# Program Documentation: ScreeningTest.py: (Medical Screening Tests)

## How To View This Document.

You may want to DOWNLOAD THIS PDF file to read it in a full feature PDF viewer. (E.g. Chrome).

This document has a convenient PDF features such as an navigation window, searching and active links which will only be available in a full featured pdf viewer.

## How To Run This Program

This program is run in a web page. Navigate to the following link in any major web browser.

The program will then instruct you on how to proceed. (Only tested in Chrome).

<https://share.streamlit.io/profbrockway/screeningtest/main/screeningtest.py>

## Contacts

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## Program And Project Purpose

This program provides full graphing and statistical reporting of a typical medical screening test given the test's parameters. The program reports the efficacy statistics for the specified test over a range of disease prevalences.

The project uses this tool to explore the effect of disease prevalence on the false positives rate.(FPR)

As a specific example this project models one of the Covid 19 antigen screening tests.

## Project Documentation

This document and all the project files are hosted at GitHub: [Project ScreeningTest.py At Github](https://github.com/ProfBrockway/ScreeningTest)

The program is self-documenting.

The "help" menu on the GUI guides the user to all files and documentation and a documentary video.

The GUI also contains contacts, error and feedback reporting etc.

# Program Input / Outputs

**Inputs**

- A GUI in the form of a web page:

- The user will enter the following medical test statistics.

- Test sensitivity.

- Test specificity.

- Start of population disease prevalence range of interest.

- End of population disease prevalence range of interest.

- Disease "Prevalence Of Interest". AKA "Prior Probability Of Infection".

- A text annotation to label the program report.

- Population.

**Outputs**

- A printable report on the input and calculated results.

- An interactive graph with:

x axis. The specified range of disease prevalences.

y axis: Any or all of the following:

- False positive percentage.

- False negative percentage.

- Positive predictive value.

- Negative predictive value.

- False Positives (NPV)

- False Negatives (NPV)

- The program permits the user to show or hide the variables to avoid clutter and examine different aspects of screening test performance.

- A display of a data grid showing the data generated from the users input and used for the plots.

- The most interesting entries will are highlighted. The grid is fully scrollable.

- Error messages reporting errors in user's input.

- Standard webpage links to all documentation, code, error reporting, contacts etc.

- Optional downloads to users' computer:

- A report on the screen test statistics as a text file.

- The data grid as a CSV file with the plot data.

- The data grid as an Excel file with the plot data.

- The plots as a static images.

- The plots as an *interactive* html web pages.

# COVID 19 Screening Tests: Background

## Basics Of Medical Screening Tests Assumed

It is assumed the reader is familiar with the basics of medical screening tests, their statistical variables and the difficulties of estimating the test's efficacy. Those basics are well documented by the CDC, FDA and other websites. The statistic variables of screening tests is nicely summarized here: [Wiki](https://en.wikipedia.org/wiki/Positive_and_negative_predictive_values). Additionally the program code itself explains all variables and calculations.

Evaluating Screening Tests Is Very Complicated

Judging the efficacy of screening tests is subtle and complicate. We can't go into this vast subject too deeply but it's important to keep in mind that simplistic summaries of screening tests using just sensitivity and specificity are extremely misleading. This fact should always kept in mind when considering the Covid 19 screening tests and how effective they are in there stated role. The linked article gives an idea of the many pitfalls in research and practice of screening tests and their statistics. [FIS](https://www.frontiersin.org/articles/10.3389/fpubh.2017.00307/full)

## Medical Screening Tests And The Low Prevalence Problem

One of the many problems with medical screening tests is that the prevalence of the subject disease in the tested population effects the proportion of true positives and true negatives.

*Uneven test accuracy and statistical challenges, especially in areas of low disease prevalence, further complicate use of antibody tests for individual decision making.*

*At 0.1% prevalence, the PPV would only be 4%, meaning that 96 out of 100 positive results would be false positives*. [FDA](https://www.fda.gov/medical-devices/letters-health-care-providers/potential-false-positive-results-antigen-tests-rapid-detection-sars-cov-2-letter-clinical-laboratory)

*Unfortunately, the false positive rate can be shockingly high. Based on the prevalence estimated throughout the US and serology studies in California, New York and Boston, the FPR (False Positive Rate) of antibody test results* [for Covid 19*] range from 2% to 88%.*  [Nature](https://www.nature.com/articles/s41598-021-84173-1#Sec11) (Refers to antibody tests but applies to all testing logic).

## Definitions:

The FDA definitions recommendations for creating and testing medical tests and all calculations performed by the program are here: [FDA](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/statistical-guidance-reporting-results-studies-evaluating-diagnostic-tests-guidance-industry-and-fda#6).

The following are convenient simplifications of those definitions as they pertain to this project.

