



VeriTest Multi Process Challenge Devices

Instructions for Use No 001

Included Products:

- VeriTest Tags
- VeriTest Multi Basic
- VeriTest Multi 360

Included Processes:

- Cleaning Effectiveness Mapping
- Process Verification
- Routine Process Monitoring

For best results, read the entire instruction manual before using VeriTest devices.



General Warnings and Cautions



Read and understand this manual before using VeriTest family products.



Always wear gloves when handling VeriTest Tags.



VeriTest contain raw animal blood and tissue.

User Assistance

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Storage and Shelf Life

VeriTest devices should be stored in a dry place at temperatures between 5°C and 25°C.

VeriTest Tags have a shelf life of 12 months from the date of manufacturing and is indicated with a "Best Before" date on the packaging label.

Environmental conditions that may affect use

Washers and Washer Disinfectors that VeriTest family of PCDs are designed to evaluate use various types of chemicals in their cleaning processes. These Chemicals are an essential addition to the processes that break down contamination. However, some chemicals may adversely affect some plastic materials.

With the variety of commercially available chemicals, it is not possible to test the compatibility of PCDs with all existing chemicals. Whenever there is suspicion of detrimental effect on VeriTest components – PCDs should not be used.

In cases where a detrimental effect is observed on VeriTest components in the form of chemical damage, cracking, discolouration etc. PCDs should not be used thereafter and the particular chemical should be reported to Aseptium Limited.

Accidental Exposure

Eyes: Immediately flush eyes with water for 15 minutes. Seek medical attention if irritation persists.

Skin: Immediately wash with soap and water. Seek medical attention if irritation develops.

Ingestion: Drink plenty of water and seek medical advice.

Inhalation: Remove affected person to fresh air. Seek medical attention in cases of breathing difficulty.



1. Purpose of the device

VeriTest is a family of process challenge devices (PCDs) created to help evaluate the effectiveness of cleaning processes used to clean surgical instruments.



2. Description of the device

VeriTest Automatic Washer (AW) Tags



- Surgical grade stainless steel tags inoculated with a 100% natural test soil.
- Emulates soiled surgical instruments in a way that is clinically relevant.
- Automatic Washer tags (AW) is designed to test automatic washers, as well as ultrasonic washer and their wash cycles.

AW tags are to be used with accompanying VeriTest Devices (VeriTest Multi Basic / VeriTest Multi 360)

For a detailed comparison of VeriTest Tags consult IFU 002.



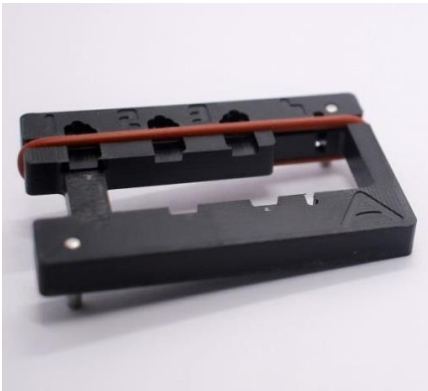
VeriTest Total Process Control (TPC) Tags



- Surgical grade stainless steel tags inoculated with a 100% natural test soil.
- Emulates heavily soiled surgical instruments in a way that is clinically relevant.
- Total Process Control (TPC), created for assessment of the entire cleaning processes.

TPC tags are to be used with accompanying VeriTest Devices (VeriTest Multi Basic / VeriTest Multi 360)

For a detailed comparison of VeriTest Tags consult IFU 002.



- Most comprehensive test within VeriTest family of PCDs.
- Consists of a specially designed holder which accommodates four VeriTest Tags (AW or TPC).
- The four locations each represent a unique challenge that emulates the most difficult to clean physical aspects of surgical instruments.
- Tags are designed to fit in the VeriTest Multi Basic Block in one orientation only, meaning correct assembly every time.
- Three-dimensional cleaning evaluation with the following four challenges:
 1. Narrow Gap Cleaning / Box Joint
 2. Bottom Surface Cleaning
 3. Top Surface Cleaning
 4. Cleaning of Angled Vertical Surface

