [52]. The additional hardware ($\sim$38 grams) installed on the cellphone is composed of an inexpensive LED (at 587 nm) with an aperture of $\sim$100 mm in front of the light source.

The development in smartphone-based microscopy greatly strengthens and expands the capability of smartphone in POC diagnosis, especially in direct specimen examination. Microscale imaging opens an avenue for

Fig. 4. ***Direct tube, strip, and specimen inspection for POC diagnostics. (a) Smartphone-based health sweat and saliva biomarker detection device [55]. (b) Different views of the smart RDT reader prototype installed on an Android phone (Samsung Galaxy S II). This device can be repeatedly attached/detached to the cellphone body without the need for fine alignment and modification [56]. (c) A picture of the iTube platform, utilizing colorimetric assays and a smart phone-based digital reader for food allergen testing [58].***

smartphone in POC diagnostics by granting it the power to directly examine bacteria, cells, and even viruses.

B. Smartphone-Based Strip, Tube, and Specimen Tests

Inspections of specimens directly, or by strips or tubes are the most commonly used diagnostic methods for many diseases [53]. In smartphone-based POC diagnostics, an image of the specimen, strip, or tube is captured first using the built-in camera or a converted microscopy as introduced in Section III-A. Then image postprocessing is used for counting targets or for colorimetric analysis in strip- and tube-based tests.

Smartphone-based microscopy can capture an image of a clinical specimen and further analyze it for target of interest. Breslauer's group developed a smartphone-based microscope to image *P. falciparum*-infected sickle red blood cells and *M. tuberculosis*-infected sputum samples and then automatically counted bacillus via image analysis [48]. Zhu *et al.* developed a compact smartphone microscopic platform to image blood samples, followed by the measurement of the density of blood cells and hemoglobin concentration through image processing [54].

Strip-based test results can be imaged using a smartphone's built-in camera, followed by colorimetric analysis. Onsescu's group demonstrated an integrated smartphone accessory for monitoring changes in pH of sweat and salivary [Fig. 4(a)] [55]. This system consists of a smartphone case, a smartphone application, and disposable strips. The strip tested with sweat or saliva sample is inserted in a slot on the smartphone case and an image is taken. The pH is determined by checking the hue-pH correlation stored inside the application. Mudanyali *et al.* demonstrated a cellphone-based rapid-diagnostic-test (RDT) reader