**"Screening test"** means the "antigen" type of quick result, at home, Covid 19 screening test**.**

**"Antigen test":** Antigen tests look for fragments of proteins that make up the SARSCoV-2 virus to determine if the person has an active infection. [Types Of Covid Test. A nice summary](https://www.dshs.state.tx.us/coronavirus/docs/COVID19-TestingExplained.pdf)

"**Prevalence"**: A COVID-19 case is counted as active and part of the disease population prevalence during the 14 days after it is confirmed. [Covid Tracker](https://covid-tracker.mckinsey.com/prevalence)

# The Utility Of The Screening Tests Is Dubious

## Screening tests are exposed to many shortcomings.

Lack of knowledge about prevalence, asymptomatic cases, pre symptomatic cases, constantly evolving Covid variants, skills of tester and many other variables, seriously undermine the credibility of covid screening tests, especially when used for diagnosis or isolation. [ASM](https://journals.asm.org/doi/10.1128/JCM.02225-20?permanently=true) [FDA](https://www.fda.gov/medical-devices/letters-health-care-providers/potential-false-positive-results-antigen-tests-rapid-detection-sars-cov-2-letter-clinical-laboratory).

## The screening tests are NOT adequate for diagnosis.

*As the antigen testing algorithms indicate, confirmatory testing may be needed regardless of the symptom or exposure status of the person being tested. Confirmatory testing should take place as soon as possible after the antigen test*. [using a serological test] [CDC](https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html#:~:text=Antigen%20tests%20are%20commonly%20used,%2DCoV%2D2.)

## The claimed test accuracy assumes *multiple* applications of the test.

These tests are widely supposed to be effective in a single test. In fact the manufacturer's documentation states that it requires two tests separated by 36 hours, which is not consistent with the claim that these are "rapid" result. In any case I suggest that most people will not repeat the tests or will not delay acting on the test until 36 hours later.

*The BinaxNOW™ COVID-19 Antigen Self-Test is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 from individuals with or without symptoms or other epidemiological reasons to suspect COVID-19 infection when tested twice over three days with at least 36 hours between tests.* [Abbot](https://www.abbott.com/BinaxNOW-Tests-NAVICA-App.html)

## The prevalence of Covid is unknown.

There is an absence of good estimates of the prevalence of Covid 19.

*At the time of this writing there are few published, population-representative COVID-19 prevalence studies.* [PNAS](https://www.pnas.org/doi/10.1073/pnas.2026412118)

This lacuna and prevalence variability across time and space, alone put a large question mark over the results of the tests since the efficacy of the tests depend upon population prevalence.

*… reliable prevalence estimates are limited. Prevalence, which affects predictive value estimates, can be considered unknown, and varies over time.* [Nature](https://www.nature.com/articles/s41598-021-84173-1#Sec3)

## Prevalence of Covid 19 appears to be typically less than 1%

Where measurement has been attempted the whole population prevalence of Covid 19 seems to be typically less than 1%.

Prevalence varies tremendously (a problem in itself) but such measurements as we have seem to put a typical range of prevalence between 0% and 3%. Brief peaks of as high as 33% are alleged but this peak occurred at a time of record low deaths, so make of that what you will.

- 1.25% to 3.09%. Highest prevalence as of Nov 2020 in UK: [Imperial College London](https://www.imperial.ac.uk/news/231715/react-study-records-highest-coronavirus-prevalence/)

- 0.05 of 1 percent. Case Prevalence in USA in June 29 2021 (1/1978) [Covid Tracker](https://covid-tracker.mckinsey.com/prevalence)

- 0.09 of 1 percent (1/107) Case Prevalence in USA in June 2020 peak was [Covid Tracker](https://covid-tracker.mckinsey.com/prevalence)

- 0.3 of 1 percent. The "Utah" Study. Prevalence very low: [Utah Study](http://www.nathanseegert.com/papers/Yang2020a.pdf)

*Our own randomized viral testing was conducted in Utah between May 4th and July 1st, 2020 and estimates that the prevalence of COVID-19 in Utah was 0.27%. [0.027]. At the same time, our method predicts a median viral prevalence of 0.3% [0.003]*

## Manufacturer's claims of accuracy have not been independently verified.

The tests are released under "emergency" FDA licenses and few of the manufacturer's claims of accuracy have been independently verified by the FDA or CDC.

*Limited data have been published for these home tests given that they are available through EUAs* [Emergency Use Authorization] *that do not require clinical trials.* [NCBI](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8196235/)

## The claimed sensitivity and specificity are not "real world".

*Sensitivity and specificity estimates shown may not be indicative of the real world performance of the tests. The number of samples in the panel is a minimally viable sample size that still provides reasonable estimates and confidence intervals for test performance, and the samples used may not be representative of the antibody profile observed in patient populations.* [FDA](https://open.fda.gov/apis/device/covid19serology/)

One of the few evaluations by the CDC of an emergency approved test discovered that a test claiming to have a sensitivity of 99% proved in fact to have a sensitivity of 35.8% in uninfected and asymptomatic groups. [CDC](https://www.cdc.gov/mmwr/volumes/70/wr/mm7003e3.htm)

## WHO expects typical sensitivity to be 34% to 80%

Based on experience with influenza *"the sensitivity of these* [Covid 19 screening] *tests might be expected to vary from 34% to 80%"* [WHO](https://www.who.int/news-room/commentaries/detail/advice-on-the-use-of-point-of-care-immunodiagnostic-tests-for-covid-19) Clearly this is very different from the manufactures typical claims for sensitivity in the high 90's% which is suspect, clearly running counter to long experience.