VeriTest Multi 360

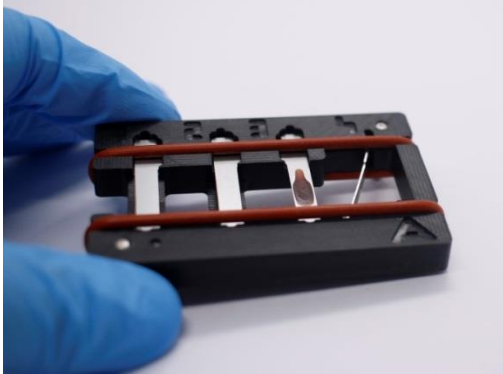


- VeriTest Multi 360 is an all-in-one consumable device.
- No assembly required – comes with VeriTest tags already inserted for quick and easy use.
- Three positions testing different challenges in three dimensions:
 1. Narrow Gap Cleaning / Top spray arm
 2. Bottom Surface Cleaning
 3. Cleaning of Angled Vertical Surface



3. Setup Instructions

VeriTest Multi Basic

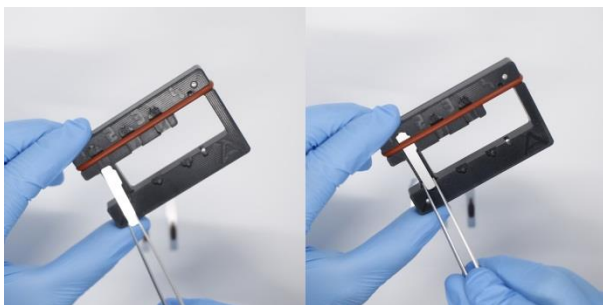


- VeriTest Multi Basic Block requires VeriTest tags to be inserted into the four locations seen.
- When assembling the VeriTest Multi Basic Block, always use gloves to avoid contamination.
- Forceps may be used to assist assembly.
- Ensure the test soil is not damaged in the process as this may affect results.
- Aseptium recommends using four tags simultaneously to ensure total process evaluation.

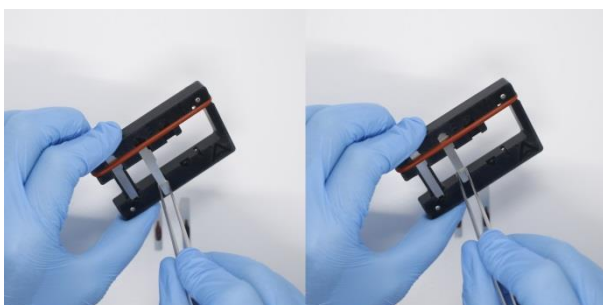
Loading VeriTest Tags into the VeriTest Multi Basic Block



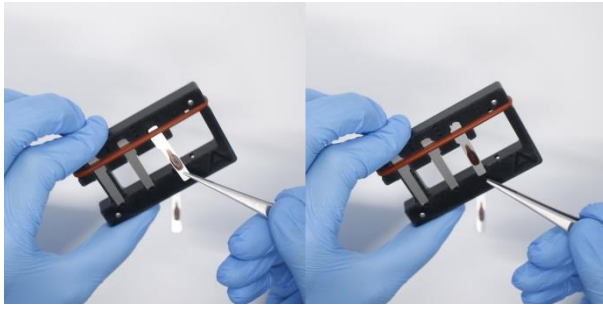
1. Remove VeriTest Tags from their protective packaging.
2. Using gloves, remove four VeriTest Tags from the strip of tags.



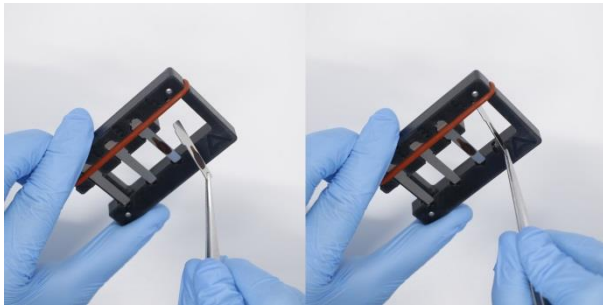
3. Insert the first VeriTest Tag in location one with the soil facing down, ensuring the VeriTest Tag is secured with the silicone band



4. Insert the second VeriTest Tag in location two with the test soil facing down, ensuring the VeriTest Tag is secured with the silicone band.



5. Insert the third VeriTest Tag in location three with the soil facing up, ensuring the VeriTest Tag is secured with the silicone band.



