ANITGEN TESTING: HOW RAPID RESULTS IMPROVE OUTCOMES

Expanding the Role of Rapid Antigen at Point of Care

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Disclosures

- Advisory Board for Safeguard Biosciences
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Point of Care Testing (POCT) or (POC)

POINT OF CARE = NEAR PATIENT = BESIDE

Is diagnostic testing that is performed near the patient where care is being provided (but typically, outside of a laboratory setting).

Influence timely clinical management decisions

Improve treatment outcomes

Improve patient outcomes

Examples of Point of Care Tests

Vitals/ Measurements

- Oxygen saturation
- Peak flow meters

Urine

- Pregnancy
- Urinalysis

Blood

- Glucose
- Hemoglobin/INR

Respiratory Secretions

- Group A strep
- Respiratory viruses

Stool

- C diff toxin

POCT

Benefits

- Allows providers to make data-based decisions at the POC
- Empowers patients to collaborate in their care and monitor health conditions
- Generally, POCT is a less expensive patient cost for laboratory data
- Provides an option for easier access to repeat testing
- Provides information to prevent spread of infectious agents in home, school and work environments

Disadvantages

- Generally, not as accurate as laboratory-based testing
- Requires education on the use and interpretation of the test’s results
- Requires staffing to perform testing and record results
- May lead to additional out of pocket costs for some patients

Common Methods Used for Respiratory Virus Testing

	LABORATORY (MOLECULAR)	POCT (ANTIGEN)
Common Names	NAAT (PCR, TMA, LAMP, Crisper)	Lateral flow, single molecule
Targets	Genetic material of the virus either DNA or RNA	Protein either secreted and/or structural components of the virus
Processing time	45 minutes to four hours	15 to 30 minutes
Time to result	2 hours to 48 hours	Immediate upon completion
Sensitivity	Highly sensitive (Gold Standard)	Sensitive in the presence of symptoms but should consider repeating (?)
Window of detection	Usually within a day or two prior to symptoms and for some viruses viral shedding can persist	Most sensitive during periods of high viral replication (symptoms)

Speed to Respiratory Virus Detection is Critical

The faster you can detect an infectious virus POC testing, the sooner you can:

Initiate treatment(s), if appropriate

- Avoiding unnecessary medications/side effects
- Reducing needs for additional testing

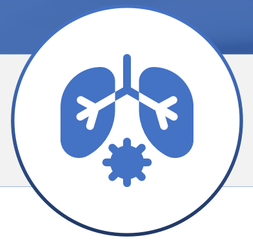
Inform the patient at the point of care

- Reducing potential additional interactions regarding results
- Initiating education about the infection

Limit spread to others

- Initiate appropriate public health precautions
- Alert recent contacts of the individual: household, work, school
- Alert public health officials, if required
- Consider prophylactic treatment of close personal contacts

Comparison of the Advantages of Respiratory Virus Testing Methods



Laboratory Based (Molecular)

- **High sensitivity**
  Higher negative predictive value
- **Detects virus at earlier time frame in replication/lowest levels**
- **Does not require repeated measures**
  Unless being used to look for clearance during treatment
- **Can be automated and highly multiplexed**

Point of Care (Antigen)

- **Highly specific**
  Great to “rule in” infectious agent
- **Positive during high levels of target protein production/high levels of virus replication**
  Infectious period”
- **Rapid assay performance supports quick provider decision**
  Ideal for infection control

Symptoms of Respiratory Virus Infection

SarS-Cov-2

- Cough
- Fever or chills
- Shortness of breath
- Fatigue
- Muscle or body aches
- Loss of taste and or smell
- Sore throat
- GI distress
- Headache

