Notice: 7-Day Incubation Period

The purpose of this notice is to explain Sterilization Monitoring Service’s (SMS) laboratory methodology regarding incubation timeline of biological indicators (BIs), or spore strips.

SMS utilizes a 7-day incubation of BIs in the laboratory. This means that tests received in our lab won’t be considered officially complete until 7 days after receipt in the lab. SMS aligns with the U.S. Food and Drug Administration’s (FDA) guidance for such a timeline. The FDA suggests that there is too significant of a difference between the percentage of growth rates of a 3-day test and a 7-day test¹.

While SMS does recognize that guidance provided by the growth media manufacturer states that incubation can stop after 3 days, SMS prefers to error on the side of caution and align with the longer incubation time to provide the most accurate results for our customers.

Please keep in mind that we will provide our customers with an immediate phone call in the event of a failed test.

Resources:


Please let us know if you have any questions or concerns.

Thanks,
Ross White