## Asymptomatic and presymptomatic unknowns have a serious effect on test accuracy.

*Rapid antigen tests have received Food and Drug Administration (FDA) Emergency Use Authorization (EUA) for use in symptomatic persons, but* ***data are lacking on test performance in asymptomatic persons to inform expanded screening testing*** *to rapidly identify and isolate infected persons.* [CDC](https://www.cdc.gov/mmwr/volumes/70/wr/mm7003e3.htm) [CDC2](https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html#anchor_1631294997480)

*Among asymptomatic participants, antigen test sensitivity was 41.2%, specificity was 98.4%, and PPV in this population was 33.3%. This low PPV was observed despite a relatively high prevalence of SARS-CoV-2 in this population (5.2% prevalence overall; 2.0% among asymptomatic persons), suggesting that PPV could be even lower when using this antigen test among populations with lower expected SARS-CoV-2 prevalence.* [*CDC*](https://www.cdc.gov/mmwr/volumes/69/wr/mm695152a3.htm)

## **The rate of asymptomatic or presymptomatic covid cases is unknown**.

In the general population the rates of asymptomatic or presymptomatic casesare uncertain. The few and low quality studies report such a wide range of percentages it would be more honest to say we have no idea what the general prevalence is. Sadly nobody gets paid for saying "I don't know" or more outragiously "It's not possible to know that".

Even the lowest estimate undermines the claimed reliability of the tests.

17% [JAMMI](https://www1.racgp.org.au/newsgp/clinical/australian-study-determines-true-asymptomatic-covi)

35% : [PNAS](https://www.pnas.org/doi/10.1073/pnas.2109229118)

25% : [Nature](https://www.nature.com/articles/d41586-020-03141-3)

50%: [PNAS](https://www.pnas.org/doi/10.1073/pnas.2019716118)

56% [IJBS](https://www.ijbs.com/v17p1119.htm)

91% [Lancet](https://www.thelancet.com/journals/eclinm/article/PIIS2589-5370(20)30461-2/fulltext)

98% [Shanghai](https://www.reuters.com/world/china/why-are-shanghais-covid-infections-nearly-all-asymptomatic-2022-03-29/)

## Interpreting the tests is subjective & requires expert intrepretation

*Interpreting the results of an antigen test for SARS-CoV-2 depends primarily on the clinical and epidemiological context of the person who has been tested (e.g., symptoms, close contact to others with COVID-19, setting in which they live, likelihood of alternative diagnoses, or disease prevalence in their geographic location).* [CDC Guidance](https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html#anchor_1631294997480)

In other words the result of the test in meaningless without the judgement of a skilled analyst and full and honest information about contact of the testee with the virus. This of course is impossible to perform with scientific consistency and accuracy in the sub-clinical settings for which the rapid tests are vaunted for use, such as at home, or mass screening in schools. Thus the CDC is allowing that these tests are not suited for the main purpose for which the FDA is "*flooding*" the country them.

*I actually have been saying that for months and months and months – that we should be literally flooding the system with easily accessible, cheap, not needing a prescription, point of care, highly sensitive and highly specific, . And that in fact, you are going to be seeing more of that soon,"* [Fauci](https://schrier.house.gov/media/in-the-news/we-need-flood-system-cheap-coronavirus-tests-fauci-says)

See also *" there is an element of subjectivity in scoring the results "* below*.*

## **Some tests are less effective or useless against new variants of Covid 19**.

*- Genetic variants of SARS-CoV-2 arise regularly, and false negative test results can occur.*

*- Test performance may be impacted by certain variants.*

*- Tests with single targets are more susceptible to changes in performance due to viral mutations, meaning they are more likely to fail to detect new variants.* [FDA2](https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/sars-cov-2-viral-mutations-impact-covid-19-tests?utm_medium=email&utm_source=govdelivery#omicronvariantimpact)

## Bias In estimating the test's efficacy "often" cannot be ruled out.

This point is not specific to the Covid 19 tests but it is one of the many difficulties of screening tests in general and reminds us to be a little sceptical, in particular with tests produced and released without usual evaluation in an "emergency".

*Sensitivity and specificity estimates (and other estimates of diagnostic*

*performance) can be subject to bias. Biased estimates are systematically too high*

*or too low. Biased sensitivity and specificity estimates will not equal the true*

*sensitivity and specificity, on average.* ***Often the existence, size (magnitude), and***

***direction of the bias cannot be determined.*** *Bias creates inaccurate estimates.* [FDA](https://www.fda.gov/files/medical%20devices/published/Guidance-for-Industry-and-FDA-Staff---Statistical-Guidance-on-Reporting-Results-from-Studies-Evaluating-Diagnostic-Tests-%28PDF-Version%29.pdf)

## “Risk illiteracy” and lack of evidence based medicine

The linked article reveals widespread misconceptions about screening tests in the medical profession and general public. The article also underlines the dangers of misunderstanding the "accuracy" of screening tests*.* [*WP*](https://www.washingtonpost.com/news/posteverything/wp/2018/10/05/feature/doctors-are-surprisingly-bad-at-reading-lab-results-its-putting-us-all-at-risk/?utm_term=.72a084d6cb1a&itid=lk_interstitial_manual_21)The article provides links to some worrying studies on medical testing in general.