Influenza A&B

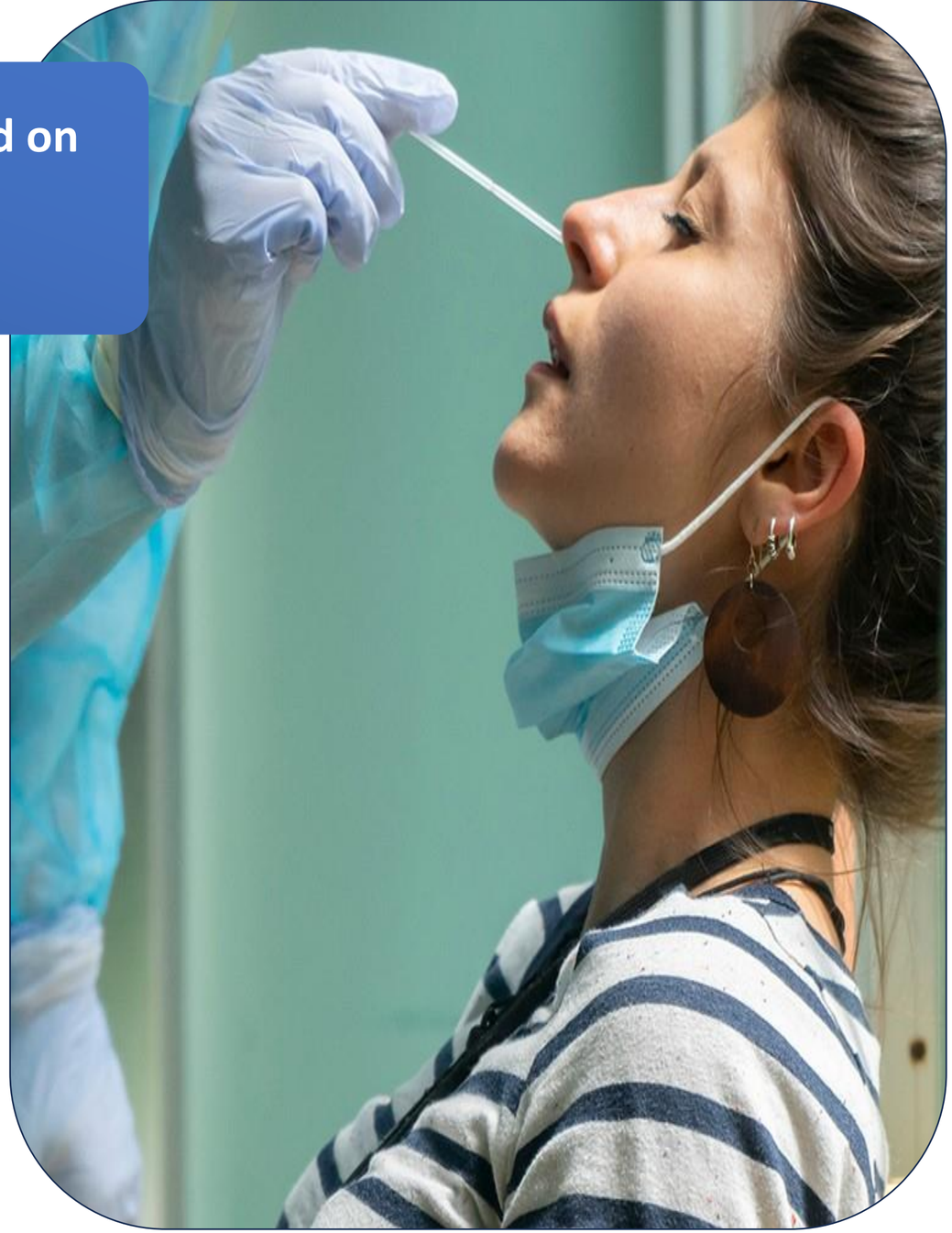
- Cough
- Whole body fever or chills
- Shortness of breath
- Fatigue
- Muscle or body aches
- Congestion
- Sore throat
- GI distress
- Headache

RSV

- Cough
- Fever
- Shortness of breath
- Sneezing
- Nasal discharge
- Wheezing
- Apnea
- Cyanosis
- Bronchiolitis

Diagnosis of Respiratory Virus Infection Based on a Patients Clinical Symptoms is Challenging

- The overlap of presenting symptoms listed for the four most frequently circulating viruses make clinical symptom diagnosis challenging.
- In addition, several other respiratory viruses can also present with clinical symptoms which mimic the four most common respiratory viruses.
- The need to specifically identify the causative virus is necessary as the agents used to treat each virus are virus-specific.
- The definitive diagnosis can be completed by either rapid antigen testing or a NAAT (Nucleic Acid Amplification Test).



