



DELIVERING THE PROMISE OF PERSONALIZED MEDICINE DIAGNOSTICS: ENABLING INNOVATION THROUGH IMPROVED REIMBURSEMENT AND MARKET ACCESS SYSTEMS

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CE QUESTIONS

1. Which organization(s) serve(s) as key accreditation programs for clinical laboratories?
a. CLIA
b. TJC (formerly JCAHO)
c. CAP
d. both A and C
2. CLIA regulations are optimized for molecular diagnostic tests.
a. TRUE
b. FALSE
3. Which accrediting agency provides regulation and an optimized checklist for molecular diagnostics and testing procedures?
a. CLIA
b. CAP
c. TJC (formerly JCAHO)
d. ASCP
4. Analytical validation of a new molecular assay should include the following:
a. disease prevalence
b. sensitivity and specificity
c. predictive values
d. all of the above
5. Which of the following factors can affect the robustness of a molecular assay?
a. type of pipette used
b. age of the instrument
c. specimen collection and preparation
d. FDA-approved test method vs. LDT test method
6. What does PCR stand for?
a. Polymerase Chain Reaction
b. Polymer Chain Residue
c. Polymerase Catalyst Reaction
d. Polymer Chemistry Reaction

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7. **What is an advantage of a molecular test over traditional microbiology culture?**
 - a. There is a faster turn-around time for results.
 - b. Infections can be identified at earlier stages.
 - c. Detection of antibiotic-resistant strains prevents misuse of ineffective anti-biotic treatment.
 - d. All of the above.
8. **Why is molecular testing becoming more feasible for even the smallest of laboratories?**
 - a. Hospital administrators have opened up additional funding for molecular diagnostics.
 - b. Simpler, easier to use, labor-saving systems are becoming more available.
 - c. Fewer patients are being admitted to the hospital.
 - d. CMS has increased reimbursement for molecular testing.
9. **Which two diseases utilize molecular methods to monitor viral loads for patient treatment?**
 - a) HIV and Influenza A
 - b) CMV and Hepatitis C
 - c) HIV and Hepatitis C
 - d) CMV and RSV
10. **How has molecular technology made a recent breakthrough for NSCLC patients?**
 - a. NSCLC patients no longer have to obtain a referral for molecular testing.
 - b. Higher reimbursement has allowed more patients to be screened for the disease.
 - c. An ALK FISH probe can now be used to identify ALK-positive patients eligible for treatment.
 - d. There are no molecular tests available for NSCLC.
11. **What is meant by the phrase "personalized medicine diagnostics?"**
 - a. "One size fits all" is no longer the best treatment plan for patients.
 - b. Each patient can have a personalized treatment plan based on molecular diagnostic results.
 - c. Each patient will have individual tests created specifically for him/her.
 - d. Both A and B
12. **What is "cost avoidance?"**
 - a. avoiding topics with costly implementation
 - b. preventative action taken to reduce future costs
 - c. the act of avoiding payment on something
 - d. avoiding the reimbursement cost determinations
13. **CLIA requires each lab to maintain documentation of the analytical validity of lab tests, but the lab is not required to demonstrate the clinical reliability or appropriateness of the test.**
 - a. TRUE
 - b. FALSE
14. **What does "LDT" stand for?**
 - a. Laboratory Differential Testing
 - b. Laboratory Designated Time
 - c. Laboratory Development Time
 - d. Laboratory Developed Test
15. **Personalized medicine already exists for what percentage of clinical pipeline products?**
 - a. 5% to 10%
 - b. 12% to 50%
 - c. 50% to 75%
 - d. less than 2%
16. **Current coding and payment for personalized medicine diagnostics fails to account for the clinical value of the diagnostic tests results and what other important point?**
 - a. reimbursement for the professionals running the test
 - b. the financial situation of the patient
 - c. the cost of developing evidence demonstrating clinical utility
 - d. third-party payers
17. **What factors impact the molecular tests that are available?**
 - a. the existence of an LDT for a specific target
 - b. whether the lab already owns a testing platform that can perform a kit-based version of the test
 - c. the reimbursement that the lab can expect for each option available
 - d. all of the above
18. **Concerns regarding future regulations for molecular reimbursement include the following:**
 - a. whether there will be different levels of reimbursement for FDA-approved tests vs. LDTs
 - b. whether payers will have the right to refuse reimbursement for molecular tests all together
 - c. that payers will not have to reimburse for any LDTs at all
 - d. none of the above
19. **Why would a value-based reimbursement system be superior to a system based on technological complexity of the test?**
 - a. It would take into account the clinical utility of the test.
 - b. It would take into account the validity of the test's effectiveness.
 - c. both A and B
 - d. neither A nor B
20. **As payment systems evolve to reconcile evidence with payment levels, who will need to take a more active role in guiding their clinical colleagues through the decision processes involved in molecular diagnostics?**
 - a. pathologists
 - b. laboratory experts
 - c. both A and B
 - d. neither A nor B

TEST ANSWER FORM

CE Test on DELIVERING THE PROMISE OF PERSONALIZED MEDICINE DIAGNOSTICS

PLUS "Molecular diagnostics is a game changer for hospital labs" and "Bridging the gap from bench to bedside" **November 2011**

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