With the medical device industry continuously evolving and the demand for faster, more reliable testing solutions growing, CMDC Labs' state-of-the-art high throughput methodologies will deliver rapid and accurate results. By utilizing advanced equipment and protocols, CMDC Labs can accommodate a more significant number of samples and yield faster turnaround times, while maintaining impeccable accuracy and precision.

Key features of CMDC Labs' expanded capabilities include:

- Enhanced Capacity: With increased equipment and optimized processes, the lab can handle a higher volume of samples simultaneously.
- Faster Turnaround Times: Advanced methodologies mean results are available quicker, aiding medical device manufacturers in reducing their product launch timelines.
- Precision and Reliability: Despite the increased throughput, CMDC Labs guarantees the accuracy and reliability that clients have come to trust, meeting all ISO 17025 standards.
- Reduced Cost to Customers: With the new technology deployed, CMDC Labs can offer significant savings for ongoing release testing.

CMDC Labs' expanded high throughput bioburden and sterility testing services are now available to medical device manufacturers globally. With a team of expert scientists and technologists on board, the laboratory is prepared to address complex challenges and deliver dependable results.

International Organization for Standardization ISO 17025 ACCREDITED LABORATORY

CMDC Labs

BIOBURDEN/ STERILITY TESTING

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What is Bioburden Testing?

The Bioburden Test determines the total number of viable microorganisms in or on a medical device, container, or component. It is performed on any product that requires control and/or monitoring of bioburden counts, usually as part of a sterilization program. This test acts as an early warning system for possible production problems that could lead to inadequate sterilization. It is also used to calculate the necessary dose for effective radiation sterilization and to monitor product routinely as part of quarterly dose audits.

CMDC Labs performs this test in accordance with ANSI/AAMI/ISO 11737-1 and is most commonly referenced in the Radiation Sterilization standards (ANSI/AAMI/ISO 11137-1 & 2) and the EO Sterilization standard (ANSI/AAMI/ISO 11135).

Applicable Standards

- ANSI/AAMI/ISO 11737
- ANSI/AAMI/ISO 11137
- ISO 11135
- USP<85>
- EN 13795

Why use CMDC Labs for your Bioburden Testing

No regulatory submission can be complete without bioburden testing. CMDC Labs can provide the expertise to keep your submission on track with our Bioburden Testing services.

Bioburden testing allows device manufacturers to determine the microbial load on their product. A client's non-sterile product is introduced to a process that provides the opportunity for recovering microorganisms present on or in the product. This process includes product specific disassembly/dissecting, one or more rinsing steps, potential membrane filtration of the rinsing fluid, and transfer of the membrane filters to growth media for microorganisms. After incubation at the chosen conditions, the microorganisms are counted in colony forming units (CFU/filter) for calculation of the bioburden.

CMDC Labs has a complete understanding of the Bioburden Testing execution process. Our expertise, along with our full suite of product types necessary for testing, will ensure you receive complete and accurate results for your regulatory submission.

CMDC Labs laboratories are best equipped, authority approved, and experienced in Bioburden Testing. With our full service offering, CMCD Labs Device Testing will ensure accurate results for your regulatory submission.

Choose CMDC Labs Device Testing to help you:

- Ensure a level of cleanliness by determining the presence or absence of bioburden on your sterile or non-sterile medical device, according to requirements of ISO 11737-1, ISO 11737-2, ISO 11137-2, and USP<85>.
- Understand the worst-case master product for your bioburden testing.
- Complete your sterilization validation using VDmax or other methods compatible with your device.
- Confirm your validation meets all regulatory requirements for USP <61>, USP<85> & ISO 11737-2.
- Execute your routine sterilization dose audits for all product families.
- Determine the quantity of samples needed to complete bioburden testing on your medical device.
- Overcome challenges based on your medical device's material composition and configuration

Routine Testing

Routine testing of medical devices should be performed to demonstrate that the manufacturing process remains in control. The appropriate frequency and number of samples depend upon the sterility assurance level (SAL), type of product, type of sterilization used, environmental control, and the process controls of the manufacturer.

In order to validate a bioburden test, a recovery efficiency needs to be performed. There are essentially two approaches available: repetitive treatment (also referred to as exhaustive recovery) or product inoculation. Ideally, a recovery efficiency should be established prior to the start of any bioburden test. It should be performed on a minimum of three samples. The recovery efficiency is then validated and can be applied to all future testing of that product.