

# MINI GRAND ROUNDS

## Right Test, Right Patient, Right Time: Choosing Wisely When Ordering SARS/COV2 and Flu A/B Tests

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# Test Utilization and Choosing Wisely



*An initiative of the ABIM Foundation*

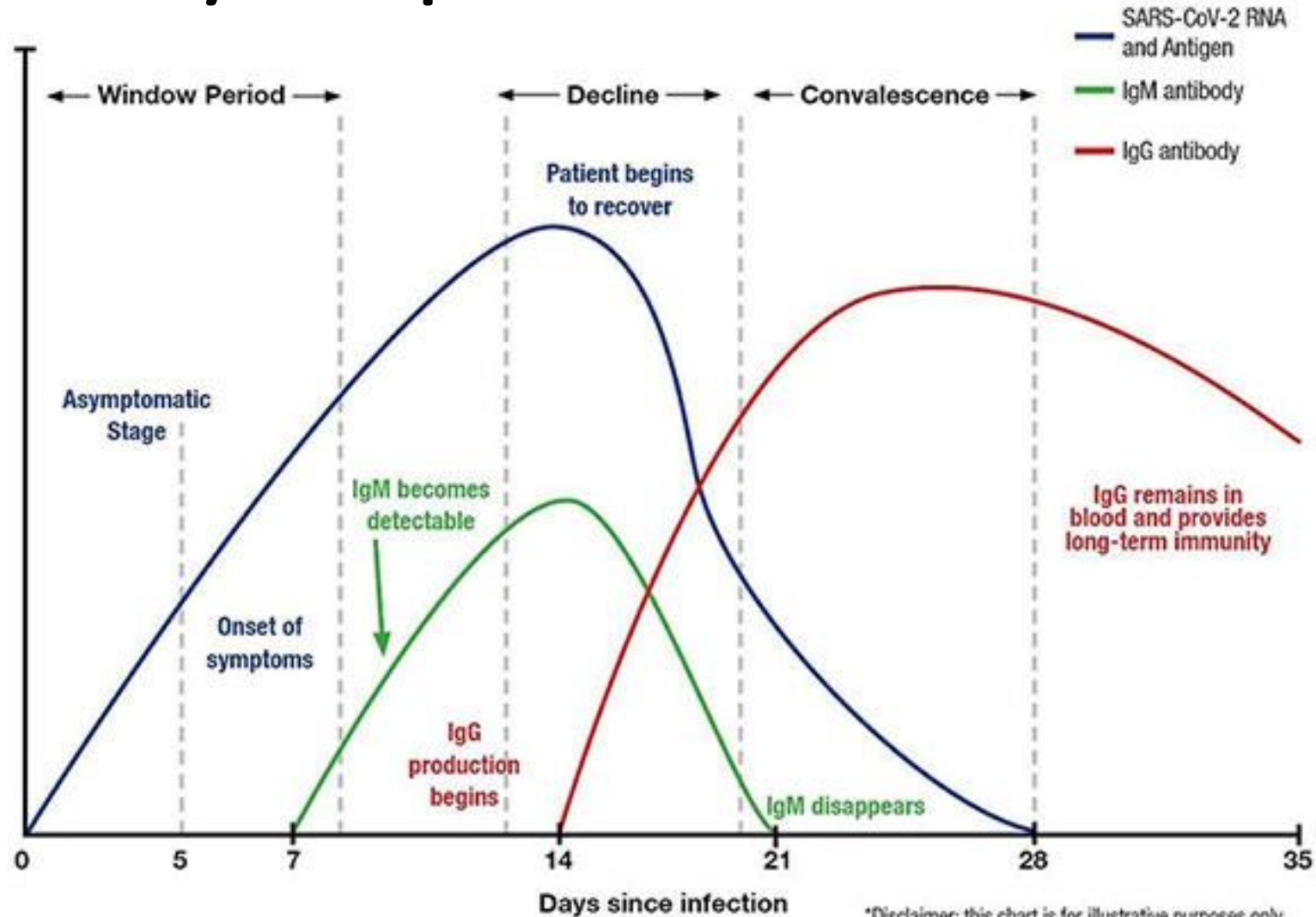
*Choosing Wisely* is an initiative of the ABIM Foundation that seeks to advance a national dialogue on avoiding unnecessary medical tests, treatments and procedures.

