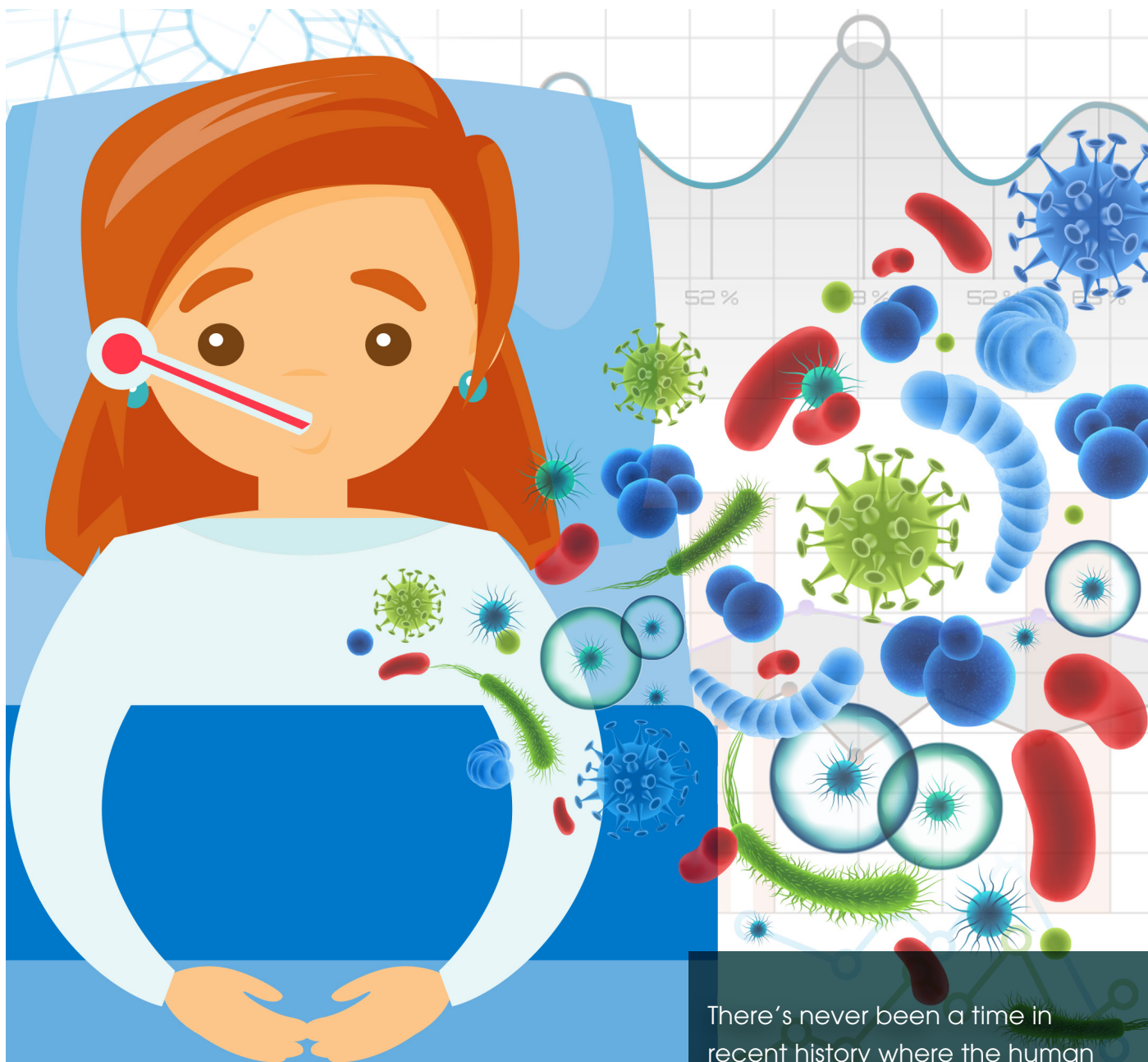




There's never been a time in recent history where the human population was as immunologically naive as it is here in 2021

Why Will Rapid Influenza Diagnostic Tests (RIDTs) Be of High Relevance During the Flu Season?

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DIAGNOSTICS
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Introduction

What appeared to be the sole redeeming feature of the pandemic might come with a dark side.