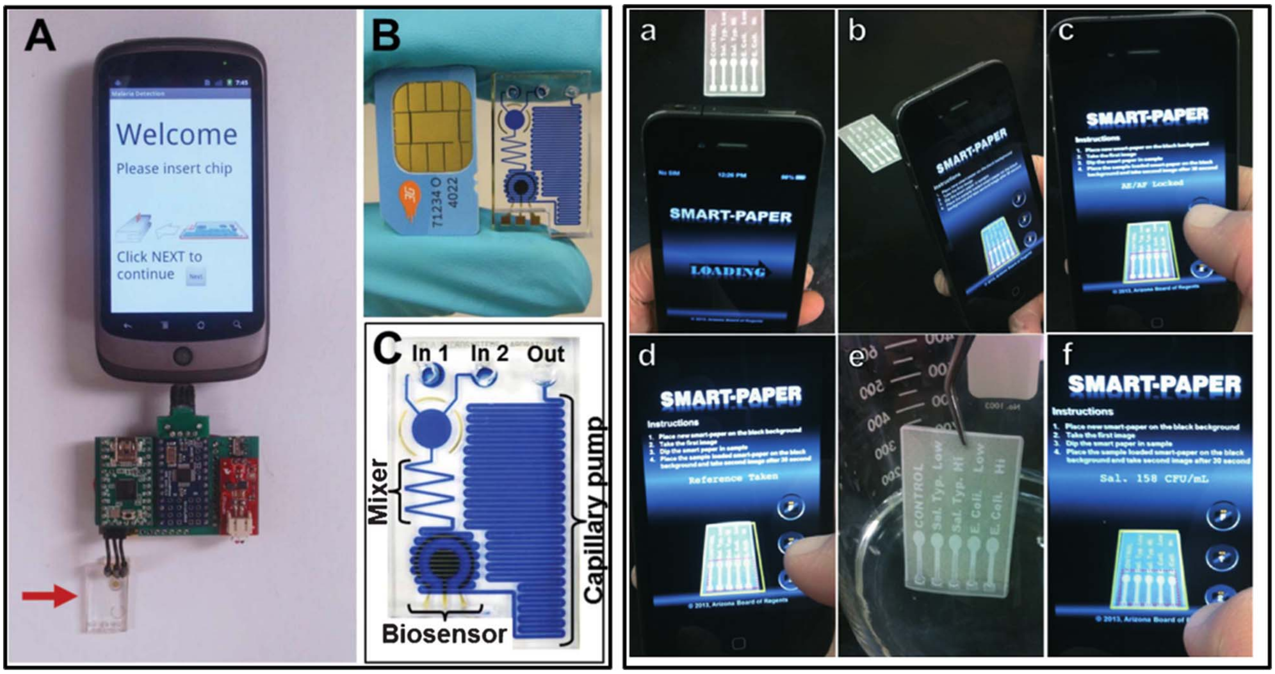

Fig. 5. ***Microfluidic based POC diagnostics. (Left) Photograph of the assembled prototype device for rapid electrochemical detection [18]. The arrow indicates the microfluidic chip. (Right) Smartphone application for Salmonella detection from a multichannel microfluidic device [69].***

platform that can work with various lateral flow immunochromatographic assays [Fig. 4(b)] [56]. This device can be attached to a smartphone, and various types of test strips can be inserted in the device and imaged by the built-in camera of a smartphone. The captured raw image can be processed through an application for result analysis, and the result together with raw images can be transmitted to a central server if necessary. Lee *et al.* presented a system for rapid quantification of vitamin D levels by evaluating serum samples with a test strip that allows colorimetric detection of 25-hydroxyvitamin D using a gold nanoparticle-based immunoassay [57].

Tube-based tests share a similar mechanism with strip-based ones. Coskun *et al.* built a food allergen testing platform that images and automatically analyses colorimetric assays performed in test tubes for sensitive and specific detection of allergens in food samples [see Fig. 4(c)] [58]. The test and control tubes are inserted from the side and are vertically illuminated by two separate LEDs. The transmission images of the sample and control tubes are digitally processed using a cellphone application. With a similar technique, they further demonstrated an Albumin Tester platform that images and analyzes fluorescent assays confined with disposable test tubes for sensitive and specific detection of albumin in urine [59].

C. Smartphone-Based Microfluidic Tests

Microfluidics-based biochemical testing technologies, which are designed to analyze small volumes of body fluids, have been widely studied for POC diagnostics [60], [61]. Microfluidic devices, coupled with different functional units (e.g., pumps, valves, and reactors), can be integrated into a miniaturized analytical system and manipulate a small volume of fluids, which greatly reduces the consumption of samples and reagents, and the complexity of operation procedures [18], [19], [62]–[64]. Microfluidic techniques can also integrate various assays into one single device to achieve multiplex assays, which greatly expands the capability, reduces the cost, and simplifies the operation of microfluidic tests.

Lillehoj's group developed a compact smartphone platform for rapid biomolecular detection [Fig. 5(a)], which consists of an embedded circuit for signal processing and disposable microfluidic chips for biosensing [18]. After the completion of each measurement, the results are displayed on the screen for immediate assessment, and automatically saved to the phone's memory for future analysis and transmission. The whole procedure can be carried out with two loading steps and takes 15 minutes to complete one measurement.

