*8. Osmosis Code: OSMOSIS-105823*

**Area:** Biostatistics and Epidemiology

**Subject:** Epidemiology

**Category:** Screening

**Question:**

A 17-year-old male comes to his physician after having unprotected sexual intercourse, concerned that he might have contracted HIV. In counseling this patient about the screening test most widely used, you tell the patient that if the result is positive, a confirmatory test will be needed. This screening test can be said to have a high level of which of the following?

**Options:**

A) Negative predictive value

B) Positive predictive value

C) Prevalence

D) Sensitivity

E) Specificity

**Correct Answer:** D

**Mean:** 32

**N:**  1129

**Rationale:**

Major Takeaway

Main Explanation The screening test most commonly used to test for HIV is the enzyme immunoassay, otherwise known as the ELISA test. It works by detecting HIV antibodies that may be present in a patient's serum. The ELISA has a high sensitivity, defined as the proportion of positive cases that are correctly identified as positive. However, the specificity of the ELISA is fairly low, so false positives (uninfected individuals who test positive) are not uncommon. All individuals who test positive on ELISA then receive a confirmatory western blot, which also detects HIV antibodies in the serum. The confirmatory western blot has a high specificity, defined as the proportion of negative cases that are correctly identified as negative. A high specificity test is used to correctly identify individuals who incorrectly tested positive on the initial screen (false positives) as true negatives. A screening test should be more prone to identify healthy individuals as ill then ill individuals as healthy because the confirmatory test can later recognize false positives. It is more desirable to subject healthy individuals to additional testing than it is to miss disease in affected individuals.

*9. Osmosis Code: OSMOSIS-9733646*

**Area:** Biostatistics and Epidemiology

**Subject:** Epidemiology

**Category:** Screening

**Question:**

A new blood test to diagnose celiac disease is evaluated in 200 volunteers. Half of the study participants have biopsy-confirmed disease, and half are healthy controls. Of the patients with celiac disease, 90 are found to have a positive blood test result, while 5 of the healthy volunteers have a positive test. Based on this study, which of the following best approximates the specificity of this test?

**Options:**

A) 90/100

B) 95/105

C) 185/200

D) 90/95

E) 95/100

**Correct Answer:** E

**Mean:** -

**N:**  9

**Rationale:**

Major Takeaway

 Specificity of a diagnostic test refers to the probability that an individual without the disease of interest will receive a negative test result.

Main Explanation In evaluating a diagnostic test, the results of the test (positive or negative) are compared with the ?known? status (by the current gold standard) of individuals (diseased or healthy). One key metric of a diagnostic test is its specificity, or the probability that a healthy individual will receive a negative test result. In this study, 95 of the 100 controls have a negative blood test result. Specificity is an inherent characteristic of a given test and, unlike positive or negative predictive value, does not depend on the prevalence of the disease in the population. Like specificity, sensitivity is another metric that depends only on the test. Sensitivity represents the probability that a patient with the disease will have a positive test result. Tests with high sensitivity are useful for screening, to ensure that individuals who have the disease are identified. Tests with high specificity are appropriate for confirmatory testing, since patients who receive a second positive test most likely have the disease. Diagnosis of HIV infection, for instance, follows a two-step process: (1) screening with the highly sensitive enzyme-linked immunosorbent assay (ELISA) and (2) confirmation with the more specific Western blot.

*10. Osmosis Code: OSMOSIS-9733706*

**Area:** Biostatistics and Epidemiology

**Subject:** Epidemiology

**Category:** Screening

**Question:**

A new blood test to diagnose a rare disease (hepatic fibrosis) is evaluated in 500 volunteers. Half of the study participants have biopsy-confirmed disease, and half are healthy controls. Of the patients with hepatic fibrosis, 210 are found to have a positive blood test result, while 15 of the healthy volunteers have a positive test. The test is now administered to 1000 individuals in the general population. Which of the following is most likely to increase?

**Options:**

A) Negative predictive value

B) Positive predictive value

C) Prevalence

D) Sensitivity

E) Specificity

**Correct Answer:** A

**Mean:** -

**N:**  19

**Rationale:**

Major Takeaway

Negative predictive value refers to the probability that an individual who receives a negative test result is truly healthy, and increases as the prevalence of the disease decreases.

Main Explanation The negative predictive value of a diagnostic test is the probability that an individual who receives a negative test result does not have the disease, calculated as (number of true negatives) divided by (total number of negatives). Positive and negative predictive value both depend on the prevalence of disease in the population. If a disease is rare, healthy individuals, representing the vast majority of the population, will receive either true negative or false positive results; these counts will far outweigh the true positive or false negative results from patients with the disease. Thus, decreased prevalence of a disease will result in increased negative predictive value and decreased positive predictive value of the diagnostic test. In this scenario, the test is initially evaluated in a study population where 50% of the participants have hepatic fibrosis. When the test is administered in the general population, where the prevalence of hepatic fibrosis is much lower, the negative predictive value will increase.

*11. Osmosis Code: OSMOSIS-9733713*

**Area:** Biostatistics and Epidemiology

**Subject:** Epidemiology

**Category:** Screening

**Question:**

A new blood test to diagnose lupus nephritis is evaluated in 100 patients with systemic lupus erythematosus (SLE). Individuals with a positive blood test undergo renal biopsy for confirmatory testing. In this study, biopsies are performed for 60 participants, 50 of whom have an abnormal biopsy and are diagnosed with lupus nephritis. Which of the following is necessary to calculate the sensitivity of this test?

**Options:**

A) Number of participants with a negative blood test and a normal biopsy

B) Number of participants with a negative blood test and an abnormal biopsy

C) Number of participants with a positive blood test and a normal biopsy

D) Proportion of patients with SLE who have lupus nephritis

E) Rate of new diagnoses of lupus nephritis annually in patients with SLE

**Correct Answer:** B

**Mean:** -

**N:**  19

**Rationale:**

Major Takeaway

Sensitivity of a diagnostic test refers to the probability that an individual with the disease of interest will receive a positive test result.

Main Explanation The sensitivity of a diagnostic test is the probability that an individual with the disease will have a positive test result. Since patients with the disease will receive either true positive (TP) or false negative (FN) results, this value is calculated as TP/(TP+FN). The study has identified that 50 participants have TP results. To calculate sensitivity, the number of FN results is needed. In this study, an individual with a FN result is a patient who has a negative blood test but actually has lupus nephritis. Sensitivity and specificity are both inherent characteristics of a particular diagnostic test and are important metrics of its performance. A test with high sensitivity is appropriate for screening, as the goal is to identify all individuals who have the disease. A test with high specificity is appropriate for confirmatory testing, where the purpose is to ensure that a positive test result truly means that the patient has the disease in question.