Strategies to Increase the Pretest Probability of Antigen Testing

Use the CDC Influenza-like-illness (ILI) reporting information.

- The CDC uses weekly physician office-based reporting on ILI.
- It also includes laboratory-based testing to identify which viruses are currently circulating.
- The website also tracks ED visits based on viral activity.

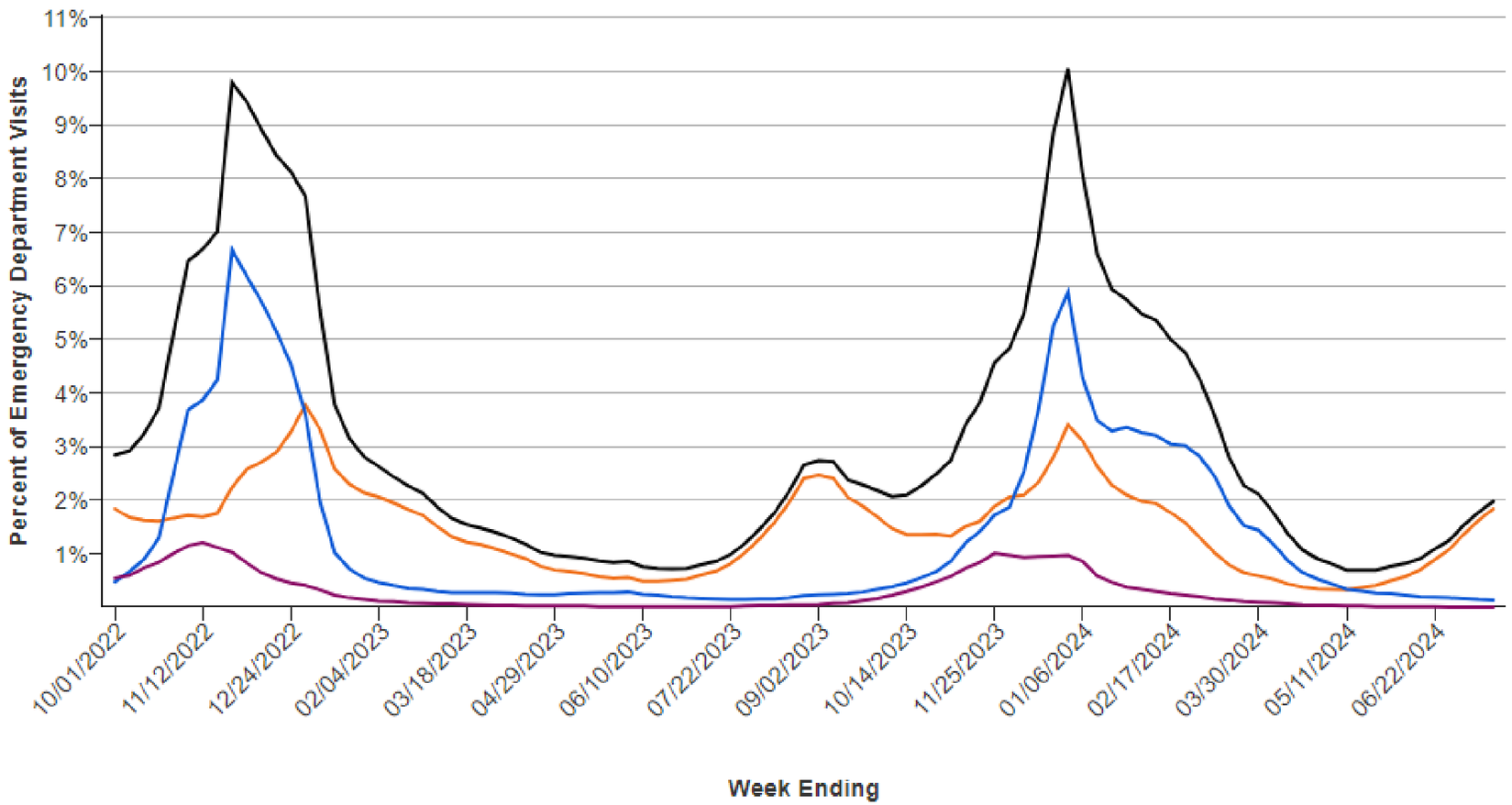
Use local or regional lab web-based reports and/or weekly e-mails.

