Using Antigen Testing in Long Term Care Facilities

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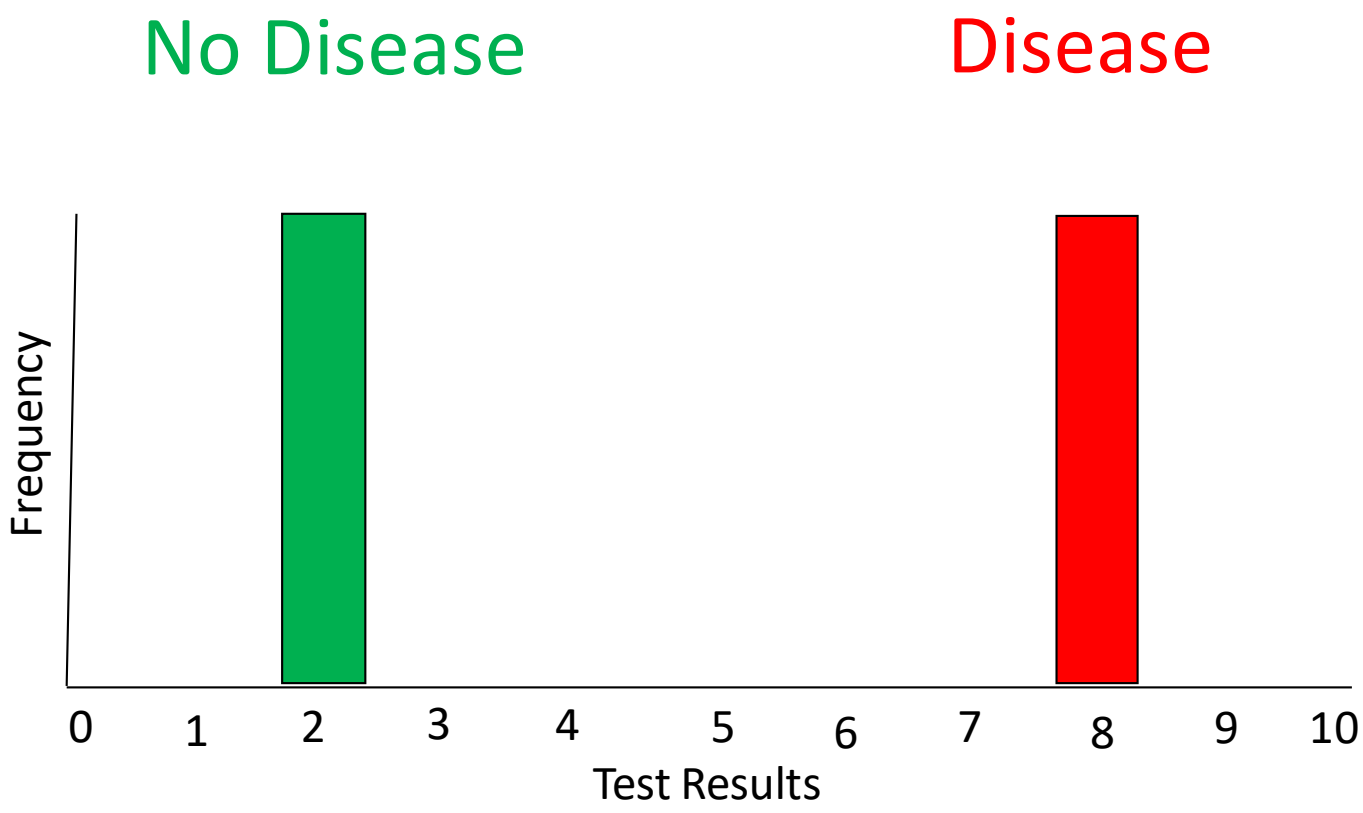
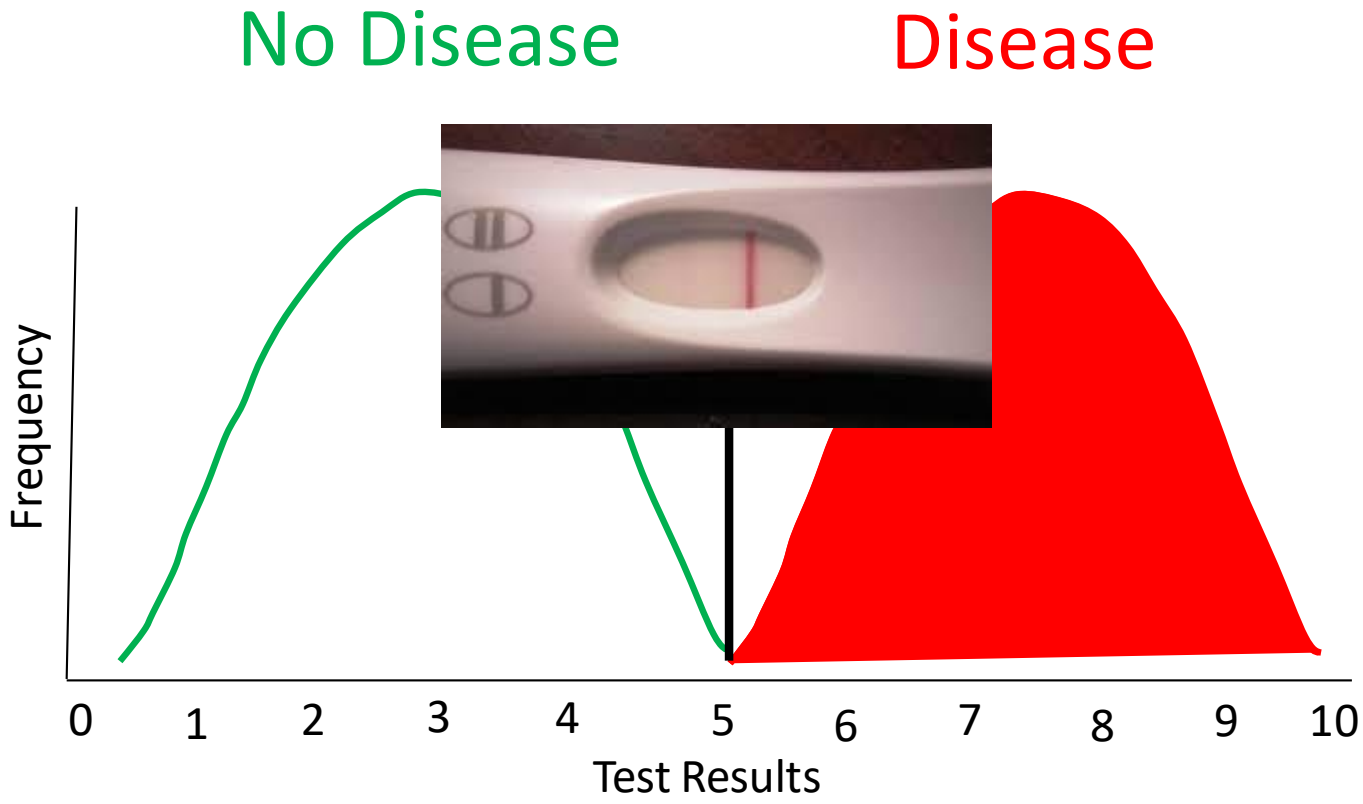
Questions addressed

- What’s the deal with false test results?
- Why should we do confirmatory testing?
- When should I use confirmatory testing?