In this past respiratory season, non-COVID respiratory diseases, including influenza and respiratory syncytial virus, or RSV, were almost non-existent, most likely due to public health measures, such as mask-wearing, social distancing and scrupulous hand hygiene.

What could be bad about that? Some experts fear that by avoiding flu, RSV, strep, adenoviruses, even common colds, we may have failed to strengthen our immunity to them. Consequently, in the 2021-2022 respiratory season, we may have to pay off our “immunity debt.”

[Between 15,000 and 60,000 people could die in the United Kingdom¹](#) from influenza this winter, according to a recent Academy of Medical Sciences report, “COVID-19: Preparing for the future, looking ahead to winter 2021/22 and beyond.”

[“There’s never been a time in recent history where the human population was as immunologically naive as it is here in 2021”²](#) Scott Hensley, a viral immunologist at the University of Pennsylvania, told The Scientist.

Testing for Influenza this winter may be more important than ever.

What is Influenza?

[Influenza³](#) is a contagious respiratory illness caused by influenza viruses. There are [four types⁴](#) of influenza viruses: A, B, C and D. Human influenza A and B viruses cause seasonal occurrences of disease (known as the flu season) almost every winter. Influenza A viruses are the only influenza viruses known to cause flu pandemics, i.e., global epidemics of flu disease. Influenza type C infections generally cause mild illness and are not thought to cause human flu epidemics. Influenza D viruses primarily affect cattle and are not known to infect or cause illness in people.

With activity peaking between December and February, [each flu season is different⁵](#), and the health impact can vary from season to season. In addition, flu viruses can change from year to year, so the vaccine is updated every year to protect against new flu virus strains that are expected to circulate.

A particular challenge during the winter season is how to differentiate between common respiratory viruses (COVID-19, Flu and the Common Cold) in order for patients to receive the appropriate treatment.

“All patients with acute respiratory symptoms in hospitals and other healthcare settings, and all specimens from sentinel primary care surveillance should be tested for both SARS-CoV-2 and influenza during the influenza season to monitor incidence and trends over time.”

ECDC¹⁷



Differentiating between COVID-19, Flu and Common Cold Symptoms

		COVID-19 ⁸⁻¹⁵	Flu ¹⁶	Common Cold ¹⁶
	Virus	Coronavirus, SARS-CoV-2⁶	Influenza A or Influenza B²	Rhinovirus (majorly)³
	Incubation period	2-14 days	1-4 days	1-3 days
	Symptom Onset	Gradual	Abrupt	Gradual
	Sore Throat	Sometimes	Sometimes	Common
	Sneezing	Rare	Sometimes	Common
	Stuffy, runny nose	Sometimes	Sometimes	Common
	Cough, Chest Discomfort	Common	Common	Sometimes
	Fatigue, weakness	Sometimes	Common	Sometimes
	Fever	Common	Common	Rare
	Body ache	Sometimes	Common	Sometimes
	Chills	Sometimes	Common	Rare
	Headache	Rare	Common	Rare
	Shortness of breath	Common	Rare	Rare
	New loss of taste or smell	Sometimes	Rare	Rare
	Nausea or vomiting	Sometimes	Rare	Rare
	Diarrhea	Sometimes	Rare	Rare

Vaccination

The European Centre for Disease Prevention and Control (ECDC) has outlined three different immunisation strategies¹⁸ for Influenza vaccine roll-out.

1. Protecting the vulnerable – The ECDC encourages the EU Member States to “[adopt and implement action plans and policies aimed at reaching seasonal influenza vaccination coverage among older age groups of 75%, and if possible that target be extended to people with chronic medical conditions](#)”¹⁸.

The following [Patient groups are at risk of Influenza complications and WHO recommends these groups be vaccinated every winter when the disease starts to spread](#)¹⁹:

- Pregnant women;
- Individuals with chronic heart or lung diseases, metabolic or renal disease, chronic liver disease, chronic neurological conditions or immunodeficiencies;
- People over a nationally defined age limit, irrespective of other risk factors (typically people over 65);
- Residents of long-term care facilities for older people and the disabled;
- Children aged 6–59 months; and
- Health-care workers, including those who work in facilities that care for older people or people with disabilities.

2. Protecting healthy children, adolescents and adults – Toddlers and younger children are prone to severe Influenza disease complications. Influenza also leads to illnesses which cause school and work absence. Hence many people choose to get immunised.

