Per the Forum of International Respiratory Societies report, five respiratory diseases are among the most common causes of severe illness and death worldwide

Point-Of-Care Testing for Emerging Respiratory Diseases



Point-Of-Care Testing For Emerging Respiratory Diseases

The human toll of COVID-19 has demonstrated the necessity – and difficulty – of quickly identifying emerging respiratory diseases. Lab-based diagnostic tests have played an important role during the pandemic. But from the viewpoint of quality of care and clinical management, timely infection control, and the ability to act upon results, the future will likely belong to portable, CLIA-waived rapid diagnostic tests.

Point-of-care tests (POCTs) are performed at the site of sample collection (e.g., bedside, physician's office or emergency department) and provide results usually in less than two hours and in some cases, within 10 minutes. They require little hands-on time and no laboratory training, as most critical steps are automated in a single device. Perhaps most important, they promptly identify the causative pathogen and help the healthcare professional choose the appropriate treatment or make the right decisions in outbreak situations, such as hospitalization or quarantine.

<u>"CLIA-waived" tests</u> refer to those that the U.S. Food and Drug Administration has determined to be simple and that present "an insignificant risk of erroneous result." (A list of tests granted waived status under CLIA may be found <u>here</u>.) Physician office labs wishing to perform CLIA-waived tests must first apply for a CLIA <u>Certificate of Waiver</u>, and then ensure that those performing tests follow the manufacturers' instructions.

Diagnostic challenges of respiratory disease

For some time, <u>point-of-care tests</u> have allowed healthcare professionals to identify whether an infectious agent is viral or bacterial. That's important, because <u>antibiotics are only needed for treating</u> <u>certain infections caused by</u> bacteria. Respiratory tract infections are a significant contributor to the global burden of respiratory tract illnesses. Per the Forum of <u>International Respiratory Societies</u> report, five respiratory diseases are among the most common causes of severe illness and death worldwide:

- Chronic obstructive pulmonary disease (COPD) around 65 million people suffer from moderate to severe COPD, from which 3 million die each year, making it the third leading cause of death.
- Acute lower respiratory tract infections are considered the top three causes of death and disability among both children and adults. It is estimated that annually 4 million deaths of children under 5 years are caused by acute lower respiratory tract infections. Respiratory tract infections caused by influenza kill between 250,000 and 500,000 people and cost between \$71 and \$167 billion annually.
- Tuberculosis 10.4 million people developed tuberculosis (TB) in 2015, from which 1.4 million died.
- Lung cancer kills 1.6 million people each year
- Asthma Around 334 million people suffer from asthma and affects 14% of children globally.

Several pathogens, including viruses and bacteria, can cause respiratory tract infections. As clinical presentations often overlap, identification of the underlying pathogen based solely on clinical criteria is <u>challenging</u>.



While some respiratory viruses -- such as influenza A virus (IAV) or human respiratory syncytial virus (RSV) -- are well-known and circulate worldwide, previously unknown or rare infectious diseases are spreading rapidly. They include human bocavirus (HBoV), human coronaviruses (HCoV-HKU1, -NL63), human metapneumovirus (HMPV), rhinovirus type C (RV-C), and human polyomaviruses (KIPyV, WUPyV), as well as SARS coronavirus (SARS-CoV), MERS coronavirus (MERS-CoV), novel strains of influenza virus A and B, and, most recently, SARS coronavirus 2 (SARS-CoV-2). Patients who develop such infectious diseases are also at risk of progressing to pneumonia which can cause even further complications. Early detection is key and leads to faster recovery.

Next generation

New and innovative diagnostic techniques, ranging from biosensors to novel portable and current lab-based nucleic acid amplification methods, offer a look at next-generation POCTs. While prototypes for some methods already exist, <u>others are still experimental</u>.

A key criterion for the evaluation of future POCTs will be their ability to identify the origin of the patient's symptoms, and to distinguish relevant pathogen(s) from bystander pathogens. Questions need to be answered about the correct timing of diagnostic testing regarding a patient's course of illness. The sensitivity and predictive value of a diagnostic test depend on:

- Specimen quality and virus load (which is usually higher in children and early in the course of illness).
- Duration of viral shedding (that is, release of the pathogen into the environment).
- Patient's immune status.
- The epidemiology of viruses in the respective season or region.

Advances in diagnostic capabilities may change the way we identify, document, and communicate respiratory viral infections. In the future, patients will increasingly demand to know the responsible pathogen and their clinical prognosis. As researchers develop pathogen-specific antiviral therapies and vaccines, new diagnostic algorithms will be needed to ensure the highest quality of care while containing costs. The more accurate the diagnosis, the faster patients are on the road to recovery.

With worldwide manufacturing facilities and an international sales and distribution network, Sekisui Diagnostics is a solid partner for healthcare professionals and distributors around the world. Among its offerings are a line of <u>CLIA-waived point-of-care tests</u> to help identify influenza virus A and B, including Acucy[®] Influenza A&B, OSOM[®] Ultra Flu A&B Test and OSOM Ultra Plus Flu A&B Test.

THE AMERICAS

SEKISUI Diagnostics, One Wall Street, Burlington, MA 01803 Phone: 800 332 1042 Fax: 800 762 6311 Email: questions@sekisui-dx.com

INTERNATIONAL

SEKISUI Diagnostics (UK) Limited, Liphook Way, Allington Maidstone, Kent, ME16 0LQ, UK Phone: +44 1622 607800 Fax: +44 1622 607801 Email: info@sekisui-dx.com

sekisuidiagnostics.com 80-8638-00-01 07/21

Because every result matters[™]

DIAGNOSTICS

SEKI

© 2021 SEKISUI Diagnostics, LLC. All rights reserved. Because every result matters²² is a trademark of SEKISUI Diagnostics, LLC.