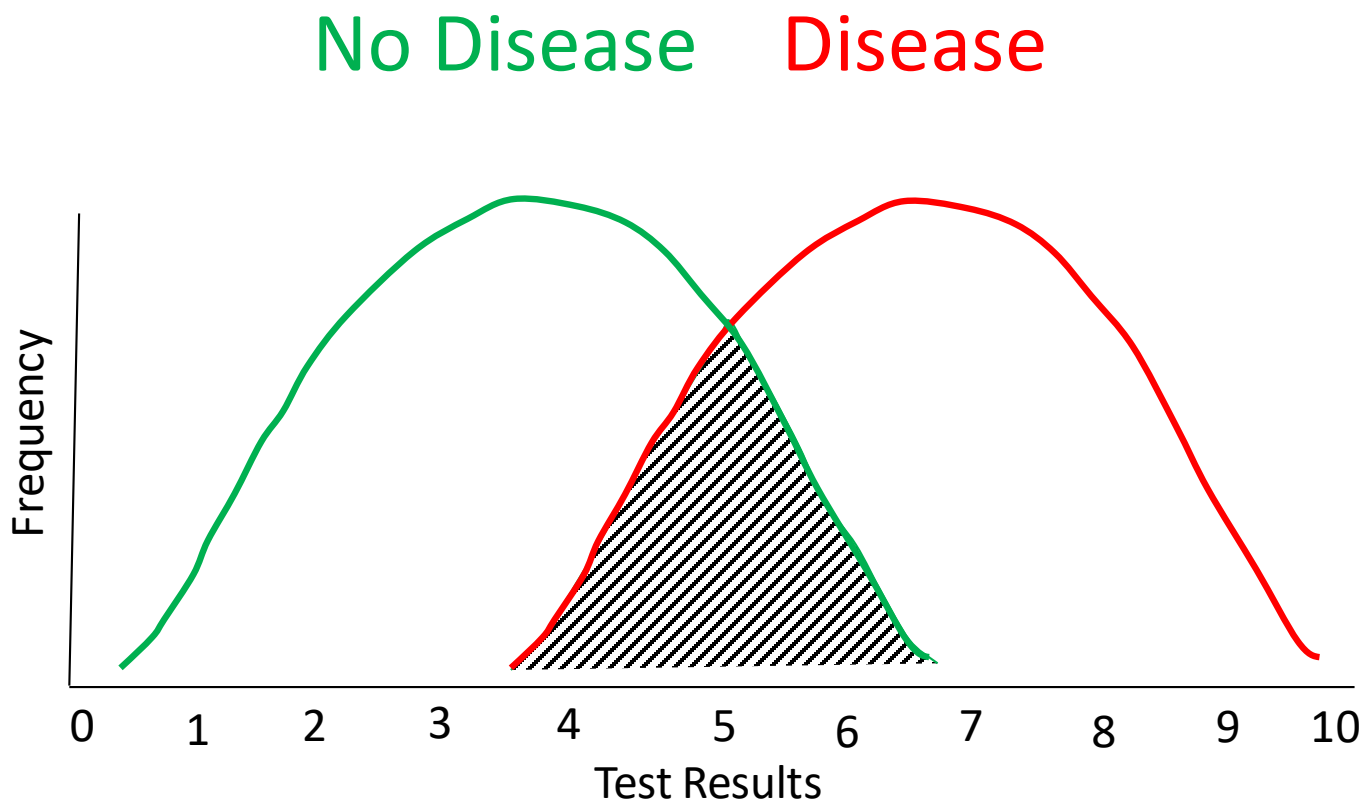
It’s it easy to tell them apart?



