Method Evaluation

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- It should be provided by the following:

1. accuracy.
2. Precision.
3. Sensitivity.
4. Specificity.
5. Linearity.

Sensitivity

- Ability to exclude false negative.
- Is to measure the incidence of positive results in patients known to have a condition, that is ‘true positive’ (TP).
- A sensitivity of 90% implies that only 90% of people known to have the disease would be diagnosed as having it on the basis of that test alone.
- 10% would be ‘false negative’ (FN).

Specificity

- Ability to exclude false positive.
- Is to measure the incidence of negative results in persons known to be free of a disease, that is ‘true negative’ (TN).
- A Specificity of 90% implies that only 10% of disease- free people would be classified as having the disease on the basis of the test result.
- They would have ‘false positive’ (FP) result.

Calculation

- **Sensitivity &Specificity are calculated as:**

$$\text{Specificity} = \frac{TN}{\text{all without disease } (FP + TN)} \times 100$$

$$\text{Sensitivity} = \frac{TP}{\text{all with disease } (TP + FN)} \times 100$$

Examples

- Specificity is ability to correctly identify individuals without disease.
- 1000 people tested:

1. 875 positive tests (275 false positive).
2. 125 negative tests (25 false negative).

$$\text{Specificity} = \frac{TN}{\text{all without disease } (FP + TN)} \times 100$$

$$= \frac{100}{275 + 100} \times 100$$

$$= 0.27 \times 100 = 27\%.$$

- Sensitivity is ability to correctly identify individuals with disease.
- 1000 people tested:

1. 875 positive tests (275 false positive).
2. 125 negative tests (25 false negative).

$$\text{Sensitivity} = \frac{TP}{\text{all with disease } (TP + FN)} \times 100$$

$$= \frac{600}{600 + 25} \times 100$$

$$= 0.96 \times 100 = 96\%.$$

- ***Positive Predictive Value (PPV):*** Explain the test result if +ve, that is means patients have a disease.

  PPV %= $\frac{\text{True positive}}{\text{Total positive}} \times 100$

- ***Negative Predictive Value (PNV):*** Explain the test result if -ve, that is means patients have not a disease.

  PNV %= $\frac{\text{True Negative}}{\text{Total Negative}} \times 100$

Measurement of Accuracy of Method

- **Achieved by many ways include :-**

1. **Comparison :-** by compare the method of the test with a reference method which define as a method with negligible in accuracy ,is the best comparative method that can be employed but it may be laborious ,complicated and time consuming .

- Beside that most laboratories are not staffed and equipped to perform reference methods ;for all that ,the accuracy of the method is measured using other method with known bias.

2. **Using control sera set :-** by way described in internal Q.C.

3. **Recovery :-** show whether a method measures all of the analyte or only part of it.

- Recovery define as a percentage different from the value of 100%.

- Method :- a test sample is prepared by adding small a mount of concentration analyte in diluents to the patient sample .

- Another sample is prepared from the patient specimen by dilute it with the same volume ,but containing only a diluents .both diluted specimen are then analyzed by the test method .the amount recovered is the difference between the measured value of the2 samples.

Ex :- specimen for blood glucose .

-patient specimen (without adding analyte)=100mg\dl.

-patient specimen (with 50 mg\dl glucose added)=145mg\dl

Recovery = $\frac{45}{50}$ x100 =90%

- The concentration recovery=conc. (diluted test)-original conc.
- Recovery(%) =$\frac{\text{conc. Recovery}}{\text{conc. added}}$ x100

4.Interferance method :-

- Used to measure systematic error caused by substances other than the analyte which cause these errors either by react with analytical reagent or alter the reaction between the analyte and analytical reagent. This method is similar to recovery except that the substance suspected of interference is added to the patient sample.

- Common interferences (hemoglobin (haemolysis)-bilirubin –lipids-anticoagulants –preservatives ,etc). Also turbidity.
- Interference minimized by using blank solution or what is called (test blank)to correct for other substance in the sample by adding the sample to the blank solution but without analytical reagent (reactive ingredient).

❖Standards (STD)

- STD solutions contains all chemicals and test substance with certain known concentration ,there are different type of STD used:-

1/ Primary STD:- with the substance or chemicals that is of the highest purity and can be measured directly to produce substance of exact known concentration.

- **Characteristics :-**

a. Has high M.W.

b. Stable .

c. Easily dissolved in water.

d. Don’t contain interfering substances.

2- Secondary STD:- is define as substance of low purity whose concentration is determined by comparison to primary STD.

3- Internal STD :- substance not normally present in sample or STD used .added in known a mount .it is useful to correct inaccuracy.

4- Arbitary STD :- contain un known concentration of analyte.

Using in case of immunoglobulin assay .

Normal or Reference values

- The amount of substance present in body fluid or excretions in healthy individual. The results are affected by both biological and laboratory factors.

- **Biological factors** :- make differences in test result among healthy people .include :-

1. **Age** :- for example :higher alkaline phosphates activity in growing children compared with adults.
2. **Sex** :- e.g. higher values of plasma urea in men compared with women during the reproductive phase of life.

3. **Diet &nutritional state** :- many tests affected by diet.

4. **Muscular activity :-** e.g. concentration of plasma creatinine rises following exercise.

5. **posture :-** e.g. plasma protein levels are lower in samples collected from patients when they are lying down .

6. **Time of the day :-** e.g. T3,T4 highly concentration at morning.

7. **Genetic factor.**

8. **Also weight –phase of menstrual cycle – emotional state –geographical location- climate or intrinsic haemostatic variation**

- can affect normal values (Race & rural or city life).

- **Laboratory factors :-**

1. **Type of sample :-** e.g. plasma glucose is 12-13 % higher than in whole blood .
2. **Test method :-** Normal value vary from one method to another because some methods are more specific than others .
3. **Lab accuracy** .