3. Reducing overall Influenza transmission - Immunising children and adolescents in addition to the older population, may reduce overall influenza transmission and protect those in the risk groups. This is an approach recently adopted by the United Kingdom rolling out a programme offering influenza vaccine to all children 2-11 years of age.

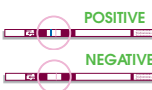
Treatment and vaccination programmes for Influenza are well established. Yet, a third factor that can inform clinical management is Influenza virus testing. [Rapid Influenza virus testing can influence clinical decisions](#)²⁰ such as whether to initiate antiviral treatment, perform other diagnostic testing, or implement infection prevention control measures for Influenza.

“Every year, people in these at-risk groups die from influenza. Worldwide, up to 650 000 people die of respiratory diseases linked to seasonal influenza each year, and up to 72 000 of these deaths are in the WHO European Region¹⁹.”



Influenza Virus Testing Methods

Overview of Influenza Testing Methods | CDC²⁰

Method	Sensitivity	Specificity	Time to result	Equipment Required	Setting required to perform test	Purpose of Test
 Rapid Molecular Assay	High	High	15 – 30 mins	Water bath or heat block	Clinical Laboratory, Clinic	Diagnosis
 Other Molecular Assays (e.g. PCR)	High	High	45 mins – hours	Thermal Cycler	Clinical Laboratory, Clinic	Diagnosis
 OOSOM Ultra Plus Flu A&B (Rapid Test)	High	High	10 mins	None	Anywhere	Diagnosis
 Immunofluorescence (Direct or Indirect)	Moderate	High	2 – 4 hours	Fluorescent microscope	Clinical Laboratory, Clinic	Diagnosis
 Viral Culture	High	High	1 – 10 days	Extensive lab apparatus	Clinical Laboratory, Clinic	Surveillance for outbreaks and vaccine development
 Serology	High	High	2 – 3 weeks	Extensive lab apparatus	Public Health or Research Lab	Research and Public Health Investigations

Guidance on rapid testing for Influenza at Point-of-Care

Rapid POC ('bedside' or near-patient) tests are not as sensitive (as RT-PCR) but can be useful in outbreak situations, for example for rapid identification of influenza infection where timely access to more sensitive and specific laboratory testing is unavailable or delayed.²¹