In short the fact that these tests are approved by the CDC and recommended by doctors does *not* mean they are useful. In a time of panic and hysteria it would be easy to promulgate useless or even counterproductive measures. [JAMA](https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2546153) [NCBI](https://www.ncbi.nlm.nih.gov/books/NBK279418/) [NCBI2](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6042667/) [Overdiagnosis](https://www.healthnewsreview.org/screening-how-overdiagnosis-and-other-harms-can-undermine-the-benefits/) Similar article. [Guardian](https://www.theguardian.com/science/blog/2014/jan/03/patients-truth-health-screening-harm-good)

# A Covid 19 Test Case

## The Abbott Binax NOW Rapid Antigen Test for SARS-CoV-2.

As a test case we look at a typical over the counter "Covid Instant Test" that might be used by (say) students at a university or at home: the Abbott Binax NOW Rapid Antigen Test for SARS-CoV-2. [Binax](https://bttnusa.com/products/binaxnow-covid-19-antigen-self-test?gclid=EAIaIQobChMI4pul_Knz9gIVrcmUCR0VFA2dEAAYASAAEgJw_fD_BwE&variant=41548371591356)

## Manufacture's claimed "accuracy" is implausible

On its "*BinaxNOW Performance*" web page the manufacturer vaunts a specificity of 99.9% on high viral load cases. While this is arithmetically correct it is selective data and highly misleading. [Abbot](https://www.abbott.com/corpnewsroom/diagnostics-testing/binaxnow-performance-from-studies-in-the-field.html).

- Except for the statement "*The BinaxNOW COVID-19 Ag Card has not been FDA cleared or approved"* the web page does not mention any of the qualifications and shortcomings listed below.

(For example the CDC found the real world sensitivity could be as low as 35.8%).

- Binax literature publishes misleading and inappropriate statistics for the their test.

?V The Binax publicity, instruction and packaging material cites accuracy using sensitivity and specificity which misleading information is passed on by the media. The accuracy for screen testing individuals should be cited using the PPV and NPV. Why would Binax do this ? Could it be because the sensitivity and specificity are impressively high numbers like 99.9 % which creates a false sense of confidence in the test ?

*Of particular importance, although it is desirable to have tests with high sensitivity and specificity, the values for those two metrics should not be relied on when making decisions about individual people in screening situations. In that second context, use of PPVs and NPVs is more appropriate.* [FIM](https://www.frontiersin.org/articles/10.3389/fpubh.2017.00307/full)

- The quality of studies cited by the manufacturer as underlying their claims, seem less than ideal.

A quick look at just one of them reveals some rather glaring shortcomings. ([MedxRiv](https://www.medrxiv.org/content/10.1101/2020.11.02.20223891v2)) :

- The study was deliberately conducted where prevalence was abnormally high. Why ?

- The study used self-selecting subjects in a public place who it may be assumed were more likely to be symptomatic or have a high expectation of having been exposed. This is like calibrating a test for Aids in an Aids ward. The results would hardly be representative.

- " *there is an element of subjectivity in scoring the results* ".

The result stripe on the test paper is often ambiguous and subjective in interpretation. So much so that the test requires "*supplementary technician training* ". This is not consistent with the vaunted "in home" use for which the US Government is using this test in staggering numbers. The complexity of interpreting the test is underscored by the complicated decision diagram for the test. [binax-training](https://unitedinhealth.org/binax-training) Studies confirm lower accuracy when not administered by a professional. *Our results, however, indicate that home use of these rapid COVID-19 diagnostics as self/caregiver-operated tests may decrease this already lowered sensitivity even further.*  [Nature](https://www.nature.com/articles/s41598-021-94055-1)

- The sensitivity claimed by Binax depended on a disputed variable "*the range* [viral load] *thought to be the most transmissible*". A "conservative" estimate of this variable estimate reduced the specificity to only 93.8% even in an unrepresentative high prevalence level. Why was this lower number not used in the Binax report ? ([MedxRiv](https://www.medrxiv.org/content/10.1101/2020.11.02.20223891v2))

- Initially the study found that, *using the manufacturer’s proposed criteria, 9/14 Binax-CoV2 (+) tests (64%) in this population were likely false positives….. Clearly, these initial criteria were problematic. Therefore, on subsequent test days, we evaluated additional criteria for classifying a band as positive, in consultation with experts from the manufacturer’s research staff.* In other words the test was catastrophically ineffective so they got together with the manufacturer to alter the criteria of a positive test and lo ! the specificity is 99% not 64%.