Stedtfeld *et al.* presented an inexpensive, user-friendly, and compact device operated on an iPod Touch (termed Gene-Z) for rapid diagnosis of multiple genetic markers [65]. It uses a disposable valve-less polymer microfluidic chip that contains four arrays with 15 reactions, each with dehydrated primers for isothermal amplification. This system is capable of simultaneous analysis of four samples for the detection of multiple

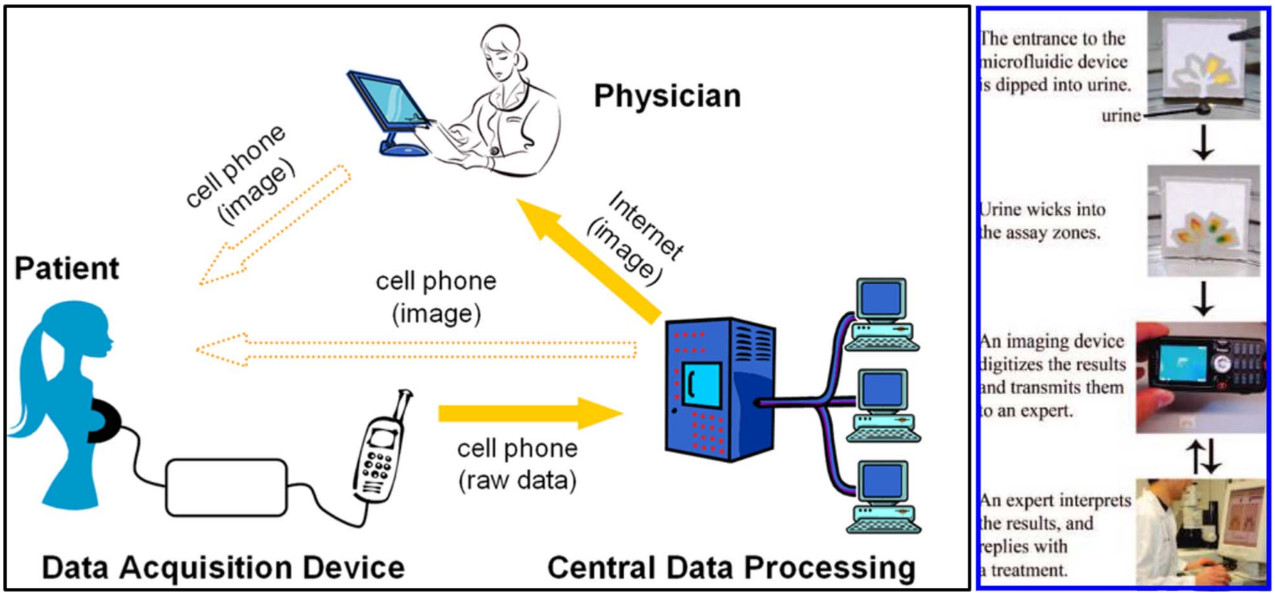

Fig. 6. *Examples of smartphone-based telemedicine diagnostics. (Left) System configuration for the breast cancer tumors patient self-test screening [77]. (Right) General strategy for performing inexpensive bioassays in remote locations and for exchanging assay results to off-site technicians [78].*

genetic markers, requiring only a single pipetting step per sample.

Besides the traditional chip-based microfluidic device discussed above, paper-based microfluidic devices are also widely used in smartphone-based POC diagnostics. Paper-based microfluidics is based on patterning sheets of paper with hydrophilic channels bounded by hydrophobic barriers, which are more cost-effective, sensitive, specific, and robust, thereby offering great advantages for developing POC diagnostics [66], [67]. Martinez *et al.* introduced a low-cost healthcare system that integrates paper-based microfluidics with camera-equipped cellular phones [68]. The results can be captured with a camera phone and transmitted to a central laboratory. Park *et al.* reported a smartphone-based *Salmonella* detection on paper microfluidics [69], [70]. The reaction result is quantified by taking digital images of the microfluidic device with a smartphone camera and implementing image-processing algorithms to calculate and display the bacterial concentration on the smartphone [see Fig. 5(b)]. The detection limit is down to a single cell level, and the total assay time is less than one minute.

