



Proper Preparation
Prevents Poor
Performance!

Before You Buy: Which Flu Test Is Right for Your Office?

SEKISUI
DIAGNOSTICS
Because every result matters™

Each year, despite forewarnings, the United States and European countries are sometimes caught off guard with a “Perfect Storm” of challenges for the influenza season. Physician offices should be stocking up on flu tests and other supplies in preparation for this year’s flu season. What do they need to know before they choose a flu test?

Planning Ahead

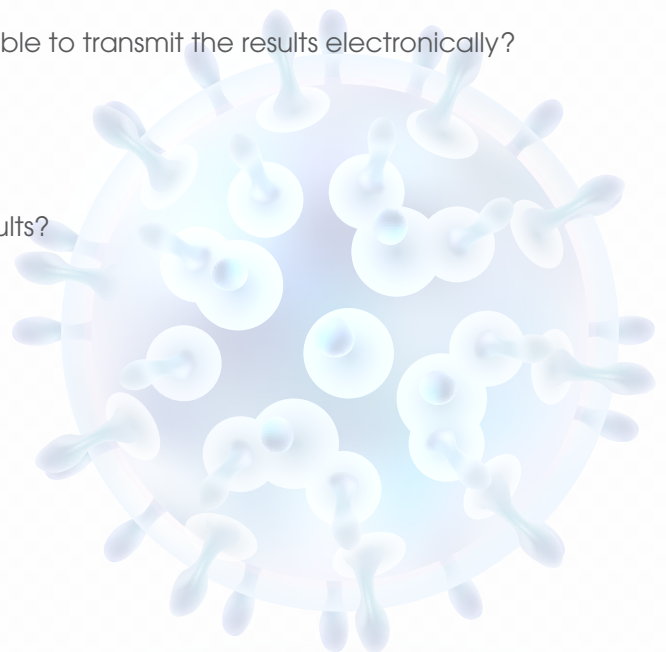
So much of flu season is a guessing game, especially when trying to plan for it. The World Health Organization (WHO), the Center for Disease Control (CDC), and the Food and Drug Administration (FDA) weigh in with their recommendation to which strains should be included in the upcoming flu vaccine well before the season gets started. Their prediction on what strains should be included will dictate how effective the vaccine will be. How severe the flu season is difficult to predict ahead of time, and the key indicators used by the WHO, CDC, and others can only be obtained after flu season begins!

So, what can clinicians and distributors do to prepare?

First, conducting a business assessment of what the clinicians experienced last year and looking at historical data can help dictate a plan to ensure they procure enough product.

Second, weigh the pros and cons of the tests they are currently using and tests they might be considering. Clinicians should consider the following:

- **Performance**—Is test sensitivity and specificity the most critical?
- **Volume**—How many tests does your facility perform during an average flu season?
- **Ease of Use**—how simple is the test to perform?
- **CLIA Complexity**—Does the facility require Waived or Nonwaived Flu test?
- **Results reporting**—Is it important for your facility to have an instrument-based result or visual read result, or is either one acceptable?
- **Sample type**—Does the test need to allow for multiple sample types (nasal, nasopharyngeal, aspirate/wash, and/or viral transport media (VTM))?
- **Connectivity**—Is it important for the testing device to be able to transmit the results electronically?
- Cost of the test
- The time to result
- Does the test require confirmation testing for negative results?



What's Out There?

There are several types of flu tests available on the market.

- Rapid molecular tests detect the genetic material of the virus and typically produce results in 30 minutes or less. These are considered to be more accurate than other methods.
- Rapid lateral flow immunochemical tests can be either read visually or by an instrument and are intended to detect the presence (or absence) of a target antigen in 15 minutes or less.
