## CDC says manufactures Binax accuracy is greatly exagerated.

- Binax is one of the few "emergency" approved tests that have been tested by the government.

CDC Evaluation of Abbott BinaxNOW Rapid Antigen Test for SARS-CoV-2. [CDC](https://www.cdc.gov/mmwr/volumes/70/wr/mm7003e3.htm)

*.. the BinaxNOW antigen test had a sensitivity of 64.2% for specimens from symptomatic persons and* ***35.8%*** *for specimens from asymptomatic persons.* Contrast this to the manufacturer's flat claim of sensitivity of 99.9%.

Bear in mind that even this appallingly low level of accuracy was exaggerated by conducting the tests at abnormally high levels of prevalence and abnormally low levels of asymptomatics and unrepresentatively skilled testers clearly working with the manufacture to increase the claimed sensitivity.

# A scenario for the simulation on our computer model:

- Imagine all the students at a university being screened using the Binax kit on the first day of term.

- We will focus our simulation on the relationship between prevalence and false positives.

**- We will simulate the Binax test with these parameters.**

**- Sensitivity: We'll test, *35.8%.* 50% and *64.2%*** Per [CDC evaluation of the test](https://www.cdc.gov/mmwr/volumes/70/wr/mm7003e3.htm).

**- Specificity: 90%.**

Sensitivity and specificity are inversely proportional, meaning that as the sensitivity increases, the specificity decreases and vice versa.

The manufacturer claims a specificity of 99%. I have not had time to research the specificity.

However the false claims about sensitivity have made me very dubious about all claims for this test. Like those dictatorships where 99.9% are supposed to have voted for the glorious leader. One becomes skeptical. Although I will model the manufactures claim, I feel more than justified in trying modestly lower values for specificity.

**- Prevalence range: 0% to 3%. Prevalence of Interest: 1%**

See " *Prevalence of Covid 19 is typically less than 1%*" above.

Note that Binax manufacturer's testing was calibrated at presumed 5% prevalence thus exaggerating accuracy.

**- Asymptomatic Cases 60%**

Asymptomatic cases in the general population is anywhere between 25% and 91%. (See above). Given the arbitrary and unknown value for this important parameter I felt justified in placing the value at a fairly high rate. Young people are more likely to experience low and absent symptoms. Also students who have symptoms or feel unwell will tend to not attend and thus not be tested.

Although higher rates of asymptomatic testees decreases accuracy of the tests the model has no code to account for this. So this variable is listed as documentation not an active input.

# Results Of The Covid 19 Test Case:

## Conclusion

The results of the model are not consistent with the manufactures performance claims:

*A positive test result means it is very likely you have COVID-19 and it is important to be under the care of your healthcare provider.* [Binax Insert](https://cdn.shopify.com/s/files/1/0532/7896/5948/files/IN195150WEB_v2.0_BinaxNOW_COVID-19_Antigen_Self_Test_Prod.pdf?v=1637104282)

When modeled on the program with the variety of conditions proposed and justified in "*A scenario for the simulation on our computer model*" above, the number of false positives render the test counterproductive. Spreading confusion, alarm and huge percentages of false positives is not a basis for individual care or public policy.

## Summary of Modeling Results

Using the CDC's value for the sensitivity of the Binax test in a highly asymptomatic group:

- At the (unexamined) manufacturer's Specificity of 0.99 , 0.73 of all positives are false.

- At a unresearched but high Specificity of 90%, 0.96 of all positives are false.

- Even at high prevalence of 3% and using Specificity of 0.99, 0.90 of all positives are false.

- Bear in mind the additional inaccuracy of high levels of asymptomatic students in not included in the model.

### At 0.01 Prevalence Using Lower Specificity

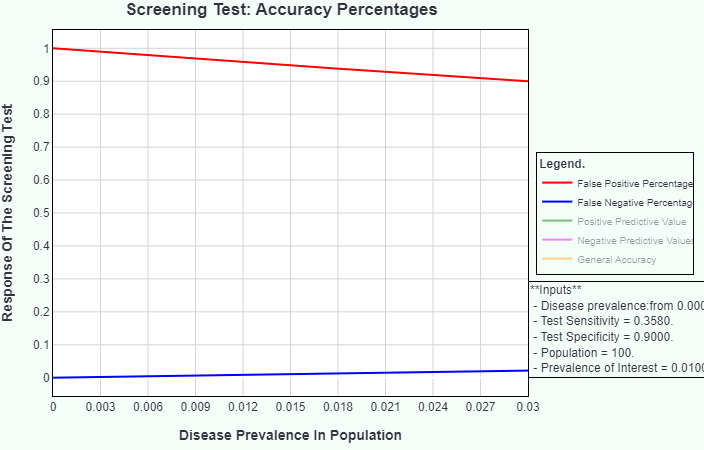
**REPORT ON YOUR SCREENING TEST**  
This is a simulation of a covid antigen screening test.