During this time of great stress, *Choosing Wisely* is providing information from partners about appropriate tests and treatments that are relevant to addressing the impact of the COVID-19 outbreak on the health care system

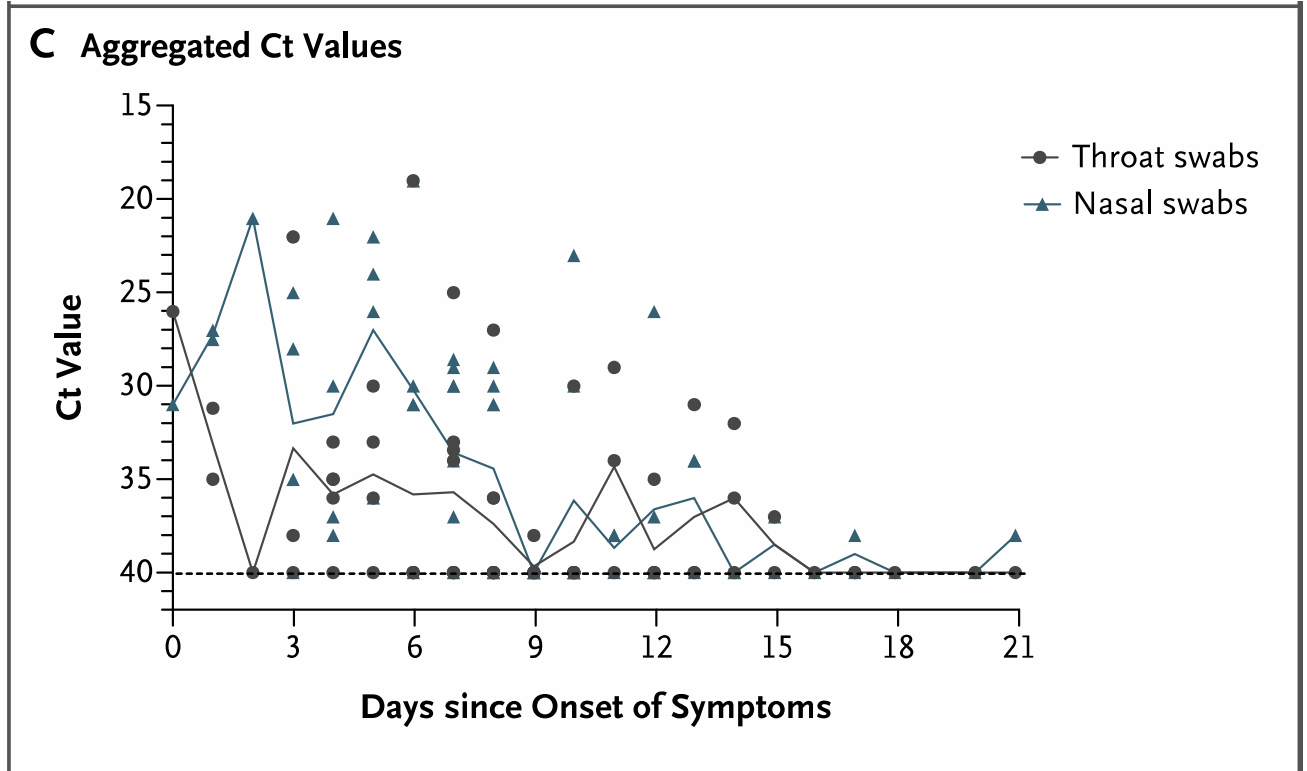
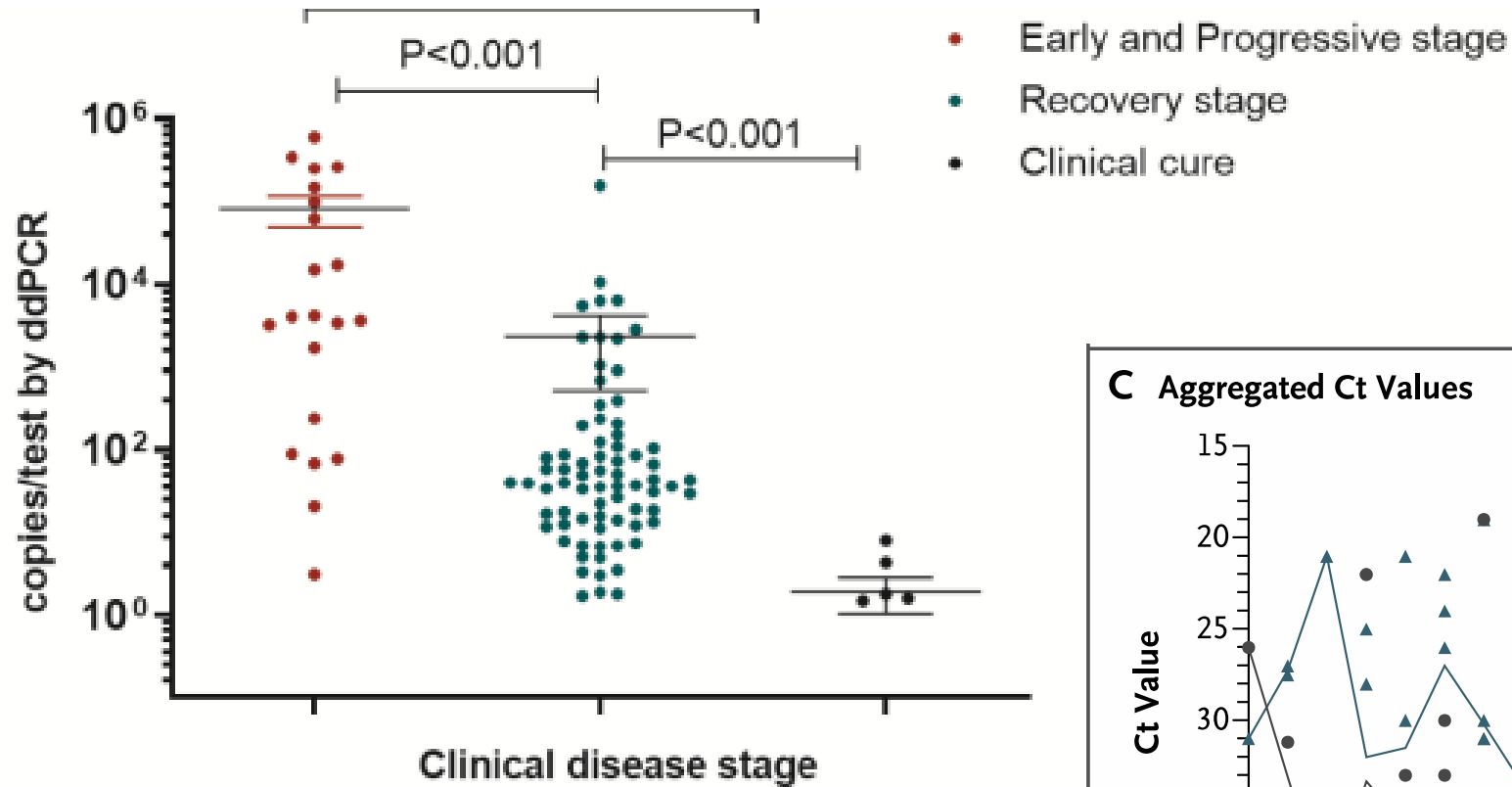
<https://www.choosingwisely.org/>