IV. SMARTPHONE IN TELEMEDICINE

Today's smartphones are able to not only provide convenient and fast near-patient healthcare, but also facilitate long distance communication between on-site patients and off-site health centers with its powerful transmission ability [71], [72]. Therefore, in cases where off-site diagnosis and decision-making is needed, smartphone can collect on-site disease data, transmit it to a health center, and receive analytical results [73]–[76]. Granot *et al.* reported a telemedicine system that physically separated the imaging, display, and analysis parts in a medical imaging system [Fig. 6(a)] [77]. This system consists of a medical imaging data acquisition device (DAD) at the patient site, a smartphone, and image reconstruction system at health center. The cell phone serves as a conduit between DAD at the patient site and the image reconstruction system.

Martinez *et al.* reported a smartphone system for the rapid quantification of bioassays and the exchange of assay results with off-site physicians [78]. This system used paper-based microfluidics to run multiple assays simultaneously and used camera phones to capture image results. The digital information was then transferred from on-site patient to off-site clinicians for analysis and the diagnosis result is transferred back via a cell phone [see Fig. 6(b)]. AirStrip Technologies developed a smartphone application that can obtain patient physiological data (e.g., ECG/EKG data, fetal heartbeat and maternal contraction patterns) collected by bedside monitoring equipment, and transmit it to health professionals in near real-time [79]. Gonzalez *et al.* reported a smartphone technique that can work in medically underserved regions in Mexico to detect intraperitoneal bleeding [80]. In this paradigm, electromagnetic coils were used to take bulk data from a magnetic field at the patient site. The data were then transmitted through a cellular phone to a central location that could processes the raw data and return the diagnostic results to the patient site in real time.

V. DISCUSSION AND FUTURE PERSPECTIVES

Smartphone-based POC diagnostics offers great opportunities for delivering healthcare to resource-limited settings. Despite the increasing popularity, smartphone-based POC diagnostics faces some unsolved issues. The main concern centers on the reliability of POC testing procedure and the security of diagnostic results. For example, technologies intended to be used for POC diagnostics should be operable for the elderly, people with low literacy, and those with permanent or temporary disabilities [27]. The result indicated by smartphone applications should be explicit and nonmisleading. The management of personal health-related data, including data capturing, storage, up-linking to a server, and transmitting it through internet, should be secure and confidential.

We envision that the future development of smartphone-based POC diagnostics will focus on the following aspects. One aspect is the development of various types of portable biosensors that can be connected to a smartphone. For example, connecting a blood pressure meter to a smartphone, which is used for procedure control and result display, can create a simple sphygmomanometer. Another aspect is the implementation of complicated 2D/3D imaging techniques and a development of sophisticated image processing algorithms. An example might be the development of a portable optical coherence tomography imaging device, which can be used in oral cancer detection. In addition, the development of even more complicated and accurate biochemical test techniques, such as multifunctional microfluidic chips, is much needed [64], [81].

VI. CONCLUSION

This article discussed the state-of-the-art advances in smartphone-based POC diagnostics. Particularly, smartphone-based POC diagnostic technologies are categorized, by how the desired signals are collected, as *in vivo* tests and *in vitro* tests.

In spite of the unsolved issues, such as the reliability and security of the testing, the need for POC diagnostics is becoming increasingly strong in recent years. In the future, smartphones will become more popular, powerful, and inexpensive, all of which are providing a promising future for smartphone-based POC diagnostics. ■

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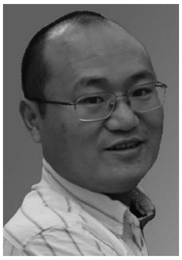

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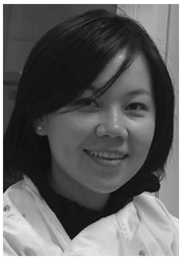

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