We have lowered the manufactures specificity from 99% to an arbitrary but high 90%.  
The test is called the " Abbott Binax NOW Rapid Antigen Test for SARS-CoV-2".  
The parameters are chosen from real world experience to the extent possible, and not from manufacturers claims.

\*\* Inputs specifying the simulation. \*\*  
-- In this simulation the disease prevalence varies from 0.00000 to 0.03000.  
-- Test Sensitivity = 0.3580.  
-- Test Specificity = 0.9000.  
-- Plot Prevalence Start = 0.00000.  
-- Plot Prevalence End = 0.03000.  
-- Population = 100.

\*\* The range of false results. \*\*  
-- The false positive rate varies from 1.00000 to 0.90032.  
-- The false negative rate varies from 0.00000 to 0.02159.

\*\* At The Prevalence Of Interest = 0.010000. \*\*  
-- About 0.96 of all positives are false.  
-- About 0.01 of all negatives are false.  
-- Positive Predictive Value (PPV) = 0.0356.  
-- Negative Predictive Value (NPV) = 0.9927.  
-- Claimed True Positives = 0.37.  
-- Claimed False Positives = 9.90.  
-- Claimed True Negatives = 89.08.  
-- Claimed False Negatives = 0.65.



### At 0.01 Prevalence Using Manufactures Specificity

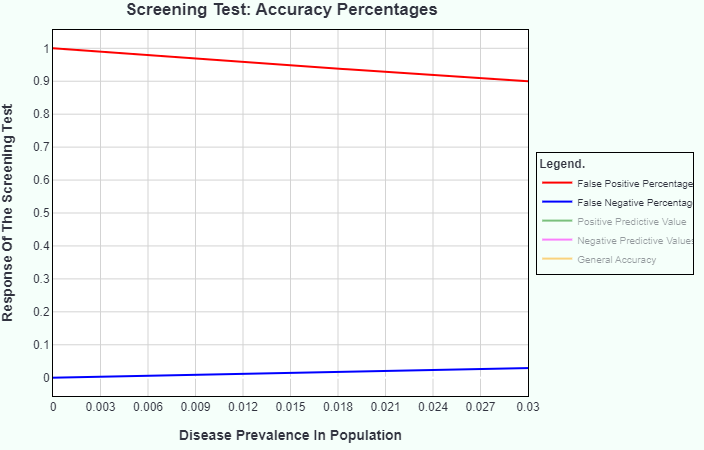
**REPORT ON YOUR SCREENING TEST**

This is a simulation of a covid antigen screening test.  
The test is called the " Abbott Binax NOW Rapid Antigen Test for SARS-CoV-2".  
The parameters are chosen from real world experience to the extent possible, and not from manufacturers claims.

\*\* Inputs specifying the simulation. \*\*  
-- In this simulation the disease prevalence varies from 0.00000 to 0.03000.  
-- Test Sensitivity = 0.3580.  
-- Test Specificity = 0.9900.  
-- Plot Prevalence Start = 0.00000.  
-- Plot Prevalence End = 0.03000.  
-- Population = 100.

\*\* The range of false results. \*\*  
-- The false positive rate varies from 1.00000 to 0.47456.  
-- The false negative rate varies from 0.00000 to 0.01966.

\*\* At The Prevalence Of Interest = 0.010000. \*\*  
-- About 0.73 of all positives are false.  
-- About 0.01 of all negatives are false.  
-- Positive Predictive Value (PPV) = 0.2695.  
-- Negative Predictive Value (NPV) = 0.9934.  
-- Claimed True Positives = 0.37.  
-- Claimed False Positives = 0.99.  
-- Claimed True Negatives = 97.99.  
-- Claimed False Negatives = 0.65.



### At 0.005 Prevalence

**REPORT ON YOUR SCREENING TEST**

This is a simulation of a covid antigen screening test.  
The test is called the " Abbott Binax NOW Rapid Antigen Test for SARS-CoV-2".  
The parameters are chosen from real world experience to the extent possible, and not from manufacturers claims.

\*\* Inputs specifying the simulation. \*\*  
-- In this simulation the disease prevalence varies from 0.00000 to 0.03000.  
-- Test Sensitivity = 0.0358.  
-- Test Specificity = 0.9900.  
-- Plot Prevalence Start = 0.00000.  
-- Plot Prevalence End = 0.03000.  
-- Population = 100.

\*\* The range of false results. \*\*  
-- The false positive rate varies from 1.00000 to 0.90032.  
-- The false negative rate varies from 0.00000 to 0.02924.

\*\* At The Prevalence Of Interest = 0.005000. \*\*  
-- About 0.98 of all positives are false.  
-- About 0.00 of all negatives are false.  
-- Positive Predictive Value (PPV) = 0.0180.  
-- Negative Predictive Value (NPV) = 0.9950.  
-- Claimed True Positives = 0.02.  
-- Claimed False Positives = 0.99.  
-- Claimed True Negatives = 98.50.  
-- Claimed False Negatives = 0.49.