***Right Test, Right Patient, Right Time***

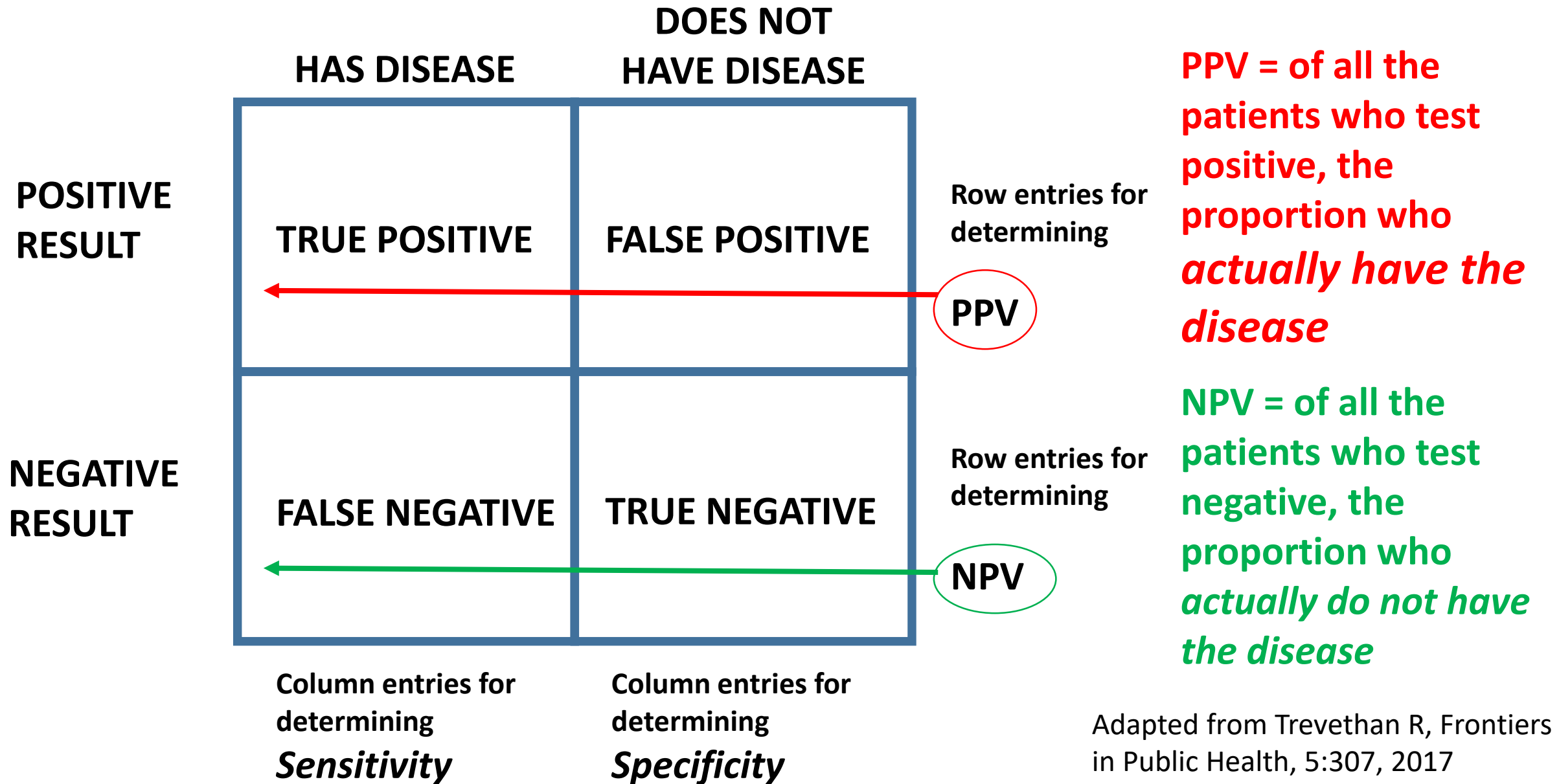
# Time Course for SARS-CoV-2 RNA/Antigen, and Antibody Responses



# Viral Copy Number & Disease Stage – COVID-19



# Positive & Negative Predictive Values



# The Power of Prevalence

## A Great Test

Sensitivity	0.990
Specificity	0.990
Prevalence	0.010
Positive Predictive Value	0.500
Negative Predictive Value	1.000

## A Crummy Test

Sensitivity	0.700
Specificity	0.700
Prevalence	0.010
Positive Predictive Value	0.023
Negative Predictive Value	0.996

# SARS/COV-2 Test Performance

## PCR (symptomatic case or exposure)

Sensitivity	0.950
Specificity	0.950
Prevalence	0.200
PPV	0.826
NPV	0.987

## IDNow (Low risk screening)

Sensitivity	0.750
Specificity	0.950
Prevalence	0.02
PPV	0.234
NPV	0.995

# SARS-CoV-2 & Flu A/B Tests Available at KHL

Platform	Analyte	Sensitivity	TAT (on machine)	Testing near Care Site	Batch vs Discrete Test
Abbott m2000	SARS/COV-2 nucleic acid	High	7 hr	No	Batch
Hologic Panther	SARS/COV-2 nucleic acid	High	4 hr	No	Batch
DiaSorin	SARS/COV2 nucleic acid	High	2 hr	No	Small batch
Perkin Elmer	SARS/COV2 nucleic acid	High	6 hr	No	Batch
Abbott ID NOW	SARS/COV2 nucleic acid	Intermediate	20 min	Yes	Discrete
Hologic Fusion	FLU A/B nucleic acid (included in a 10 analyte respiratory virus panel)	High	6 hr	No	Batch
BD Veritor Flu A/B and RSV	Flu A/B and RSV antigen	Low	15 min	Yes	Discrete



# SARS-CoV-2 & Flu A/B Tests Coming Soon (KHL)

Platform	Analyte	Sensitivity	TAT ( on machine)	Testing near Care Site	Batch vs Discrete Test
ThermoFisher	SARS/COV-2 nucleic acid	High	3 hr	No	Batch
ThermoFisher	SARS/COV-2 Flu A/B nucleic acid	High	3 hr	No	Batch
Cepheid	SARS/COV-2 Flu A/B RSV nucleic acid	High	45 min	Yes	Discrete or small batch
BD Veritor	SARS/COV-2 antigen	Low	20 min	Yes	Discrete
Abbott BinaxNOW	SARS/COV-2 antigen	Low	10 min	Yes	Discrete