Biology Means Diversity



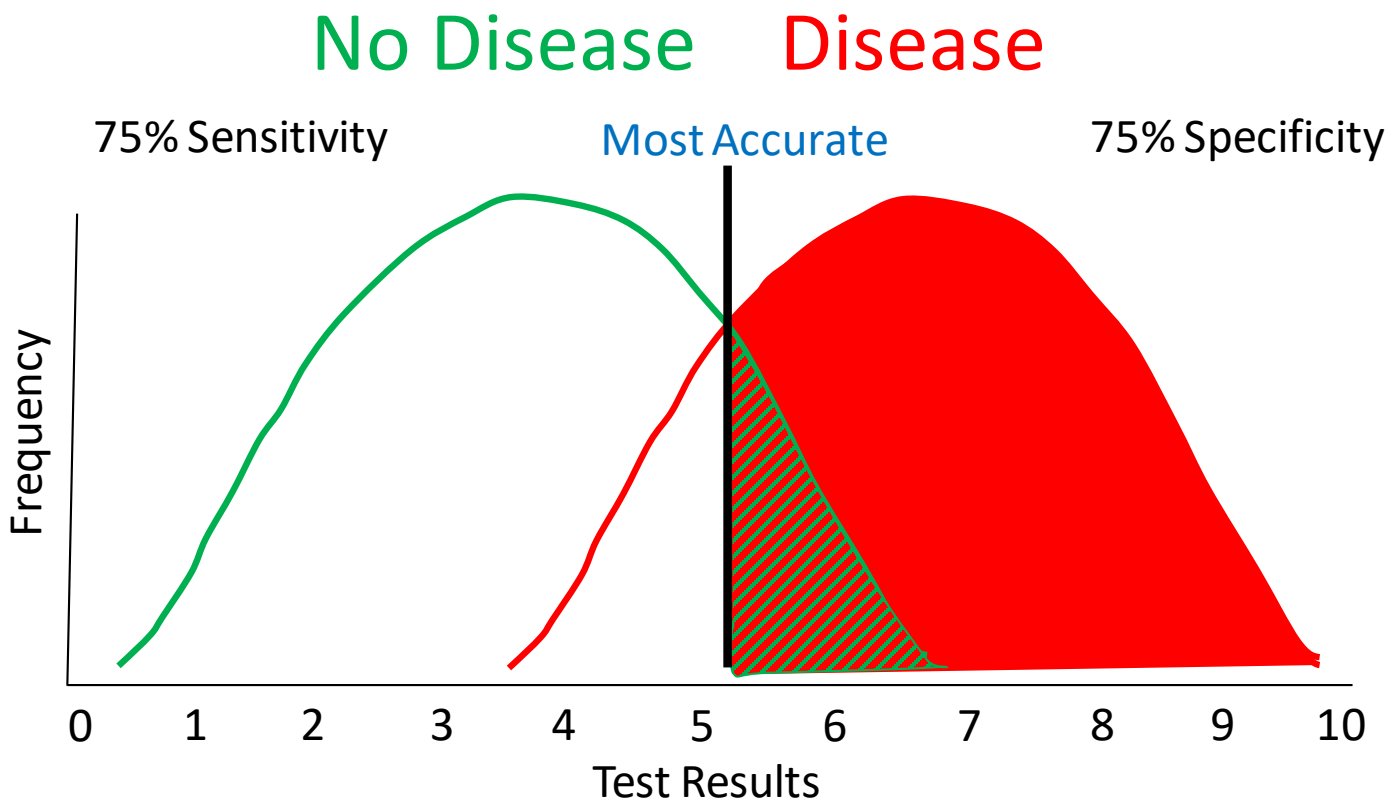
There’s a Gray Zone



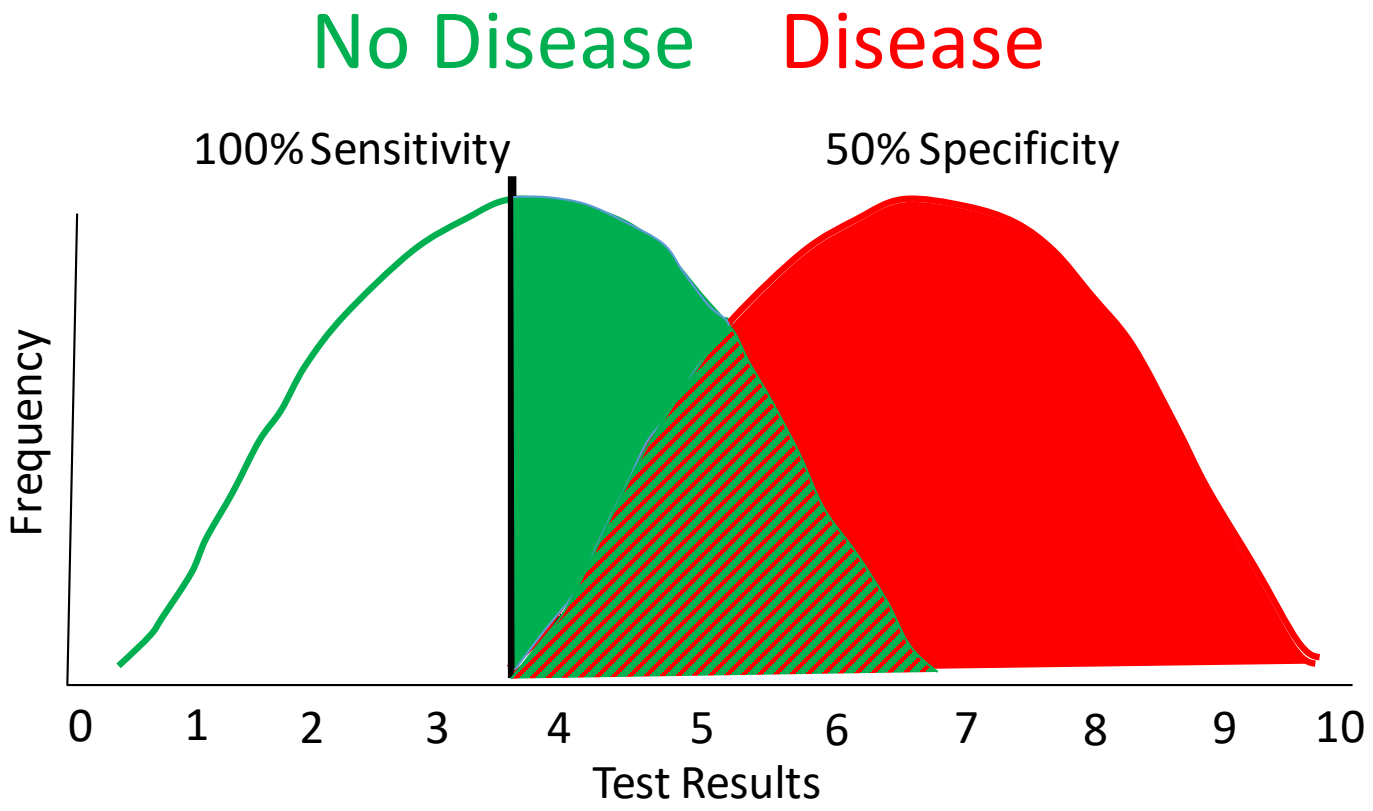
What Causes the Overlap?

- Human error
  - Improper collection
  - Improper transport
  - Mix-up in the lab
  - Contamination
  - Using the test on pets
  - Not following instructions
- Defective testing supplies or broken equipment
- Interfering substances (nose spray, antibiotic gel)
- Error is intrinsic in the test itself

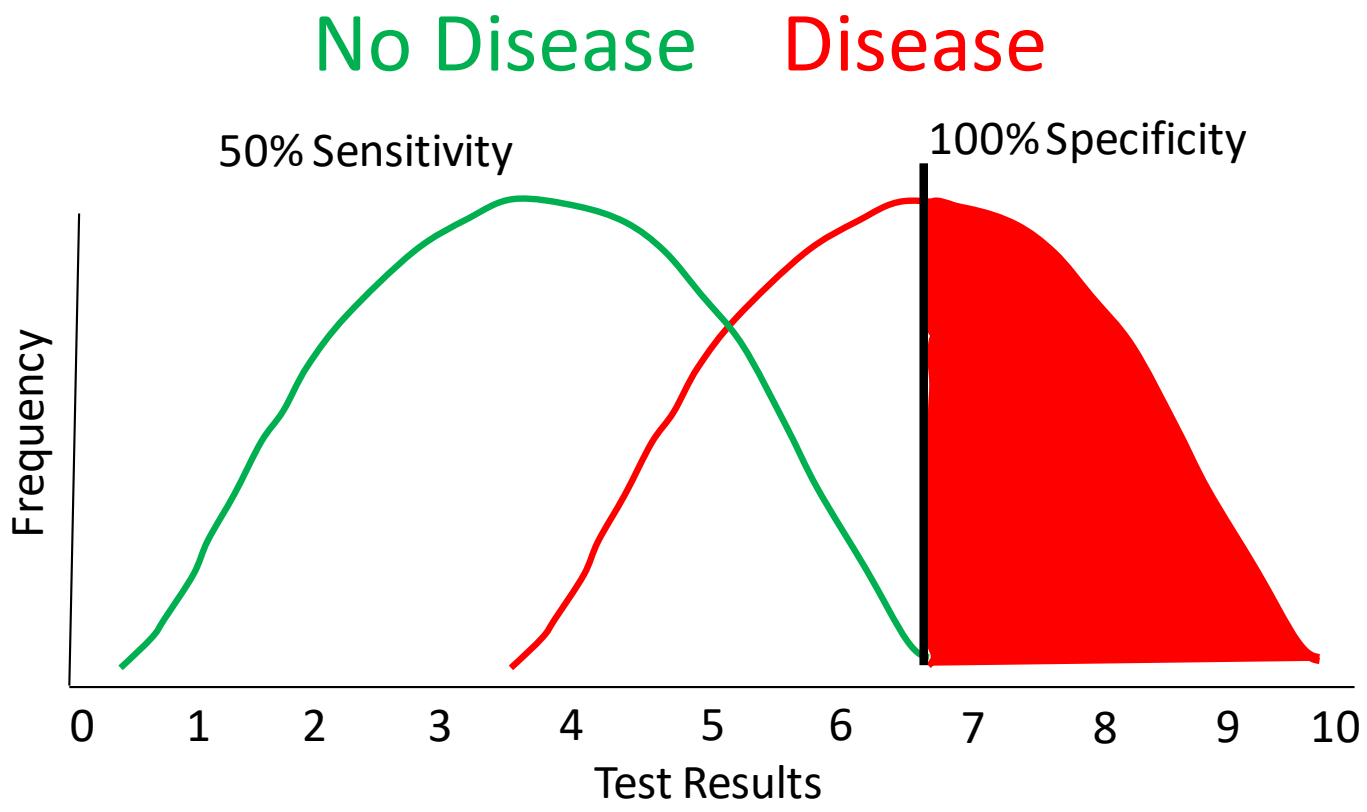
Where's the best place to set the cut-off?



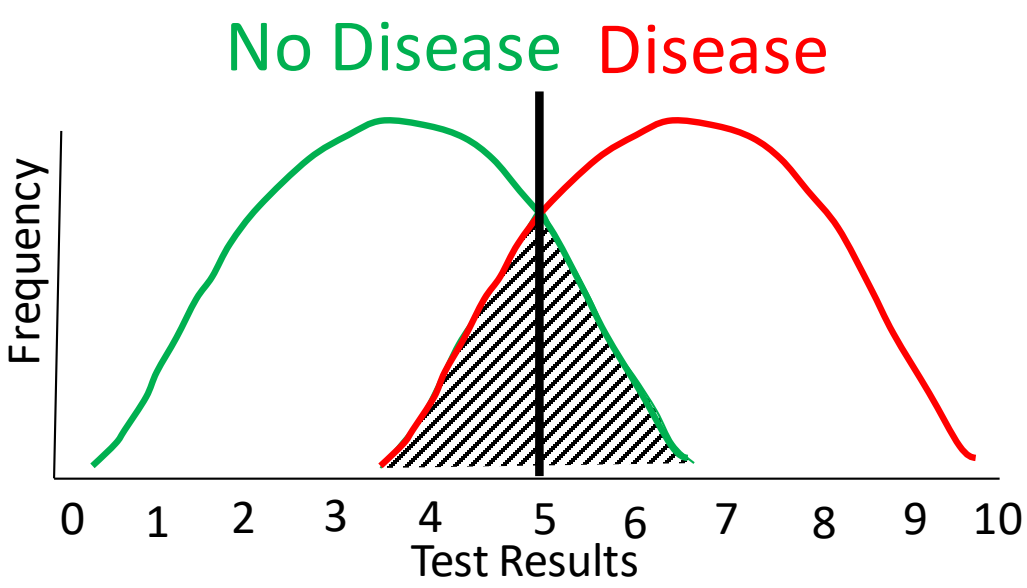
If it’s most important to not miss any positives



