**Course Pre-Test**

1. **How do you find the FDA test complexity of your kits or test systems?**
2. **By asking your manufacturer or sales representative**
3. **By looking on the FDA website:**

**http://www.accessdata.fda.govscripts/ccdrh/cfdocs/cfClia/analyteswaived**

1. **By calling your friends**
2. **By relying on manufacturer’s publicity**
3. **What is the CLIA requirement for performing waived tests?**

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**3. What parts of the manufacturer’s product insert should one focus on when performing waived tests?**

 **a.) Intended Use**

 **b.) Specimen Collection and Preparation**

 **c.) Storage**

 **d.) Test Procedure**

 **e.) All of the above**

1. **What is the difference between built-in controls and external controls?**
2. **They are different in name only**
3. **Built-in controls don’t have to be recorded and external controls do**
4. **External controls don’t have to be recorded and built-in controls do**
5. **Built-in controls are procedural controls within the test itself while external controls are positive and negative materials that are used like patients**
6. **As good laboratory practice, do you need to run external controls when a new kit is opened?**
7. **Yes**
8. **No**
9. **Which of the following is an example of good laboratory practice?**
10. **Do test on unlabeled specimen**
11. **Use old or outdated product inserts when testing**
12. **Recording the name of test, lot number, and expiration in the patient’s chart or elsewhere in the laboratory**
13. **Perform tests on expired reagents**