# The Four Vectors of Choosing a Test Wisely

- ✓ **What is the Clinical Estimate of a Positive Test Result ?**
- ✓ **How Quickly is the Result Needed to Support Decision Making ?**
- ✓ **What Level of Analytic Test Sensitivity and Specificity is Needed ?**
- ✓ **What is the Laboratory Capacity to do the Test ?**

**Clinical Estimation  
of Risk**

**TAT  
Total**

**Analytic  
Sensitivity**

**Analytic  
Specificity**

**Capacity**

**HIGH  
RISK  
vs  
LOW  
RISK**

**<1  
hr**

**2-8  
hr**

**8-24  
hr**

**24-48  
hr**

**5  
days**

**HIGH**

**LOW**

**HIGH**

**LOW**

**VERY  
LIMITED**

**SOMEWHAT  
LIMITED**

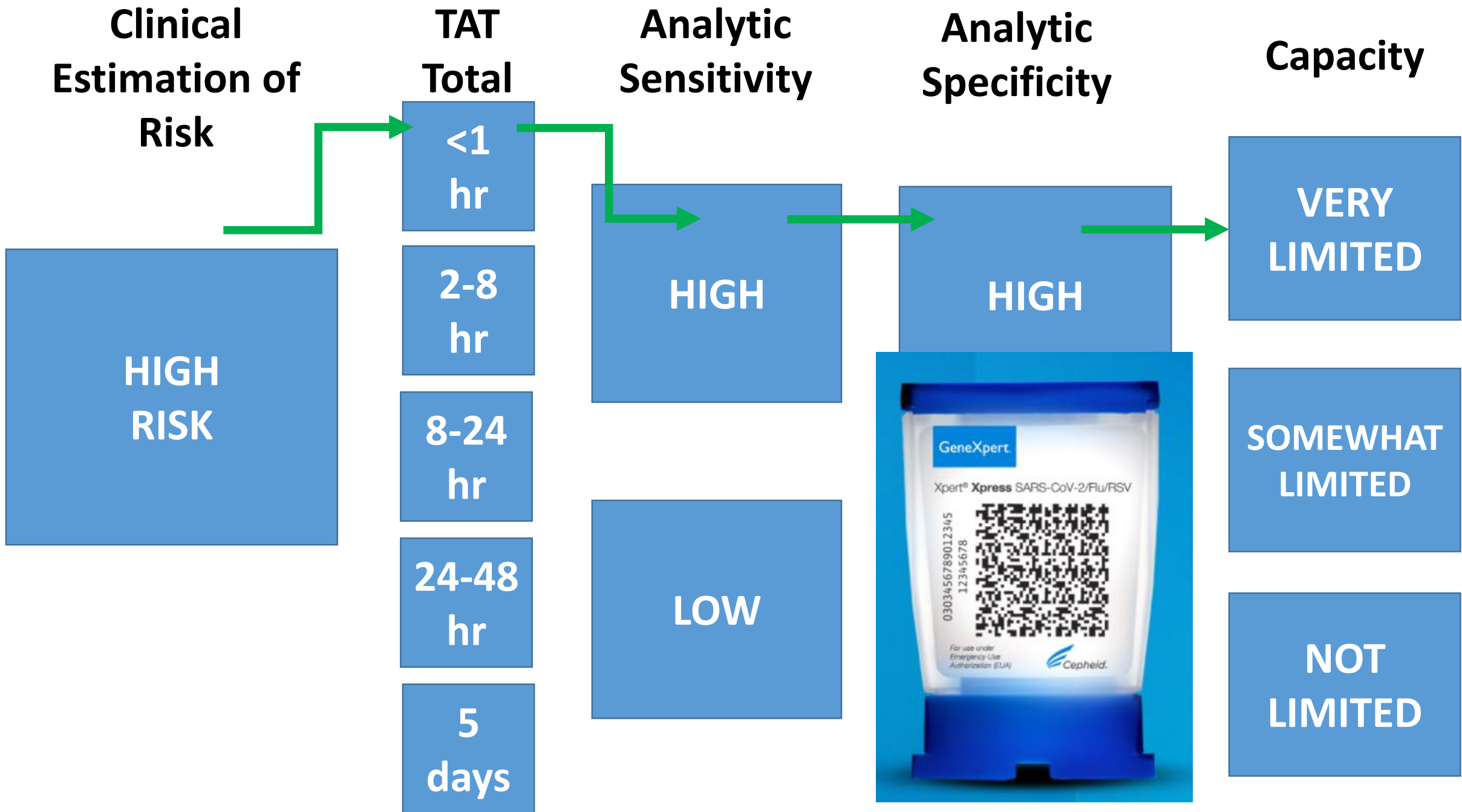
**NOT  
LIMITED**

# Analytic Targets of Tests

- Viral Nucleic Acids
- Viral Antigens
- Antibody Responses to Virus

# Case Vignette #1

- A 59 yo woman with DM and CAD is admitted to the hospital with fever, myalgias, dyspnea and non-productive cough x 3 days
- She appears ill, is tachypneic and has T=102° F.
- SpO2 = 94% on RA.
- Routine lab work is unremarkable.
- CXR reveals scattered interstitial infiltrates.
- Viral respiratory illness ?



# Co-Circulation of SARS-CoV-2 & Influenza A/B

	2020 Season	SARS-CoV-2	FLU A/B
Phase 1	Early Winter	Absent	Seasonal Prevalence
Phase 2	Late Winter-Early Spring	High Prevalence	“Reduced Seasonal Prevalence”
Phase 3	Summer	Low Prevalence	Low Prevalence
Phase 4 ( expected)	Late Fall-Early Winter	Increasing Prevalence	Increasing Prevalence

# Clinical Response to Rapid Cepheid Results

Clinical Estimation for Risk of Active Infection	Cepheid Result	Clinical Response to Test Result
LOW	NEGATIVE	ACCEPT as NEGATIVE
SIGNIFICANT	NEGATIVE	ACCEPT as NEGATIVE
LOW	POSITIVE	ACCEPT as POSITIVE
SIGNIFICANT	POSITIVE	ACCEPT as POSITIVE



# Case Vignette #2

- A 59 yo man with DM & CAD presents with severe substernal chest pain and diaphoresis. There is no travel history or contact with known COVID–19 cases.