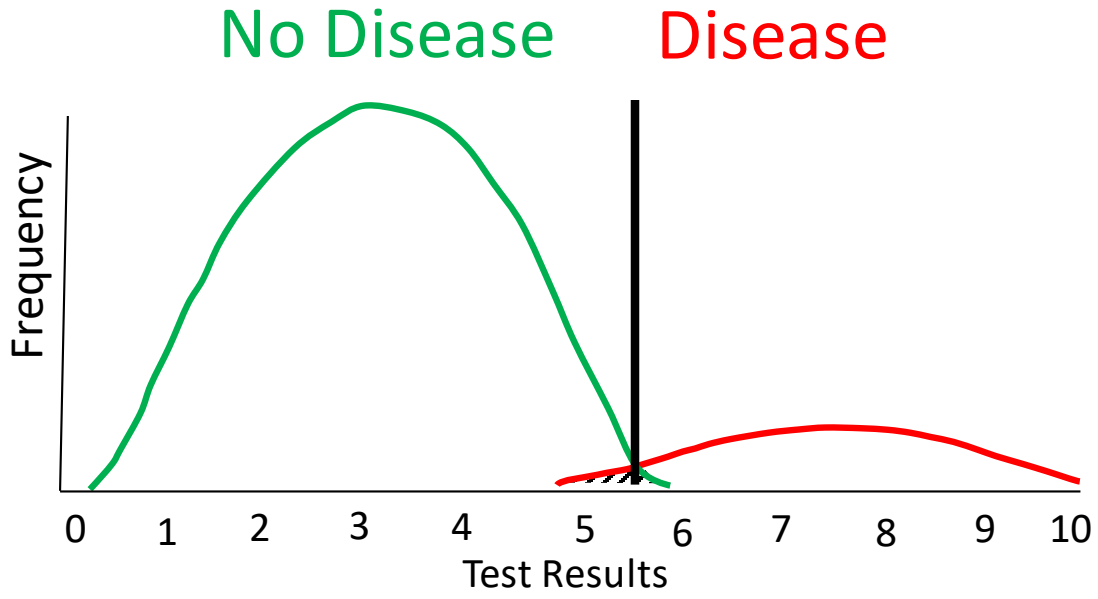
If it’s most important to have no false positives



Comparing Test Accuracy



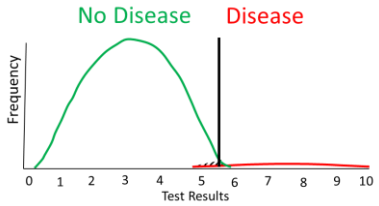
75% Sensitivity, 75% Specificity



96% Sensitivity, 99% Specificity

Let’s Test Everyone in America!

- Antigen tests are sent out across the country for at home testing. All 328 Million American tests themselves **Once**. . .
- Current COVID-19 prevalence of active infections in the US is predicted to be around 1%
- The Antigen test has a sensitivity of 85% and specificity of 97%.



What if we mass test everyone in the US?

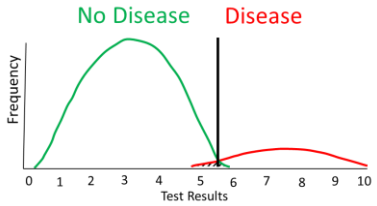
	Patients **with** Disease	Patients **without** Disease	**All Patients**	
Positive Test	2.788	9.74 False positive	12.528	PPV 22.2%
Negative Test	0.492 False negative	314.98	315.03	NPV 99.8%
Total	3.28	324.72	328*	

85% Sensitivity 97% Specificity

1% Prevalence

A test is only as good as the population tested

*numbers in millions



What if we mass test everyone in the US, but there is 10x more disease?

	Patients **with** Disease	Patients **without** Disease	**All Patients**	
				PPV
Positive Test	27.88	8.86 False positive	36.74	76%
				NPV
Negative Test	4.92 False negative	286.34	291.26	98%
Total	32.8	295.2	328*	