- Hospital or labs have web-based reports of weekly virus activity.
- Hospitals or labs provide weekly emails summarizing virus activity.

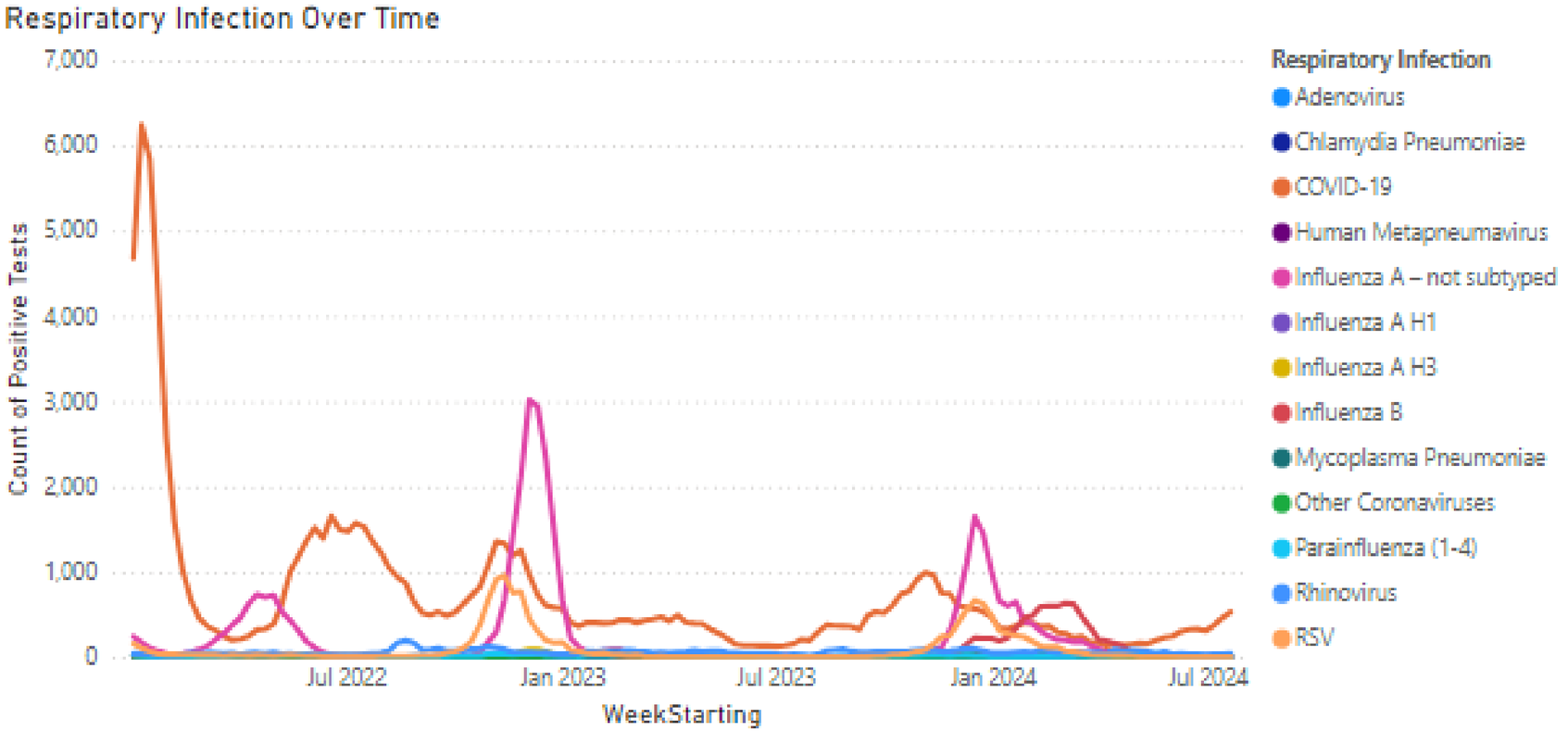
Use reporting platforms from diagnostic companies.

- Several diagnostic companies have web-based weekly virus reports which show the virus activity of each laboratory using a vendor’s test.

