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COURSE CODE: 14M1WBT332

COURSE NAME: Clinical Diagnostics

COURSE CREDITS: 03

MAX. MARKS: 15

MAX. TIME: 1-HRS

**Note**: All questions are compulsory

Q1. Explain each of the following in brief: [1 X 5]

I. Once an assay is validated and out in market as a regular diagnostic test, you think, its validity is guaranteed forever? Why or why not?

II. When would one go for:  a. Asymmetric PCR

b. Inverse PCR.

III. Polyclonal antibodies are commonly used as capture antibodies in Sandwich ELISA.

IV. " A commonly used test based on the principle of Agglutination"?

V. Positive and negative control cut-off values differs with the intended purpose for which an assay is developed?

Q2. Answer each of the following with the underlying rationale:

I. What do you understand by CT value in a qPCR? Is it meaningful to evaluate CT value during plateau phase of amplification in a qPCR reaction? Justify [2]

II. "Good antibodies are a basis of a range of clinical diagnostic tests". What do you understand by "Good Antibodies"? [1.5]

III. How can one go ahead with the process of assay development and validation, even when one has limited access to appropriate control samples to develop a diagnostic test? [1.5]

Q3. Answer each of the following: [2.5 x 2]

I. Differentiate between a direct and an indirect assay method. "For an infectious disease, both antibody-antigen based as well as nucleic acid based detection tests are available". Which one you will prefer and why? [2.5]

II. You are planning to come up with a clinical diagnostic laboratory as its coordinator. What all you would consider before you start your actual functioning diagnostic laboratory? [2.5]