### At 0.02 Prevalence

**REPORT ON YOUR SCREENING TEST**  
This is a simulation of a covid antigen screening test.  
The test is called the " Abbott Binax NOW Rapid Antigen Test for SARS-CoV-2".  
The parameters are chosen from real world experience to the extent possible, and not from manufacturers claims.

\*\* Inputs specifying the simulation. \*\*  
-- In this simulation the disease prevalence varies from 0.00000 to 0.03000.  
-- Test Sensitivity = 0.0358.  
-- Test Specificity = 0.9900.  
-- Plot Prevalence Start = 0.00000.  
-- Plot Prevalence End = 0.03000.  
-- Population = 100.

\*\* The range of false results. \*\*  
-- The false positive rate varies from 1.00000 to 0.90032.  
-- The false negative rate varies from 0.00000 to 0.02924.

\*\* At The Prevalence Of Interest = 0.020000. \*\*  
-- About 0.93 of all positives are false.  
-- About 0.02 of all negatives are false.  
-- Positive Predictive Value (PPV) = 0.0684.  
-- Negative Predictive Value (NPV) = 0.9804.  
-- Claimed True Positives = 0.07.  
-- Claimed False Positives = 0.98.  
-- Claimed True Negatives = 97.01.  
-- Claimed False Negatives = 1.94.

### At 0.03 Prevalence

**REPORT ON YOUR SCREENING TEST**  
This is a simulation of a covid antigen screening test.  
The test is called the " Abbott Binax NOW Rapid Antigen Test for SARS-CoV-2".  
The parameters are chosen from real world experience to the extent possible, and not from manufacturers claims.

\*\* Inputs specifying the simulation. \*\*  
-- In this simulation the disease prevalence varies from 0.00000 to 0.03000.  
-- Test Sensitivity = 0.0358.  
-- Test Specificity = 0.9900.  
-- Plot Prevalence Start = 0.00000.  
-- Plot Prevalence End = 0.03000.  
-- Population = 100.

\*\* The range of false results. \*\*  
-- The false positive rate varies from 1.00000 to 0.90032.  
-- The false negative rate varies from 0.00000 to 0.02924.

\*\* At The Prevalence Of Interest = 0.030000. \*\*  
-- About 0.90 of all positives are false.  
-- About 0.03 of all negatives are false.  
-- Positive Predictive Value (PPV) = 0.0997.  
-- Negative Predictive Value (NPV) = 0.9708.  
-- Claimed True Positives = 0.11.  
-- Claimed False Positives = 0.97.  
-- Claimed True Negatives = 96.03.  
-- Claimed False Negatives = 2.89.

# Editorial review of the Binax test

My editorial impression of the Binax test is of a highly selective use of data that undermines confidence in the objectivity of those creating and advocating these tests and even in the underlying theory that mass screening is necessary and effective for controlling Covid. This difference between the publicized claims for the test and the much less optimistic and nuanced studies leaves the impression of deceptive practice.

Above in *The Utility Of The Screening Tests Is Dubious* and "*Manufacture's claimed accuracy is implausible*" I list some of the more obvious distorting or erroneous assumptions or misleading choices made in the researching and documenting the Binax test. It is remarkable that all of those interventions *exaggerate* the accuracy of the test. This distribution of shortcomings is not conclusive proof of experimenter bias but, if accurate, it is clearly is not consistent with random and genuine errors. (See "*Bias In estimating the test's efficacy "often" cannot be ruled out*." above).

The following remarks are beyond the scope of the project but are related to it.

The entire theory of medical screening testing as a countermeasure to Covid has been widely accepted as necessary and effective. However the theory itself is suspect, not just the tests. Mass screening for Covid-19 may be an expensive waste of resources. The financial and political desire for widespread community testing may sell well financially and politically but it is quite possible that the deployment of mass screening has gotten ahead of science based medicine.

The following links are just a few raising some common sense questions about mass screening.

*In the absence of evidence that mass-testing of asymptomatic people for COVID-19 has been beneficial, we cannot know whether the resources poured into such measures will return the public health value being pursued.* [*ASM*](https://asm.org/Articles/2021/December/Real-World-Performance-of-COVID-19-Rapid-Antigen-T)

*The coupling of rapid, cheap and simplicity may not be the best option for widespread community testing.* [Nature](https://www.nature.com/articles/s41598-021-94055-1).

*The US Department of Health and Human Services purchased 150 million BinaxNOW™ tests to expand testing capacity and started distributing these tests to states on September 28, 2020. A major objective of the deployment of these tests was to safely reopen schools. However, little data was available on the performance of these tests among asymptomatic school age children..* [PLOS](https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0249710#sec008)

*Information detailing population-wide* [mass screening] *testing strategies for SARS-COV-2 is largely missing from the peer reviewed literature, meaning that the evidence available to guide countries in their decision-making is limited. ….* [European meta study of screening Covid 19](https://www.ecdc.europa.eu/sites/default/files/documents/covid-19-population-wide-testing-country-experiences.pdf)

Finally we cannot avoid considering the self-interest of those responsible for policy especially if we see evidence of panic, poor or faked science and a public more fearful of an alleged danger than losing their basic rights. It is unfortunate that nobody gets paid for saying "I don't know". The desire to "do something" or to *appear* to "do something" often explains dramatic but ineffective actions by authorities. Implementing unnecessary or ineffective measures would be especially easy in a period of mass panic and hypochondria. It is not an ad hominin argument to point out that test manufacturers, politicians and public health institutions have an incestuous relationship and some perverse incentives. Science is objective. Scientists are not.