85% Sensitivity 97% Specificity

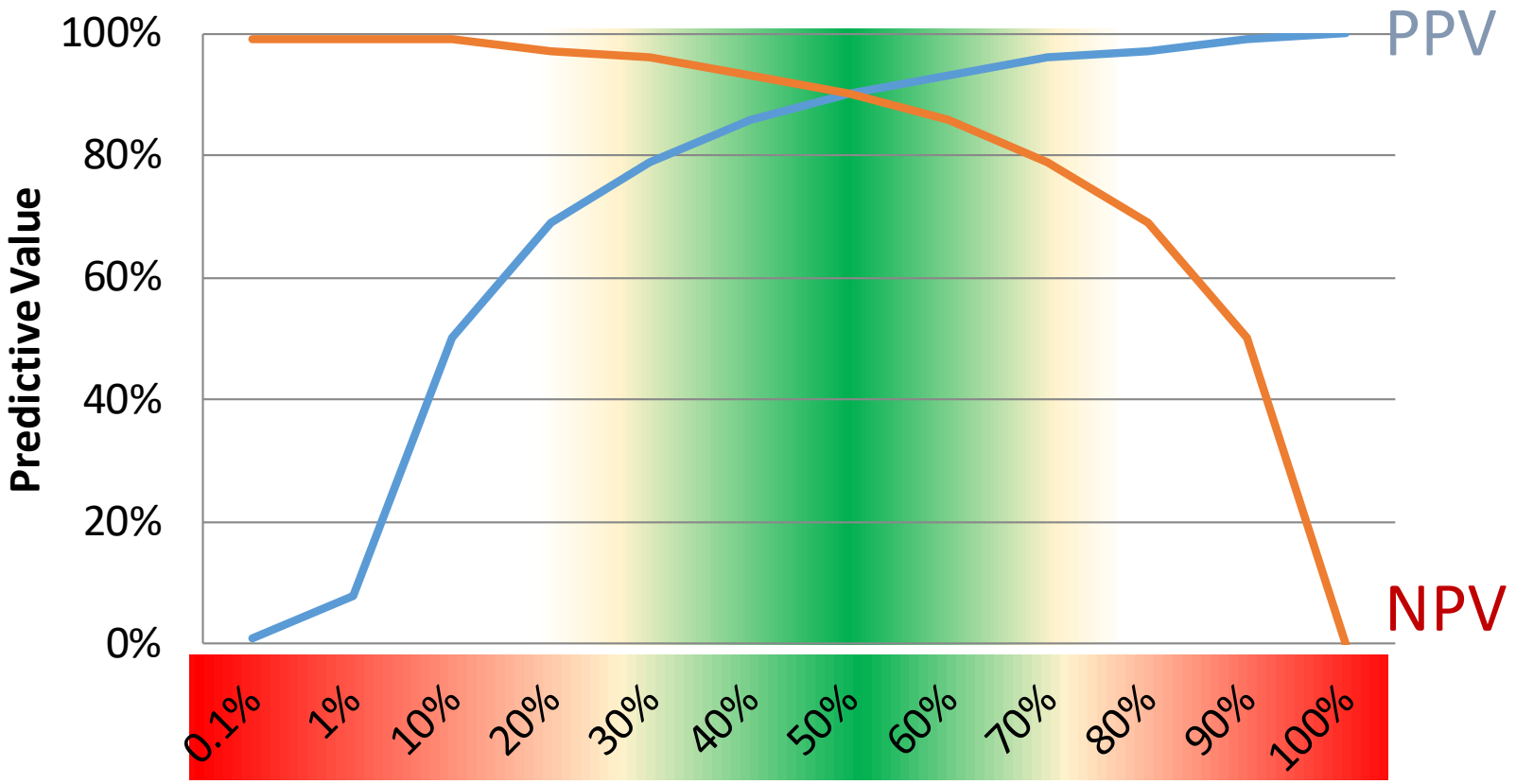
10% Prevalence

A test is only as good as the population tested

*numbers in millions

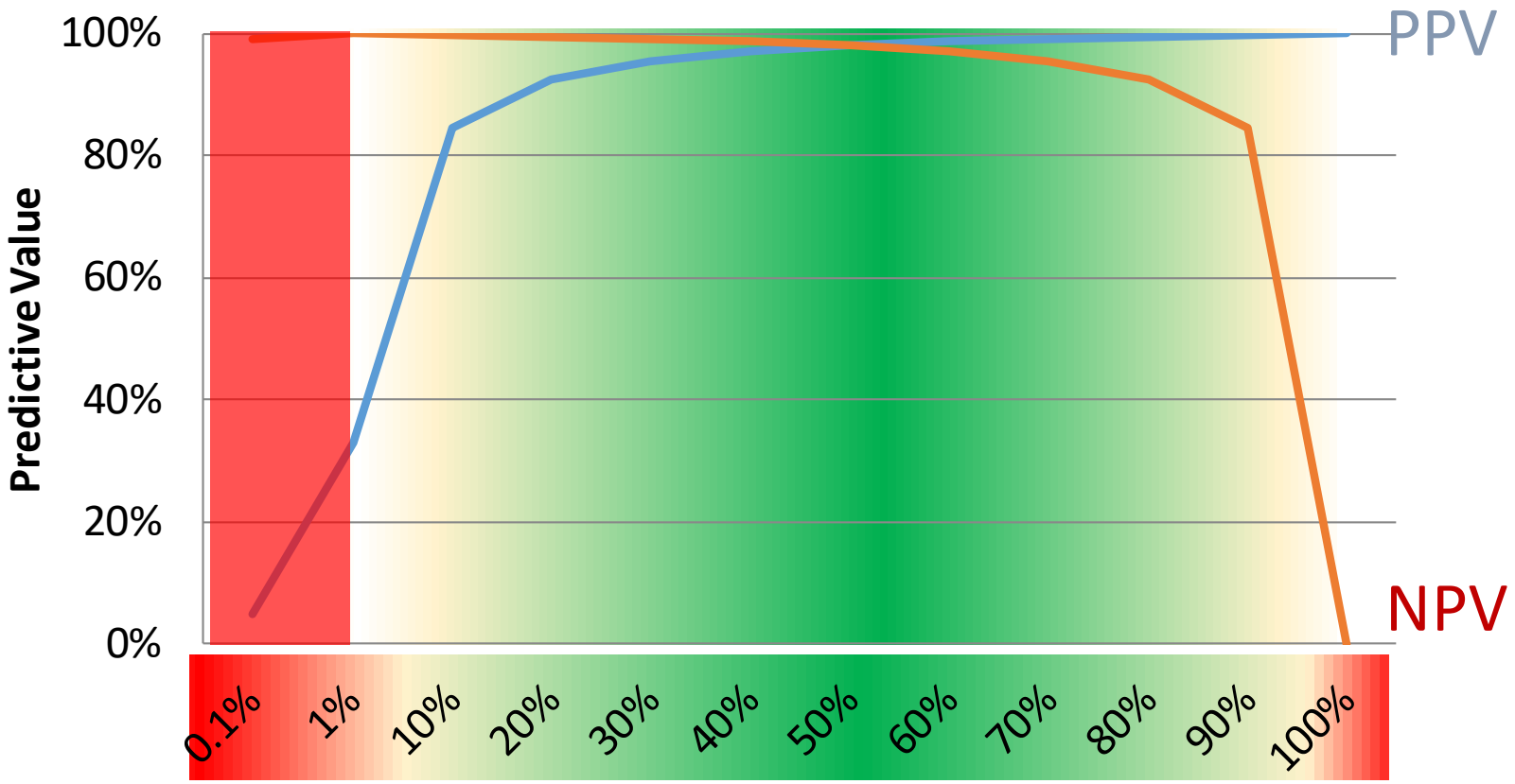
What prevalence can you test?

Sensitivity and Specificity at 90%

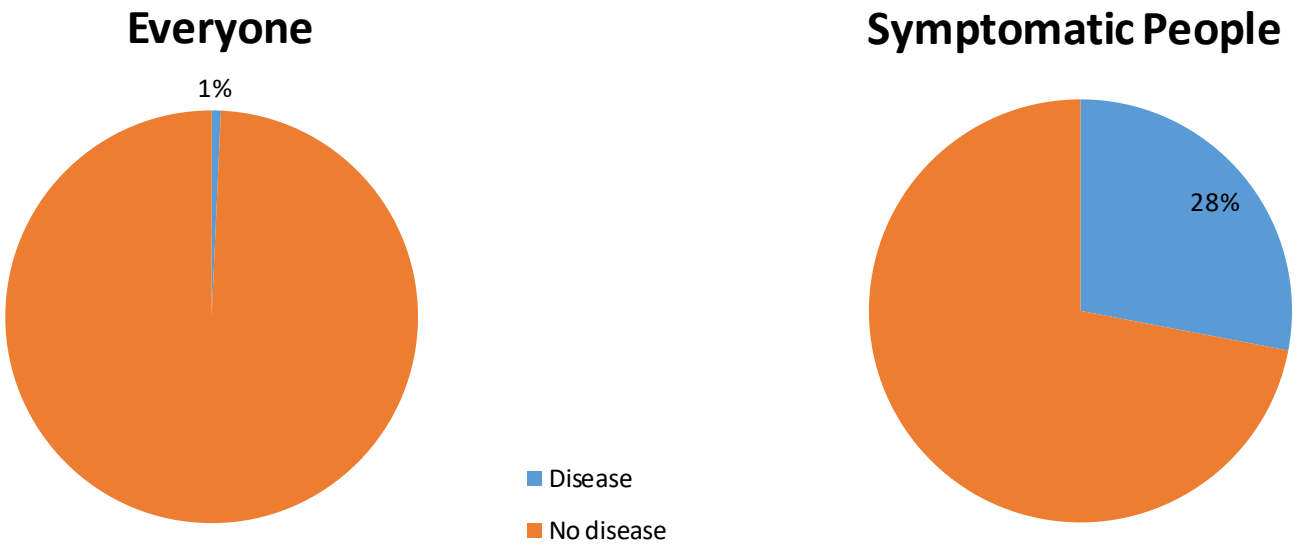


What prevalence can you test?

Sensitivity and Specificity at 98%



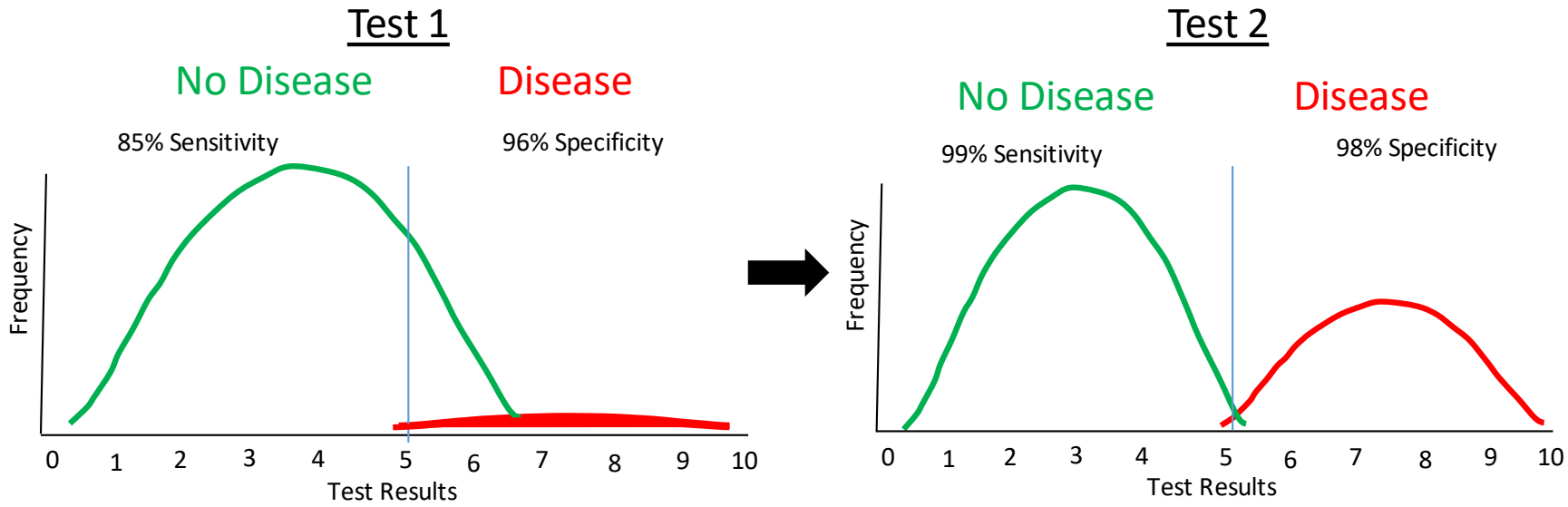
How can you test when the prevalence is low?