Percentage of ED Visits Based on Virus Activity



Respiratory Virus Activity Over Time (Tricore)



Respiratory Virus Activity by Age (Tricore)

3.51%

13-18 years old

0%

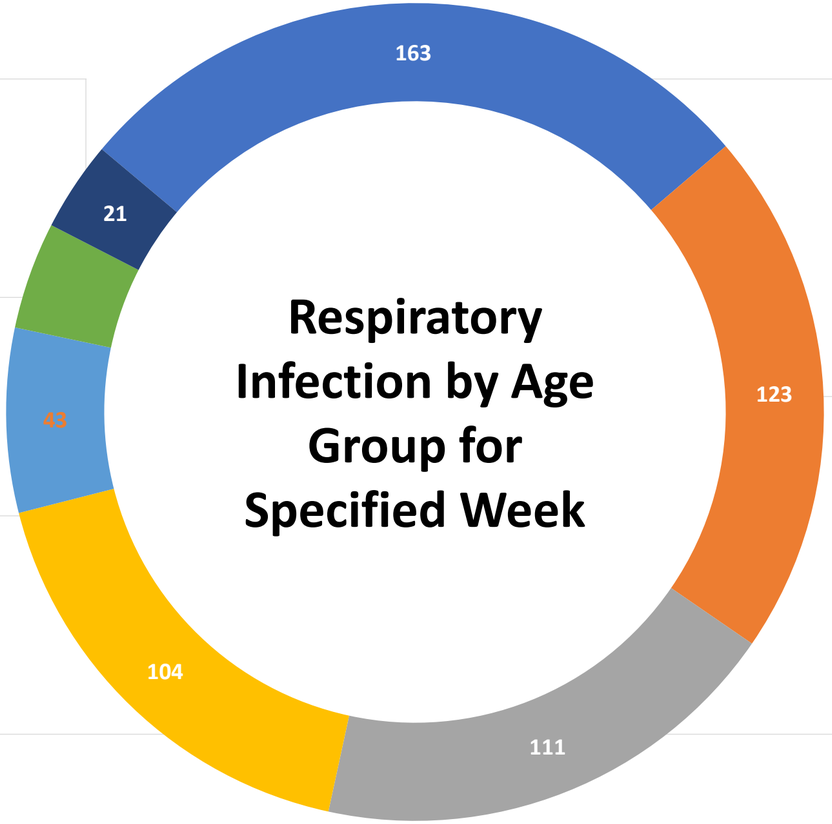
6-12 years old

7.19%

19-25 years old

17%

0-5 years old



27.26%

65 years and older

20.57%

26-45 years old

18.56%

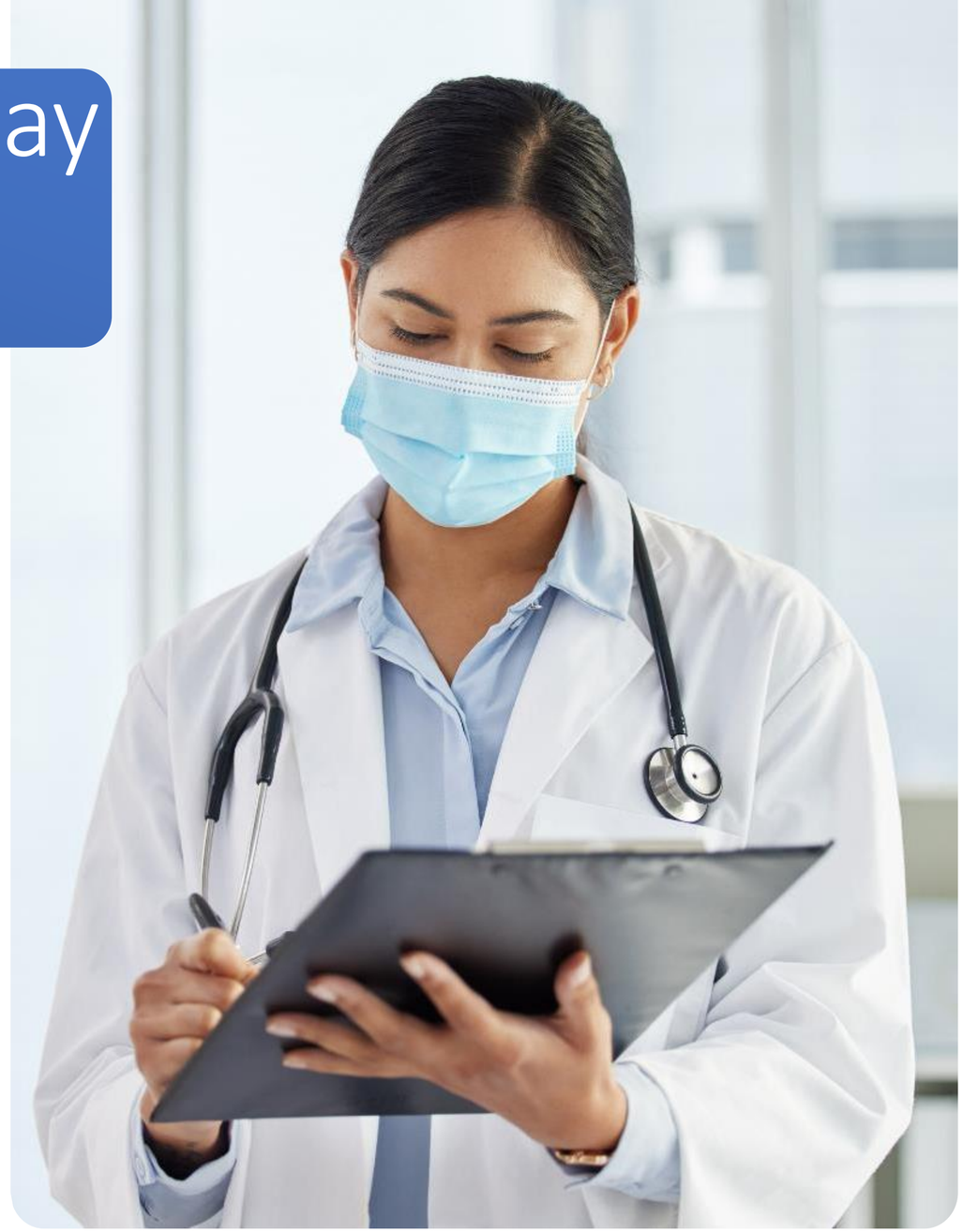
40-65 years old

Weekly Infectious Disease Report (Tricore)

Week Starting on: 7/21/2024			
Respiratory Infection	**Total Results**	**Total Positives**	**Two Week Trend**
COVID-19	2877	532	*
Adenovirus	244	9	—
Chlamydia Pneumoniae	244	0	—
Human Metapneumavirus	244	1	—
Influenza A – not subtyped	2445	2	—
Influenza A H1	453	0	—
Influenza A H3	244	0	—
Influenza B	2445	1	—
Mycoplasma Pneumoniae	244	5	—
Other Coronaviruses	244	3	—
Parainfluenza (1-4)	976	5	—
Rhinovirus	244	40	—
RSV	723	1	—

Using Frequency Data May Help Streamline Testing

- Can you use a single-analyte antigen test?
- Can you use a multiplex antigen assay?
- Does this fit into your organizational POC testing scheme?
- How does reimbursement effect the organization and patient coverage?



Multi-analyte Tests for Respiratory Disease

What is it?

Multi-analyte tests can simultaneously detect and differentiate between multiple pathogens known to cause respiratory symptoms from one patient specimen.

Potential Benefits

- Workflow efficiency (1 sample, 1 test, 3 actionable results)
- Increased diagnostic confidence
- Guided prescribing (decreased risk of inappropriate abx use)
- Ability to detect coinfections
- Increased patient convenience
- Conservation of healthcare resources and supplies (PPE, reagents, etc.)

How will you Read the Virus Antigen Testing at POC?

Will You Use Manual Reading/Reporting?

- Subjective, visual line-interpretation by the operator.
- Manual recording of results.
- If you don’t record the result, it is no longer available if the device is discarded.
- No instrumentation required.

Will You Use an Analyzer or Reader to Determine Results?

- Objective, results are digitally-interpreted and +/- results for each target are displayed on a screen.
- Results can be maintained in the instrument.
- The results can also be stored on routine storage devices.
- Results can be transferred to HIS or EMR depending on how data is captured.