WHO Recommendations on the use of Rapid Test.²³

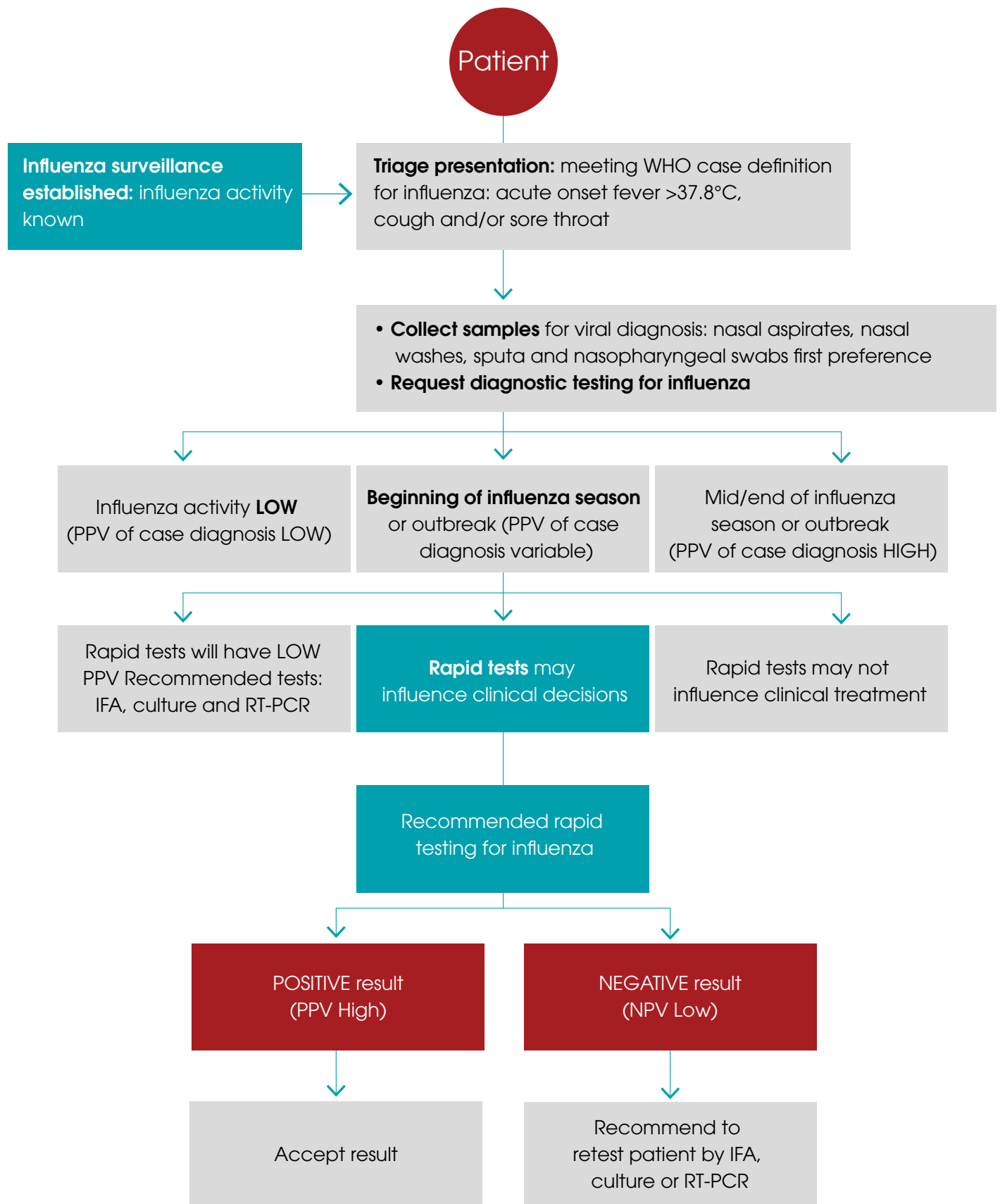
The use of rapid tests in countries with influenza surveillance in place. In countries where influenza surveillance is established, the recommendations for the use of Rapid Tests is as follows:

- Influenza surveillance should be used to guide the optimal use of rapid tests.
- During periods of low influenza activity, if rapid tests are used, positive results must be interpreted with caution and confirmed by immunofluorescence assay (IFA), viral culture or RT-PCR.
- At the beginning of the influenza season or an influenza outbreak, rapid tests may influence clinical decisions and contribute to clinical awareness.
- During periods of high influenza activity, it is impractical to test every individual meeting an influenza case definition. Clinical judgment and local influenza surveillance data should be used for case management in the first instance. Rapid tests are recommended to be used only when they can influence timely patient management.
- Because of the differing complexity of rapid tests, education of laboratory personnel about methods and limitations prior to their use is essential.

“ According to Public Health England (PHE), the recommended setting for use of Rapid Influenza Diagnostic Tests: Emergency Departments, medical admission units, outpatient clinics.²² ”



The use of rapid tests during the season occurrence of A/H1, A/3 and B virus infections



The use of rapid tests during the season occurrence of A/H1, A/3 and B virus infections²³

- Use rapid diagnostic tests with high sensitivity and specificity.
- Collect respiratory tract specimens as early in the illness as possible, (within 3-4 days of illness onset).
- Follow manufacturer’s instructions, including handling of respiratory specimens, as described in the device package insert.

OSOM Ultra Plus Flu Test

The [OSOM Ultra Plus Flu A & B Test](#) is an in vitro rapid qualitative test that detects influenza type A and type B nucleoprotein antigens directly from nasal swab and nasopharyngeal swab specimens obtained from patients with signs and symptoms of respiratory infection.



- Meets the Influenza reclassification requirements for rapid antigen tests. [FDA requirement](#)²⁰ is now for Rapid Influenza Tests to achieve a sensitivity of 80% when compared with RT-PCR. Sekisui Diagnostics performs Annual Flu Strain Reactivity Testing to ensure consistency and accuracy of the OSOM Ultra Plus Flu Test. View the 2020 Annual Flu Strain Reactivity Testing Summary [here](#).

