CE Exam

Sterility Testing of Stem-Cell Products by Broad-Range Bacterial 16S Ribosomal DNA Polymerase Chain Reaction

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1. Which of the following is NOT a useful method for detection of bacteria in blood and stem cell products?
   A. Gram stain
   B. Culture-based methods
   C. Nucleic acid amplification test (NAT)
   D. Electron microscopy

2. Bacterial 16S ribosomal DNA (rDNA) gene consists of highly conserved regions interspersed with:
   A. 23S ribosomal DNA sequences
   B. Bacteriophage DNA sequences
   C. Introns
   D. Genus or species specific variable regions

3. Which of the following is a detection sensitivity of 16S rDNA PCR described in this study?
   A. < 0.1 CFU/mL
   B. 10-100 CFU/mL
   C. 1 x 10^3-1x10^4 CFU/mL
   D. >1x10^5 CFU/mL

4. One source of a false-positive result in 16S rDNA PCR is derived from:
   A. Non-viable bacteria in the products
   B. Blood type of the donor
   C. Leukocyte counts of the donor
   D. Low-temperature preservation of the products

5. The FDA has indicated that molecular microbiological test methods can be considered for:
   A. Classification of bacteria
   B. In-process control and release testing of the drug products
   C. Infection controls in medical institutions
   D. Prevention of infectious diseases

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