- He is afebrile and lung exam is normal.
- Routine labs are unremarkable except for elevated troponin.
- CXR reveals no infiltrates.
- Urgent PCI is planned.
- Clear for procedure?

## Clinical Estimation of Risk

## TAT Total

## Analytic Sensitivity

## Analytic Specificity

## Capacity

LOW  
RISK

<1  
hr

2-8  
hr

8-24  
hr

24-48  
hr

5  
days

HIGH

LOW

HIGH

LOW

VERY  
LIMITED

SOMEWHAT  
LIMITED



# Clinical Response to Rapid IDNow Results

Clinical Estimation for Risk of Active Infection	IDNow Result	Clinical Response to Test Result
LOW	NEGATIVE	ACCEPT as NEGATIVE
SIGNIFICANT	NEGATIVE	ORDER REFLEX PCR
LOW	POSITIVE	ORDER REFLEX PCR
SIGNIFICANT	POSITIVE	ACCEPT as POSITIVE (if something does not fit consider confirmatory PCR)



Does the individual tested have  
symptoms consistent with COVID-19?

**SYMPTOMATIC**

ID NOW COVID-19 Assay

**POSITIVE**

No confirmatory  
test needed.

Isolate and  
initiate contact  
tracing.

**PRESUMPTIVE NEGATIVE**

Perform confirmatory test  
immediately with a laboratory-based  
molecular test for SARS-CoV-2 and  
test for other respiratory pathogens.

Quarantine until results of  
confirmatory test available.

**LAB TEST POSITIVE**

Continue isolation and  
contact tracing.

**LAB TEST NEGATIVE**

Discontinue quarantine.

October 2020

October 2020

**ASYMPTOMATIC  
ASSOCIATED WITH A  
CONGREGATE SETTING**

ID NOW COVID-19 Assay

**POSITIVE**

Perform confirmatory test  
within 48 hours with a  
laboratory-based molecular  
test for SARS-CoV-2.

Quarantine pending  
confirmatory test.

**LAB TEST POSITIVE**

Isolate and initiate  
contact tracing.

**PRESUMPTIVE NEGATIVE**

Negative results should be  
considered in the context of  
an individual's exposures,  
history, and clinical signs  
and symptoms consistent  
with COVID-19.

**LAB TEST NEGATIVE**

Discontinue quarantine.