FLU DIAGNOSTIC OPTIONS ACCURACY, TIME AND COST COMPARISON

Flu Diagnostic Testing Comparison

DIAGNOSTIC CHALLENGES

There are a number of diagnostic options available. However, choices may have to be made in terms of:

- ACCURACY**
Patient receives correct diagnosis
- TIME**
Patient receives correct diagnosis in a timely manner
- COST**
Diagnosis is obtained cost-effectively and affordably

METHOD	FEATURES			
CLIA WAIVED VISUAL MOLECULAR	<ul style="list-style-type: none">• Rapid PCR molecular platforms can be smaller and faster, and can be brought closer to the patient, for improved clinical impact• Molecular performance• Next generation molecular assays have focused on ease of use providing the familiar workflow of traditional lateral flow assays• Cost is less than traditional molecular with same reimbursement• Considered a Gold Standard of testing along with viral culture¹			
MOLECULAR	<ul style="list-style-type: none">• Highly accurate and definitive results• Labor-intensive workflow• Cost of rapid molecular tests is higher than lateral flow, but that may be offset by reducing unnecessary use of antibiotics• Considered a Gold Standard of testing along with viral culture¹			
READER IMMUNOCHEMICAL	<ul style="list-style-type: none">• Easy to perform• Affordable, making them suitable for use in a variety of settings from laboratories to near-patient• Typically provide results in minutes, allowing clinicians to test and treat quickly• Improves objectivity by removing visual read			
VISUAL IMMUNOCHEMICAL	<ul style="list-style-type: none">• Easy to perform• Affordable, making them suitable for use in a variety of settings from laboratories to near-patient• Typically provide results in minutes, allowing clinicians to test and treat quickly• Better accuracy with the FDA Flu Reclassification²			

1 https://www.cdc.gov/flu/professionals/diagnosis/clinician_guidance_rid1.htm
2 Federal Register / Vol. 82, No. 8 / Thursday, January 12, 2017 / Rules and Regulations

Depending on what characteristics (from above) are important to the clinician will help determine what type of test is a good fit for the facility. The manufacturer and distribution representative would be able to help guide the clinician to a product that is just right for them.

It should be noted that no flu test provides 100% accuracy. Results depend on the type of test used, the strain of virus and the integrity of the sample. It is very important when bringing on any test to review any limitations of the test, such as strain detection, any patient age limitations and performance data, along with sample collection and handling best practices and make sure that all staff is trained to provide the best in class testing.

The Importance of Testing

Due to the known performance issues surrounding the rapid tests, some physicians may argue that it's not necessary to administer a flu test in order to diagnose and treat.

Testing does not usually change how a patient will be treated for a flu diagnosis, so why bother? It turns out there are several reasons.

- Empirical treatment has a disadvantage in that many more patients are receiving treatment than actually have the flu giving rise to a possible antiviral shortage and possibly delaying the right treatment for another health issue.
- Testing patients provides valuable information to the clinician that can enable them to rule out other illnesses, helps determine a more direct therapy plan, and reduces the risk of unnecessary antiviral or antibiotics therapy, while increasing the chances that the patient will receive anti-viral therapy early when it is most effective.
- Testing will also help [determine whether an outbreak of flu is occurring](#). Since the implementation of rapid molecular tests and the drive by the FDA reclassification to have better RIDTs into the market clinicians can have the opportunity to utilize a highly accurate test to be more confident in the results to drive direct therapy.



How SEKISUI Diagnostics Can Help

The CLIA-Waived [OSOM® Ultra Plus Flu A & B Test](#) is rapid lateral flow qualitative test with performance equivalent to or exceeding reader devices, without the need for an instrument.

The CLIA-Waived Acucy® [Influenza A&B Test](#), used on the Acucy® System, provides clinicians flexibility in workflow and accurate, standardized results for improved patient care. It utilizes a traditional rapid lateral flow test paired with a reader.

The 5 “Ps”

In the end, it comes down to the 5 “Ps” – **Proper Preparation Prevents Poor Performance!** Don't be afraid to keep stock of flu tests all year round. Understand new options—with the fear of changing strains, new technologies are more important than ever. Just remember, you have choices!

Learn more about your options at www.flutesting.com



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