

FAQs for Sterility Testing



Q: How many samples are required for the test?

A: This depends on several factors.

- 1 First, what is your product? Medical devices and pharmaceuticals may have different test requirements. If your product is a pharmaceutical, you will likely be testing according to the U.S.P. The number of samples will depend on what the product is being used for, and how large your lot size is. U.S.P. has reference charts that will help you determine how many samples to send. Keep in mind that the U.S.P. test requires the use of two different media types. The sample size listed on the chart provides the number of samples, per medium, that you will need to send. So if the chart tells you 10, you will need to send 20, 10 for each medium. The same can be said for medical devices that are to be tested according to the U.S.P. test.
- 2 Second, how was your product sterilized? If your product was sterilized using Gamma radiation or E beam, typically you will follow AAMI test guidelines for a validation or dose audit. The number of samples required for an AAMI test depends on the validation method that is being used. Please reference the AAMI guidance document to determine the appropriate number of samples to be tested.
- 3 Third, if you have no idea how to answer either of the above two questions, please contact a member of Nelson Staff to determine sample numbers.

Q: What is the TAT for a sterility test?

A: Typically a Sterility test, including generation of the final report, takes about 20 days to complete. The actual incubation time is 14 days. The additional days are needed to get samples on test, score and release the samples, allow for study director review of the test data, typing of the final report, final review of the report and mailing.

GLP tests often take more than 20 days to complete. This is due to the extra documentation that is required. A protocol must be issued and approved in writing by the sponsor. The study must be tracked and audited by our QA unit, and the final test data and report must be reviewed by both the study director and the QA inspector before it can be mailed to the sponsor.

STAT tests are processed on a fast track priority. There is an additional charge to have a test placed on STAT priority. These studies are placed on test within 24 hours of login. To do this usually requires technicians to work late or over the weekend. STAT tests are also released from test first, reviewed first and reported first ahead of other studies. Their TAT is reduced to about 17 days.

Q: How do I know whether to follow U.S.P. or AAMI guidelines?

A: If your product is a pharmaceutical product, you will need to follow USP guidelines. Otherwise, it will usually depend on what type of sterilization your product has undergone. Typically, irradiated products follow the AAMI guidance and every other sterilization follows the USP. However, this is not a hard and fast rule. If in doubt, follow USP.

Q: What is the difference between the cleanroom and the isolator?

A: The main difference is how the testing technician impacts the test. In the cleanroom, the technician is fully gowned from head to toe and works in a very clean environment. The technician aseptically opens the samples and carefully transfers the sample into the appropriate test medium.



In the isolator, the technician is completely separated from the sample, which is placed inside the isolator. The interior of the isolator, the surface of the samples, and all of the equipment is fully decontaminated before the samples are tested. The technician accesses the samples through glove ports that are fully sealed to prevent contamination from the technician.

Virtually any sample can be tested in a cleanroom, however, not all samples can be tested in the isolator. Primarily due to the limited space in the isolator, but also due to the surface decontamination that must be done before testing may begin. Vapor phase hydrogen peroxide is used to decontaminate the interior of the isolator and the surface of the samples. Sample packaging must be tested to ensure that the H_2O_2 doesn't penetrate through the packaging and affect the outcome of the sterility results.

Q: How often do we check on the samples?

A: A normal sterility is observed approximately halfway through the incubation period and then again at the completion of the incubation period. If you would like your samples observed more frequently, you may request additional reads. There is an extra charge for additional reads.

Q: What is the difference between pooling samples and testing individually?

A: Pooled samples are tested together as one sample. They are all placed in the same container. When the test is released, their will only be one result reported. When samples are tested individually, each sample is placed in its own container. When the samples are scored and release, each sample will have individual results.

Pooled samples are typically liquid samples sent in for membrane filtration.

Device samples can be pooled, however it is not recommended. Some sterilization methods, such as radiation, may allow for a certain number of growing samples. Also, most regulations require individual test results for each sample tested.

Q: What is a package validation?

A: When samples are tested in the isolator unit, the samples as well as all of the media and instruments used for the tests are exposed to a decontamination cycle prior to testing. The cycle uses 35% hydrogen peroxide in a vapor phase (VHP). This sterilant can penetrate through certain packaging types and interfere with the product or the original sterilization results. Any packaging or container that will be exposed to the VHP sterilant must be validated against the chemical to ensure that only the exterior surface of the sample, media and equipment comes in contact with the VHP. Packing configurations that cannot act as a barrier to the VHP cannot be tested in the isolator.