## Title for Online Report

This is a simulation of a covid antigen screening test. The test is called the " Abbott Binax NOW Rapid Antigen Test for SARS-CoV-2". The parameters are chosen from real world experience to the extent possible, and not from manufacturers claims.

# Video plan

*Once you get my approval, submit your final project’s PowerPoint slides as a PDF file at the end of the semester (see the class web page for due dates.)*

*If you’re taking this class as STAT 476, then please turn in a presentation that’s 10 to 15 slides long. If you’re signed up for STAT 576, then please make your PDF 18 to 25 slides long.*

*Make sure your file names are of the form “Final Project YourLastName.” For example, I would call my slides “Final Project Bilisoly.pdf” and my code “Final Project Bilisoly.txt.”*

- Welcome to this presentation of the screening test project.

- The technical goal of this project is to explore the options for getting our python and data science work online and accessible.

- A problem with data science and python is that the work is trapped on local computers. Ouput is cut and pasted into static documents for publication.

- Much better would be placing the program online with fully interactive plots and data.

- There is only one sensible way to do this. A GUI based in an html webpage.

- So I have used a web page as the GUI for the screening test project.

- Here it is.

- Before getting into the screening test, let's look at the housekeeping features built into this web page.

- Here's the typical web page options menu.

- Settings: Narrow and wide presentation.

- The "about" menu is programmed to document everything about the program.

- There's all the usual description, contact and version information.

- Then we have links to all the documentation you could need to understand or maintain the program.

- In this case the entire project is stored at Github but of course it could be stored anywhere online.

- Let's look at the links:

Program documentation: Here's' a pdf.

It could be read online, but if we download it we get all the benefits of

an active pdf document. Index, active links etc.

Program source code:

All program documentation:

Report a bug. This is very valuable. Feedback from you users is indispensable.

- Record a screencast:

This is a great tool for both the developer and the user.

The developer can easily present his or her work.

The user can create real time videos of the program in action.

Interactive graphs. Recording bugs or other behaviour the user wants changed and so on.

- Moving on to the screening test program itself.

- Menu.

- Over here on the left we have a menu for specifying the users inputs.

- We fill in the details of the medical test we want to model and click "plot now"

- Go through the input fields.

- Pop up help icons. Demonstrate.

- Input Verification.

- The input has to be verified by the program but the web page widgets do some pre-submission verification. I'll enter an invalid number 2 into the sensitivity field. See how the value is rejected.

- Program based verification.

I'll enter an invalid value into the population field (99) and the program rejects it.

Error messages are returned to help the user correct the input.

- OK let's just display the default settings for the test.

- The output appears on the right of the screen.

- Basically we have:

- A report on the calculated screening test statistics.

- An pair of full interactive graphs simulating the screening test.

- A data grid showing the table of values for all the prevalences in the specified range of prevalences.

- A reminder of how to access all documentation.

- A video describing the program.

- Buttons to download all the outputs. Reports, graphs etc.

- The report.

- Content is self-explanatory.

- It can be downloaded as text for inclusion in reports etc.

- The Graphs.

- Show full screen.

- Fully interactive. Show hover text over the displayed prevalence range.

- Zoom in or out.

- Graph content can be altered by the user dynamically using the legend.

- Static download using the plot menu.

- DOWNLOAD Button IS INTERACTIVE.

- Data Table:

- Show full screen.

- Scrollable in both dimensions.

- Can be colored and formatted to make it easier to read.

- This table is configured as output only. But it could also be configured to accept input.

- User can download the data in almost any format. The demonstration offers csv and excel.

- Excel DOWNLOAD Button preserves fields and formatting.

- Video and all media.

- Adding media to web pages is easy and can improve the value of information.

- Now let's look at really using the Screening Test program on real data.

# OLD STUFF ?V

## The tests are completely impractical for "Test To Stay".

*When using ‘Test-to-Stay’ strategies as an alternative to large-scale isolation, asymptomatic close contacts of a positive case need to do rapid antigen testing daily. When using ‘Voluntary Asymptomatic Screen Testing’ strategies, asymptomatic individuals should do rapid antigen testing 3-5 times per week.*

[Science Brief.](https://covid19-sciencetable.ca/sciencebrief/use-of-rapid-antigen-tests-during-the-omicron-wave/)

This is completely impractical in (say) a school. And yet vast resources are being spent for schools to test only once a week. [CCSU](https://www.ccsu.edu/blueprint/testing-requirements.html)

https://www.ecdc.europa.eu/sites/default/files/documents/covid-19-population-wide-testing-country-experiences.pdf