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Opinion

On-site diagnosis for Infectious Diseases

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On site test or Penside or Point-of-care testing (POCT) also known as portable test, field test refers to laboratory testing performed on the site, in the proximity of the patient so that prompt and accurate diagnosis can be made and adequate treatment can be given to the patient well in time. Thus, it aims to bring the laboratory at the door step of the patient, for the convenience of the doctor as well as the patient. Various rapid diagnostic test/tools with variable sensitivity and specificity in diagnosis of important infectious diseases have been developed to facilitate on field diagnosis of various diseases in humans as well as in animals. Standard laboratory procedures like blood culture, high-throughput immunoassays, polymerase chain reaction (PCR) and mass spectrometry (MS), which have been hitherto relied upon for their accurate results usually take much longer time and sophisticated laboratories with costly equipments and trained people [1]. Sometimes, treatment is so much delayed that it becomes redundant. Main priority of a point-of-care (POC) test is to provide rapid 'on-site' results at the site using limited resources, supporting timely and proper treatment [2].

Why should we invest in developing POC test?

WHO has given ASSURED" criteria to the POC tests so that they can be beneficial and easy to use (Affordable, Sensitive, Specific, User-friendly, Rapid and robust, Equipment-free and Deliverable to end-users) [3]. Normally, the transport time of clinical sample to the laboratory is more than 24 hours. This causes a considerable delay in deciding the course of treatment. In some cases where the disease is peracute, this delay might prove to be fatal. A POCT aims to cut down this transportation time to minimum so that there is no delay in aggressive therapy provided to the patient. A quick diagnosis will also be very beneficial in taking prompt decisions and course of action while facing an epidemic. These tests strive to be user friendly and do not require much expertise to arrive at a diagnosis, thus are ideal for use in developing and third world countries with poor lab infrastructure. Sensitive, specific and rapid diagnostic plays a critical role in preventing the transmission and control of infectious diseases and could provide a powerful tool for herd health management. These rapid tests can support local decisions and shift the burden of diagnosis to the veterinarians on the farm.

Where are we and how much have we achieved?

POC tests are emerging as promising, cost-effective diagnostic tools, especially for developing countries. Various POCTs based on different principles have been developed and are commercially available. Paper-based assays (PBAs) are the most promising assays available. To acquire additional functionality and qualitative analysis, PBAs are being combined with Cell phone (CP) detection. Most common PBA formats include Lateral Flow Assays (LFAs), dipstick assays, and microfluidic paper-based analytical devices (μPADs). Paper (filter paper/chromatography paper)/nitrocellulose membrane, and paper/polymer or paper/nanomaterial composites are widely used substrates for POCTs.

Home pregnancy test strip which detects human chorionic gonadotropin (hCG) in urine, is the best known paper-based LFA. Both qual¬itative and semi-quantitative Lateral flow assays (LFA)

have been developed. Similar test has been employed to detect primary hepatic carcinoma biomarkers, HIV diagnosis etc. in humans. Qualitative dipstick tests which detect color change in the analyte are available. Antigen-lateral flow devices (Ag–LFDs) detect antigen using portable immuno-chromatographic strip tests. These tests are commercially available for the detection of FMDV, RPV, Avian Influenza Virus etc. The most frequently used POC tests target diseases of companion animals, like there is a commercially available lateral flow assay for heartworm detection in dogs [4]. Various commercial Cell Phone-based devices and smart applications to monitor weight, heart activity, pulse rate, blood pressure, blood oxygen saturation, physical activity and sleep in humans have become available. CP-based colorimetric readers for urine and pH test strips, IAs, and biochemical assays are available for OTC use. Recently, a CP dongle was developed for the detection HIV, syphilis, and active syphilis infection in 15 min [5].

Challenges associated with the implementation of point-of-care testing

The POC tests are usually developed to be user friendly so that a non technical person can also perform the diagnosis. They are meant to be sold over the counter (OTC) for the ease of availability to the enduser. Despite all benefits and numerous technological advances, the use of POCT remains relatively low for veterinary diagnostics, with most assays still in the research and development phase. Low through put (limited number of sample tested per test), costly raw material and slim profit margins make these tests costly and not appropriate to be used for mass testing of large number of animals. None of these POCTs yet appears in the OIE Terrestrial Manual as an approved diagnostic test, with the exception of the Ag–LFD for FMDV [6]. There may be so many reasons for this. It is often difficult to persuade the animal owner to invest in modern technologies. Exposure to heat, cold, light, moisture and inappropriate storage conditions can compromise the device, or the reagents used in the POC application. Powering of portable analytical devices may be a problem in remote or underdeveloped areas lacking electricity.

POC testing is an emerging technology that has tremendous potential in veterinary practice. They can serve as the foundation of "patient centralized" diagnosis and treatment of infectious diseases. The rapidity and portability provided by these tests is significant for animal health management. Wider application of POC testing in veterinary is regulated by economic, commercial, environmental and social factors. These tests need to be validated under field condition. Bridging the gap between assay development and marketing of the tests is the key to their wider usage. The global veterinary diagnostics market is expected to grow at the rate of 8.6% from 2016 to 2021 [7]. The scientific and technological breakthroughs and interdisciplinary research of engineers, biologists and animal experts, are expected to provide new POC applications in the near future which will be more in tune with the requirement of veterinary field.

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