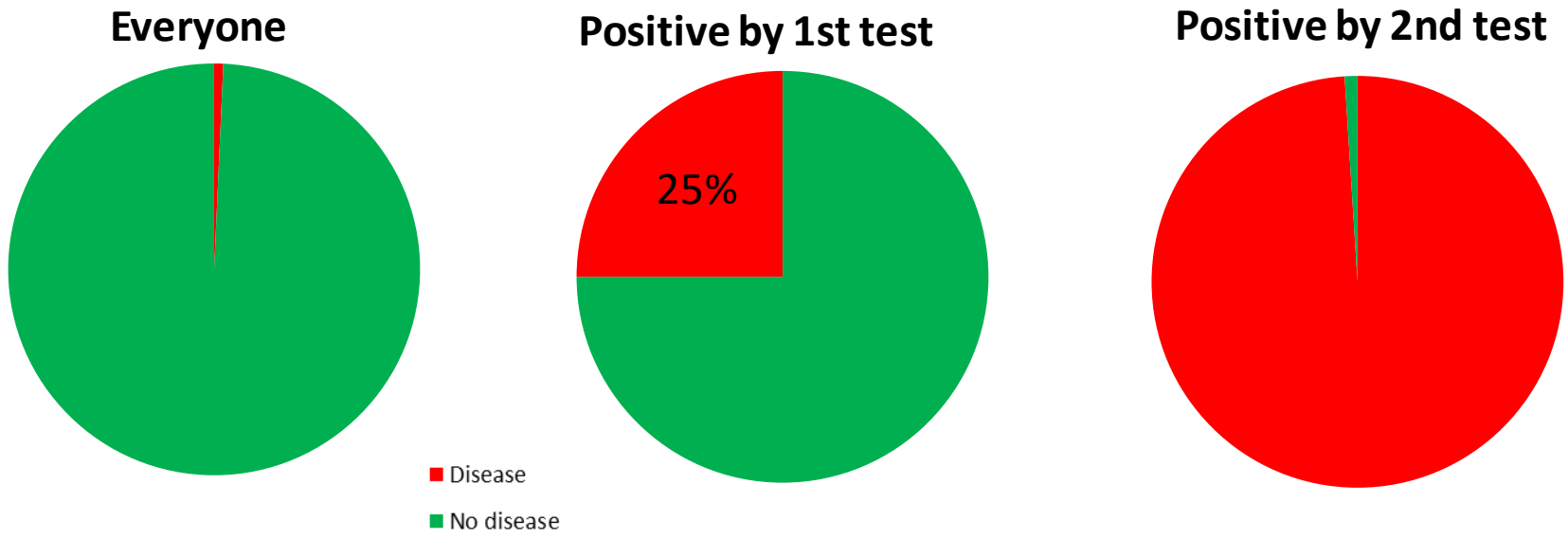


If the prevalence of a disease is low

1. The positive predictive value can be increased by only testing symptomatic or high risk patients.
2. Confirming results by a second test

2 tiered testing to improve predictive value





Recent CDC Guidance

Table 3. Relationship between pre-test probability and the likelihood of positive and negative predictive values

Pretest Probability*	Negative Predictive Value**	Positive Predictive Value**	Impact on Test Results
Low	High	Low	Increased likelihood of False Positives Increased likelihood of True Negatives
High	Low	High	Increased likelihood of True Positives Increased likelihood of False Negatives

*Sensitivity and specificity of tests are generally stable and not affected by pretest probability.

**Predictive values are affected by pretest probability.

https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html?deliveryName=USCDC_2067-DM35559

Types of COVID-19 Tests

Molecular (PCR)

- Currently the most commonly used test
- **Pro:** Generally highly accurate
- **Limitations:** Time intensive and complex processing

Antigen (lateral flow)

- Test method being provided by HHS
- **Pro:** Fast POC results
- **Limitations:** Lower accuracy

Antibody

- Detect antibody response to document previous exposure to the virus
- **Limitations**: Not suitable for diagnosis of infections

Laboratory

- **Pro:** High throughput, quality, and oversight
- **Limitations:** results take longer than POC tests, more expensive

Point-of-Care (POC)

- **Pro:** Less complex, cheaper, and faster results
- **Limitations**: Lower accuracy may require confirmatory laboratory testing

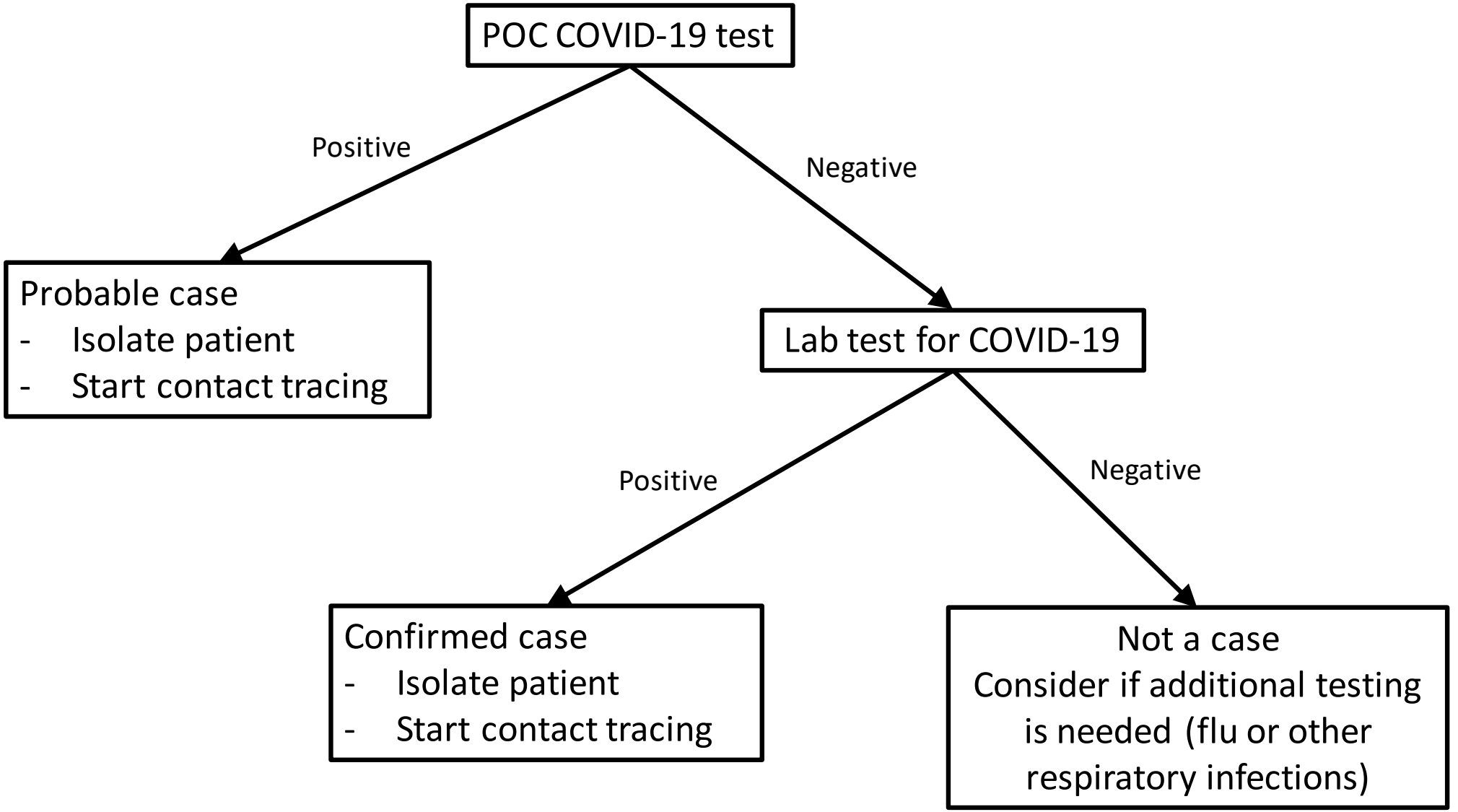
Point-of-care (POC) tests

Test	Method	Run time	Swab types
Abbott ID NOW	Molecular	5-13 min	NP, nasal, OP
Cepheid GeneXpert	Molecular	40 min	NP, OP, nasal, mid-turbinate, nasal wash
Accula	Molecular	30 min	Nasal
Cue	Molecular	25 min	Nasal
Quidel Sofia	Antigen	17 min	NP and nasal
BD Veritor	Antigen	15 min	Nasal
LumiraDx	Antigen	15 min	Nasal
BinaxNOW	Antigen	15 min	Nasal

