



# A Dozen Words of Wisdom from the Test Lab

White Paper

**Ensuring a successful testing regimen of a medical device is a delicate matter of close communication and a common level of understanding between the OEM and the testing solution partner. To help achieve this, one lab has shared 12 tips to aid the manufacturer in understanding the best approach to take when working with a test partner.**

While testing is a necessary evil for medical device companies, one option is to outsource the testing needs to a third party lab. As in any business relationship, good communication and knowing how the other party operates can make for a more productive relationship. Product development and testing is a game of details where a minor misstep can have devastating consequences. In the spirit of making projects go more smoothly and making the test lab/medical device company relationship that much better, following are a dozen tips test labs would like to share.

### **1. Know the Test Standard**

When using an accepted standard, such as an ASTM or ISO standard, it is a worthwhile investment to purchase and understand the standard. This allows the device manufacturer and the test lab to speak the language of the standard and address any interpretational issues.

### **2. Organize Samples and Document What Is Sent**

Upon receipt of multiple samples, test labs will organize them for upcoming testing. When samples arrive organized and clearly labeled, it saves time and prevents confusion as to which samples are which or why it looks like samples are missing (or there are too many samples). Documenting what was sent in an email or by another means also helps create a trail of information that can be used to verify what was sent against what was actually received.

### **3. Provide Set Ups**

Providing extra samples for test set ups helps the chosen lab in the event that there is a need to do any exploratory work. Sometimes, it is unavoidable and only enough samples for the actual testing can be provided. When the lab is free to use set up samples (for example, to determine the best load cell to use on a universal tester), they can destroy specimens without consequence and without unintentionally reducing the sample size.

### **4. Don't Assume the Test Lab Knows the Product Well**

Test labs do their best not to make any assumptions on the test samples they receive. A good lab will always call the device manufacturer whenever there is any uncertainty. On the manufacturer's part, be sure to tell the lab anything special that it needs to know.

## **5. Assign One Point of Contact**

Having one point of contact at the test lab and one at the device manufacturer makes communication easier for both parties. Email makes communications almost instantaneous but when multiple people chime in at different times and direct each other in divergent paths, efficiencies screech to a halt, confusion can set in, and testing, as well as test results, can suffer. Assigning a point person on each end ensures a higher degree of clarity and greatly reduces any chance for confusion between test lab and device manufacturer.

## **6. Beware of Scope Creep**

It's not unusual for test results to be different from expectations. A common reaction is to try something slightly different in hopes of getting a better result. It's also not unusual to second guess a decision during the testing and want to try a variation of the original test. Most of the time, this results in wasted efforts at a cost to the device manufacturer. Thinking ahead, making a plan, and sticking to it is usually one of the best approaches a company can take.

## **7. Completely Read and Understand the Test Lab's Quote**

The sales process, which culminates in a sales quote, can be very involved and detailed, taking several phone calls and numerous emails. While the sales professional at the test lab does his best to capture everything, it is never fun for either party to realize that something has been left out or misinterpreted that can jeopardize the customer's project.

## **8. Understand the Order of the Testing**

If multiple tests are to be performed but not enough specimens are supplied for each test, work with the lab to address the order of testing. When lack of specimens is an issue, the test order needs to be discussed. There are two general routes to consider; the first is to subject the samples to progressively more intense tests, while the second is to begin with the most robust test and work down from there. Selecting the method that makes the most sense is dependent upon several factors, such as intended use, expected operating conditions, and expected performance.

## **9. Don't Expect the Test Lab to Diagnose Unrelated Problems**

If a device fails a test, a good test lab will only comment on the testing that was performed. For a device manufacturer to depend on a test lab that may lack the expertise to diagnose, for example, a design problem, is not a good idea. The manufacturer is truly the expert on its device. Test labs can offer insight on the details of the testing but shouldn't be expected to provide advice outside its area of expertise.

## **10. Communicate Special Requests Upfront**

Special requests are not a problem but be sure to communicate them upfront so as to not delay the project. During the sales process, be sure to mention any special needs or considerations that might be required. Most labs are happy to accommodate the request provided they are informed ahead of time.

## **11. Have a Clear Objective for the Testing**

Companies that are unspecific about what the testing is to accomplish may not achieve the desired result. This relates to tip number six where planning is paramount. Having a clearly stated objective for the testing helps both parties understand the purpose of the testing and can prompt questions from the test lab that can lead to more appropriate test method selection.

## **12. Prepare Specimens to the Standard**

In an effort to save money, some manufacturers will prepare their own test specimens. If not performed correctly, the testing may be compromised or have to be redone, saving nothing in the end. If the route of preparing one's own specimens is going to be taken by a manufacturer, a short discussion with the test lab might offer several best practices that make this route worthwhile.

## **Conclusion**

Similarly when working with any design or manufacturing partner, clear communication is key to success. Maintaining that should help to ensure that many of these tips can be easily followed, resulting in a positive testing experience.

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