	PCR Results (CLIA Waiver Studies)*	
	Sensitivity	Specificity
Influenza A	90.3%	96.7%
Influenza B	88.0%	99.2%

*Refer to Package Insert for additional performance claims

- High performance – equivalent to or exceeding the performance of reader devices, without the need for an instrument
- Simple CLIA-waived** procedure with pre-measured extraction buffer for swab samples
- Accurate, differentiated interpretation of results in 10 minutes to test and treat patients in one office visit

**CLIA-waived tests are laboratory examinations or procedures that are approved by the FDA... that are simple enough to have an insignificant risk of an erroneous result including those that²¹:

- Employ methodologies that are so simple and accurate as to render the likelihood of erroneous result by the user negligible
- Pose no reasonable risk of harm to the patient if performed incorrectly

“The CDC recommends using Rapid diagnostic tests with high sensitivity and specificity to minimize false results with RIDTs²⁴.”

CDC



Influenza Treatments

Currently two drugs are mostly recommended for the treatment of influenza, in Europe these are Oseltamivir (the trade name is Tamiflu) and Zanamivir (Relenza)²⁵. They are often only recommended as a treatment for influenza in those considered to be 'at risk' of developing more serious complications from flu infection, such as the elderly or those with underlying conditions like asthma or heart disease. Similarly to antibiotic resistance with bacteria, the Influenza virus can become resistant to antivirals if these are overused²⁵. Antivirals should therefore be prescribed only when considered necessary.

For otherwise healthy adults with ordinary influenza, the recommendation is to suggest at [home remedies](#)²⁶:

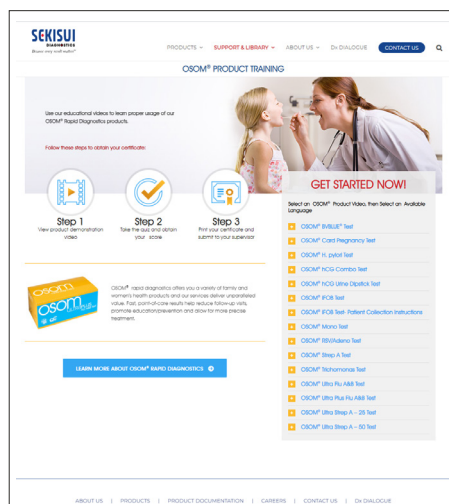
- Rest and sleep
- Keep warm
- Take paracetamol or ibuprofen to lower your temperature and treat aches and pains
- Drink plenty of water to avoid dehydration



Advantages of a Test and Treat Approach

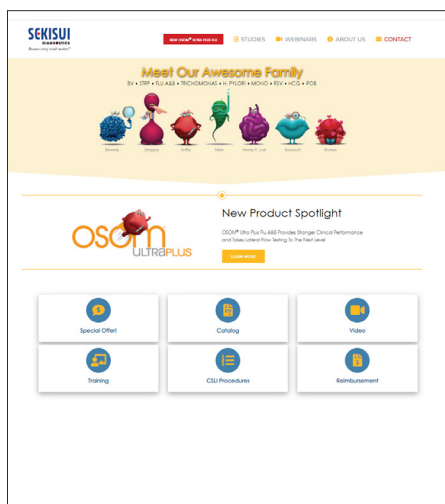
- ✓ **Prevent Spread** – Quick diagnosis allows the clinical to provide appropriate treatment to prevent further spread of the virus
- ✓ **Prevent inappropriate treatment** – Accurate diagnosis results in avoidance of unnecessary prescription of antibiotics or antivirals, resulting in good antibiotic stewardship
- ✓ **Patient Compliance** – Ensures the patient begins treatment immediately (if required)

Find Out More



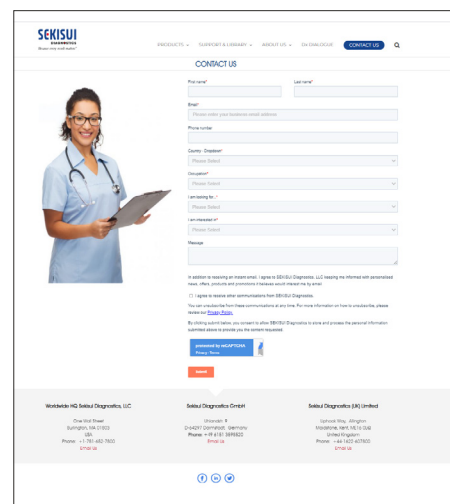
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