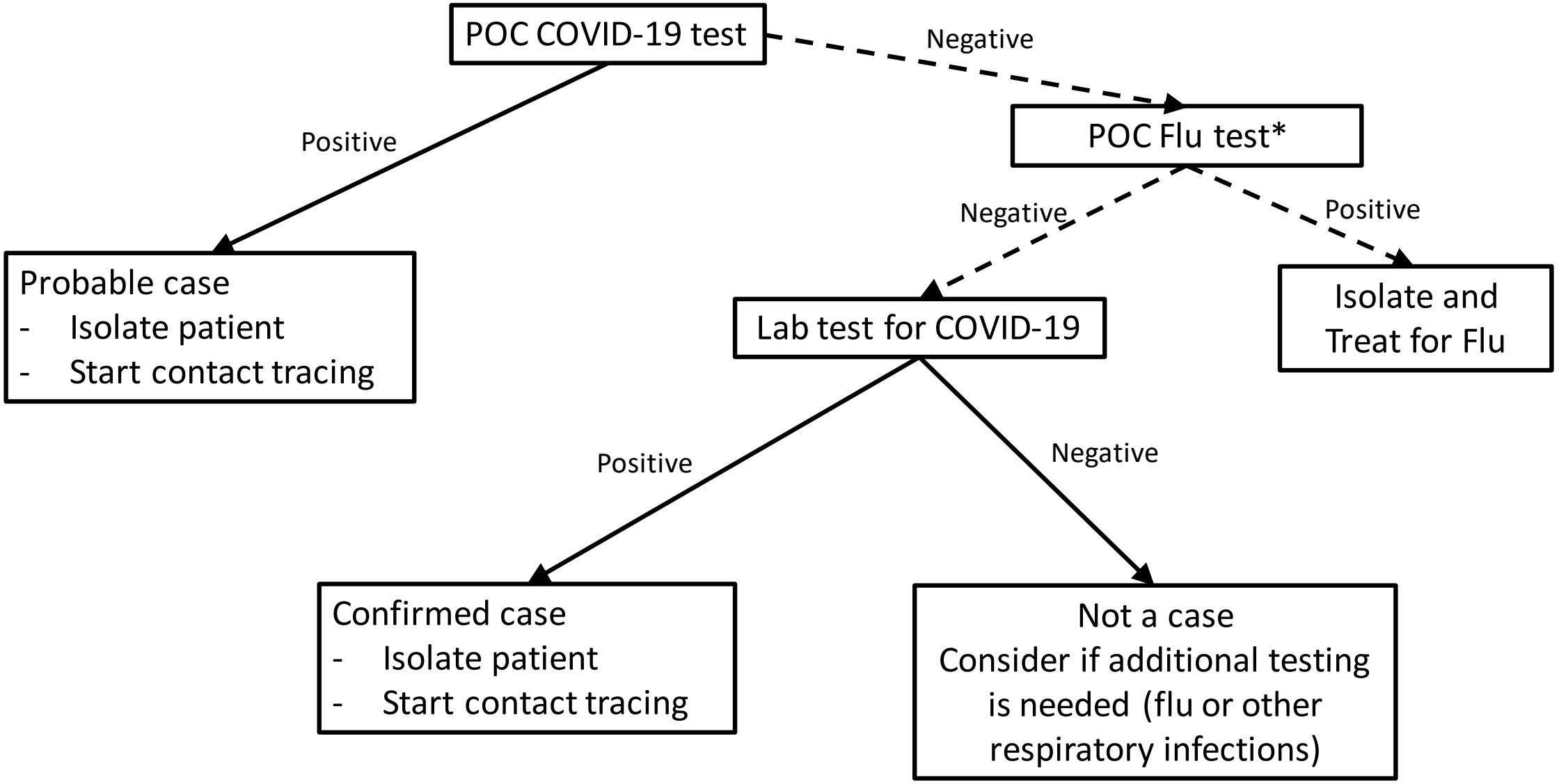
- Allow for rapid, actionable results
- Veritor and Sofia being provided to LTCFs with a CLIA waiver

Testing Decision Trees

Testing Strategy for **Symptomatic People** (High Risk)



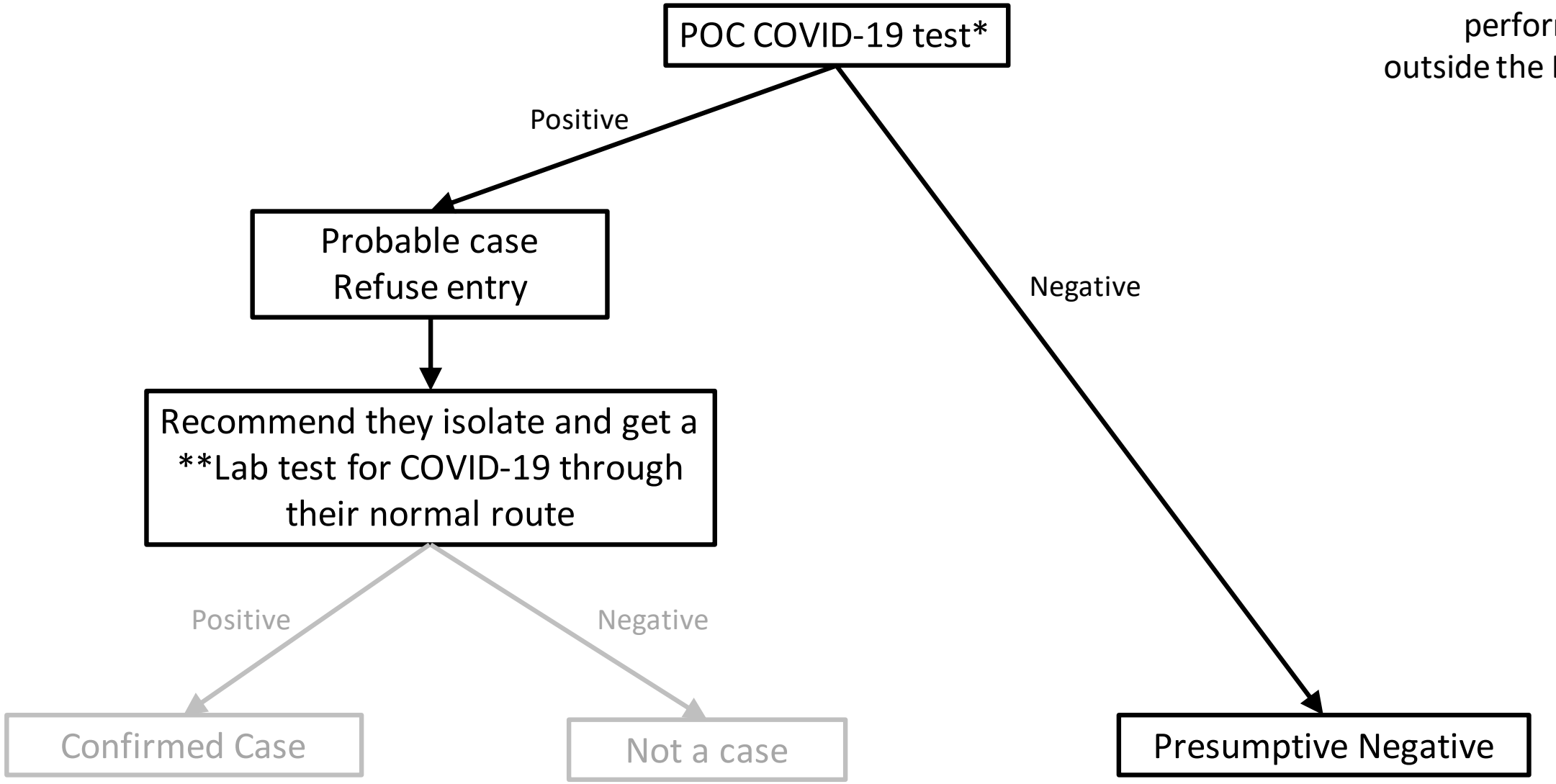
Testing Strategy for **Symptomatic People** during flu season (High Risk)