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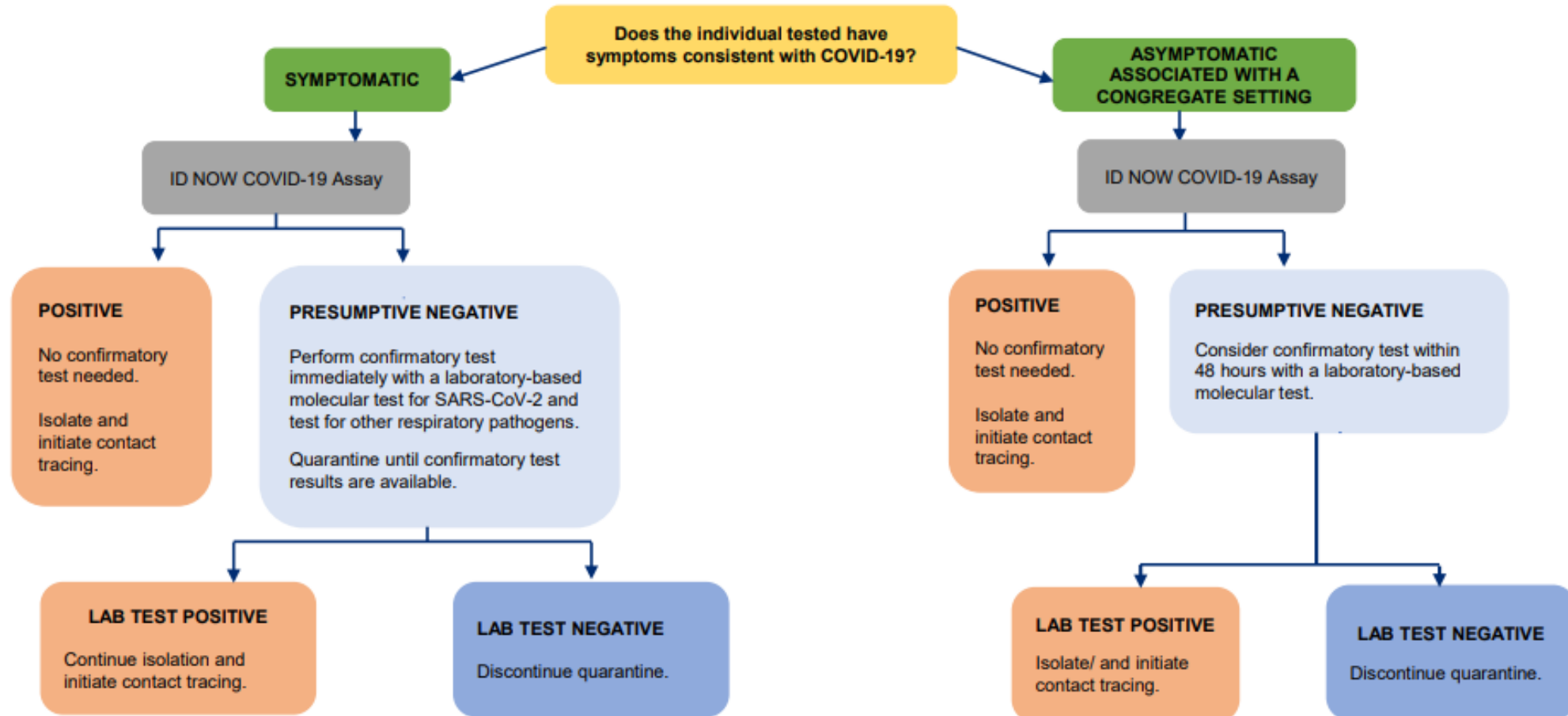


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# ID Now Use – High Prevalence

## ID NOW COVID-19 Assay Testing in an Outbreak/High Prevalence Area

1



# Case Vignette #3

- A 59 yo man with DM and CAD presents with fever, myalgias and non-productive cough x 3 days. He recently returned from visiting family in Lincoln, NE.
- He appears ill and has T=102° F.
- SpO2 = 90% on RA.
- Routine lab work shows leukocytosis.
- CXR reveals scattered infiltrates & CT chest shows peripheral ground glass opacities.

