

Test Methods, Validation, and Verification

Quiz-Answer Key

Passing score = 80% [Answers in RED]

Select the correct answer.

1. T F New non-standard methods must be validated. (Answer: T)
2. T F A laboratory cannot use methods that they design. (Answer: F)
3. T F Range and accuracy of a validation study should never include cross-sensitivity against interferences. (Answer: F)
4. T F Validation confirms the new method meets requirements for a specific use. (Answer: T)
5. T F Data integrity procedures do not need to be implemented for computer data. (Answer: F)
6. T F Laboratory software and modifications to commercial software need to be validated. (Answer: T)
7. Policies and procedures should be (Answer: D)
 - A. Up to date
 - B. Readily available to staff
 - C. Stored under lock and key
 - D. A & B
8. Deviations from instructions need to be (Answer: D)
 - A. Accepted by the customer
 - B. Documented
 - C. Authorized
 - D. A, B & C
9. What data does not need to be checked in a systematic manner? (Answer: B)
 - A. Manual and electronic calculations and data transfers
 - B. Any Excel spreadsheet
 - C. Excel spreadsheets with calculations
 - D. A & B only
10. Deviations do not have to be (Answer: C)
 - A. Documented
 - B. Technically justified
 - C. Documented as a nonconformance
 - D. Authorized and accepted by the customer
11. Match the correct term and definition:
 - A. Policies
 - B. Processes
 - C. Procedures
 - D. Forms & records

___How to do it	(Answer: C)
___How it happens	(Answer: B)
___What we do	(Answer: A)
___What happened	(Answer: D)