Testing Strategy for **Guests** (Low Risk)

(Asymptomatic screening in low prevalence population)

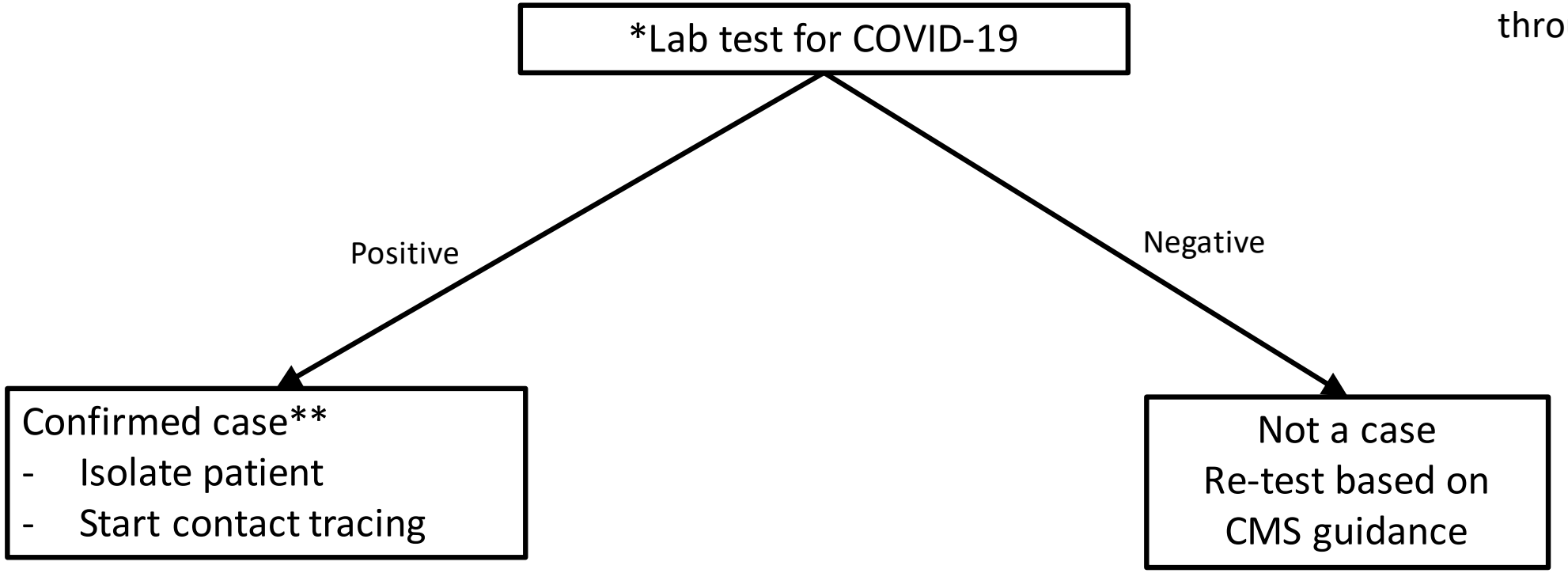
*Off-label use of these tests
**Items in gray performed outside the LTCF



Testing Strategy for **Asymptomatic** people (Low Risk)

Appropriate for both routine testing of staff and outbreak testing of staff and residents not identified as close contacts

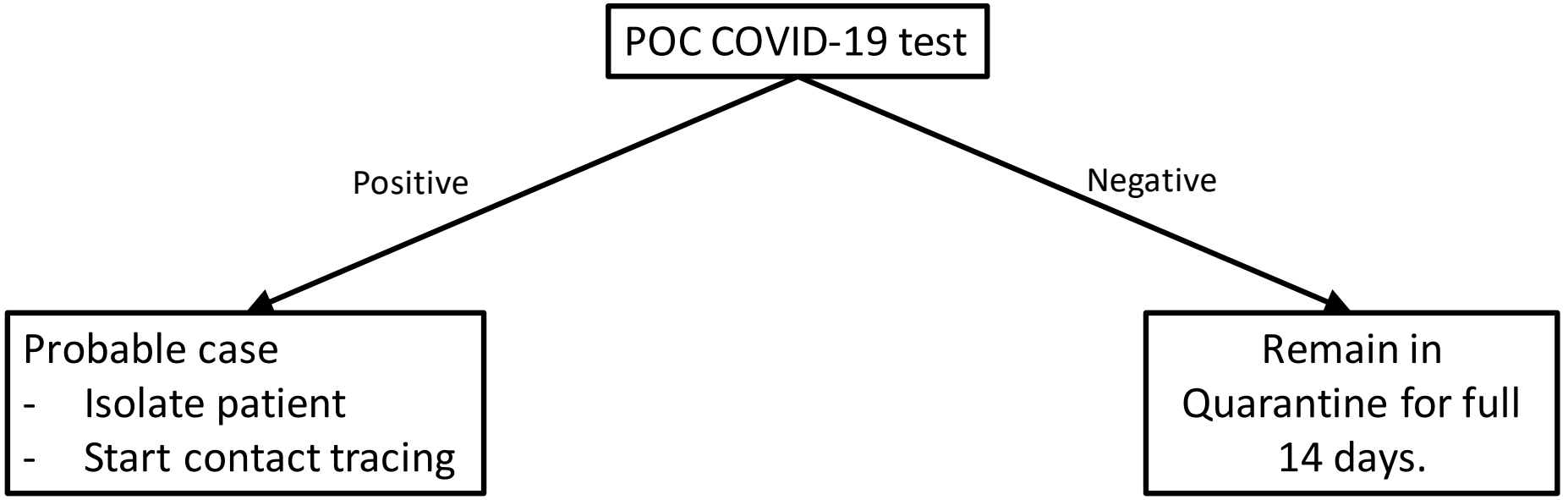
*Testing available fee-exempt through the SEOC



**Possible risk for false positives.
2 consecutive negative tests can get someone out of isolation early

Testing Strategy for **Close Contacts** of Positive Cases

Close contacts should be placed in quarantine as soon as they are identified.
Testing is not required



- Testing a close contact that is positive can aid in contact tracing related to the new case
- If a person is positive the isolation window is potentially smaller than the quarantine window
- A molecular test may also be appropriate in place of an antigen test

Reporting

- All results are required to be reported to HHS
- Results may also need to be report to the DHS via WEDSS

Definitions

- **Diagnostic Testing**: intended to identify current infection in individuals and is performed when a person has signs or symptoms consistent with COVID-19, or when a person is asymptomatic but has recent known or suspected exposure to SARS-CoV-2. It is reportable and must be done in a CLIA regulated environment.
- **Screening Testing**: intended to identify infected persons who are asymptomatic and without known or suspected exposure to SARS-CoV-2. It is reportable and must be done in a CLIA regulated environment.
- **Surveillance Testing**: intended to monitor for a community- or population-level infection and disease, or to characterize the incidence and prevalence of disease. It is not reportable and does not require CLIA oversights. However, individual patient results cannot be communicated to the patient or used for medical treatment.

Definitions

- **Isolation**: For infected individuals. Currently, 10 days and 24 hours symptom free OR 2 consecutive negative tests at least 24 hours apart. (test of cure not recommended due to long periods of shedding)

- **Quarantine**: For Close contacts of diagnosed people. Avoid human contact for the entire 14 days incubation period of the virus. A negative test does not release someone from quarantine. Viral loads may be too low to detect early in disease.

Reference

CDC Interim Guidance for Rapid Antigen Testing for SARS-CoV-2

https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html?deliveryName=USCDC_2067-DM35559