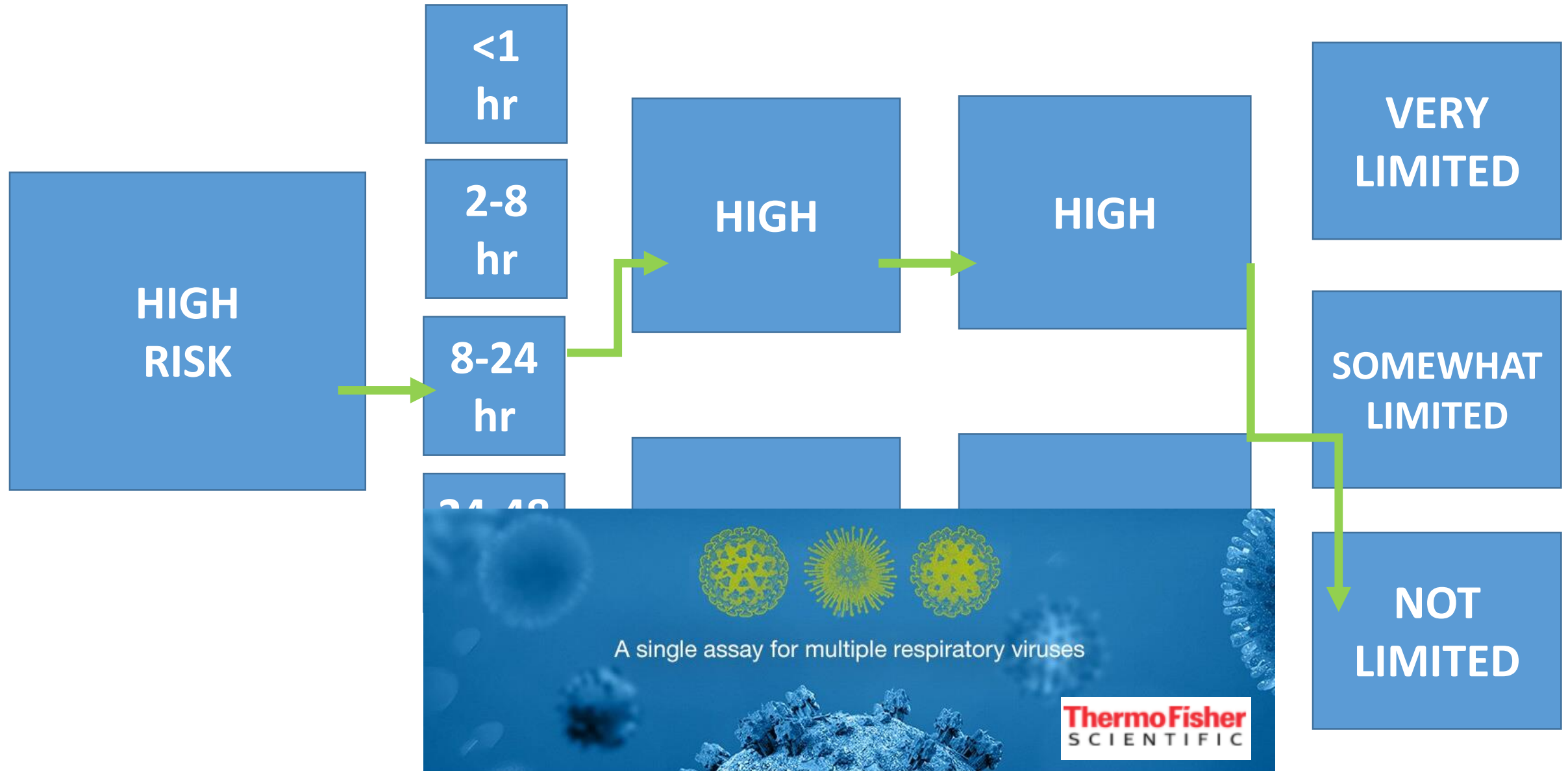
**Clinical Estimation  
of Risk**

**TAT  
Total**

**Analytic  
Sensitivity**

**Analytic  
Specificity**

**Capacity**







# Clinical Response to ThermoFisher Multiplex Results

Clinical Estimation for Risk of Active Infection	ThermoFisher Multiplex SARS-CoV-2/Flu Result	Clinical Response To Test Result
LOW	NEGATIVE	ACCEPT as NEGATIVE
SIGNIFICANT	NEGATIVE	ACCEPT as NEGATIVE
LOW	POSITIVE	ACCEPT as POSITIVE
SIGNIFICANT	POSITIVE	ACCEPT as POSITIVE



# A Quick Guide for COVID-19 Testing

Powerchart Order	Low Risk	High Risk	Lower Sensitivity	Higher Sensitivity	Predictive Value Leveraged
SARS-CoV-2 ID Now Rapid	+++	+/-			 NPV
SARS-CoV-2 PCR	+	+++			 PPV

# Communications on Choosing Respiratory Virus Tests Wisely

- Provider communications by e-mail
- EMR notices from Dr. Levy
- Kaleidoscope postings
- Live presentations
- Educational links at order entry planned
- Decision support logic at order entry planned
- Laboratory Medicine Physicians, Clinical Lab Scientists, and Clinical leadership always available for questions



**THANK YOU !**