6. Insert the fourth VeriTest Tag in location four with the soil facing out to the right, ensuring the VeriTest Tag is secured with the silicone band.



7. The VeriTest Multi Basic is now ready for use.

VeriTest Multi 360



- VeriTest Multi 360 comes pre-assembled with VeriTest Tags already loaded into the three locations.
- Simply follow the guide for Cleaning Effectiveness Mapping, Process Verification or Routine Process Validation.



4. How to Use VeriTest Multi Devices

VeriTest Multi Device Overview

VeriTest Multi Devices (Both Basic and 360) are used in three main ways:

A. When introducing the VeriTest Multi into your process or a new washer, the first stage is what we call “Cleaning Effectiveness Mapping”. This involves testing different locations in either an Automatic Washer or Ultrasonic Washer to evaluate the washer’s baseline cleaning performance and to identify the location with poorest cleaning performance.

Cleaning Effectiveness Mapping should take place when introducing VeriTest to a department for the first time, when using a new washer or whenever a major change is made that may affect cleaning.

Cleaning Effectiveness Mapping uses an “empty” washer without a load of instruments.

B. The second use of VeriTest Multi Devices is for Process Verification. This method should be used whenever a change has been made to the washer, or when introducing a new chemical or wash cycle.

Process Verification uses a “full” washer with a load of instruments to emulate normal conditions.

C. The third use for VeriTest Multi Devices is Routine Process Monitoring. This involves testing the washers routinely, according to local/national regulations and evaluating the results to ensure compliance with relevant guidelines/limits of contamination.

Routine Process Monitoring uses a “full” washer with a load of instruments under normal conditions that are intended to be cleaned for use.



5. Cleaning Effectiveness Mapping

When to Perform Cleaning Effectiveness Mapping

It is recommended that departments perform Cleaning Effectiveness Mapping under the following circumstances:

1. When introducing VeriTest to a department for the first time.
2. Quarterly to ensure maintained performance.
3. When introducing VeriTest Multi Devices to a washer for the first time.
4. Any time a major repair/change has taken place that may affect process performance
5. Any time there is a change in chemistry (type of chemical used) or to process parameters.

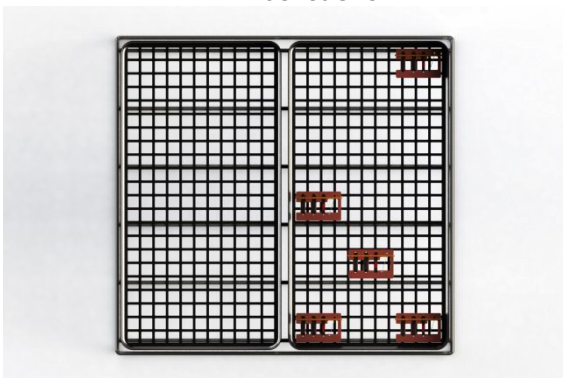
Mapping of Automatic Washers

Wash basins of Automatic Washers and their accompanying instrument carriers are diagonally symmetrical (front left corner identical to Back right corner due to rotation of the spray arms). This means that when mapping the wash chamber of an Automatic Washer, VeriTest Multi devices can simply be placed in one half of the instrument carrier on each level, while still capturing the entire wash capabilities of the chamber. Only one VeriTest Multi should be used per shelf/level.

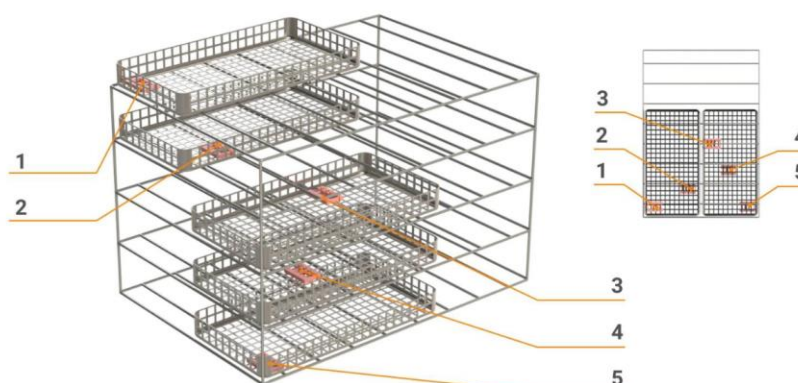
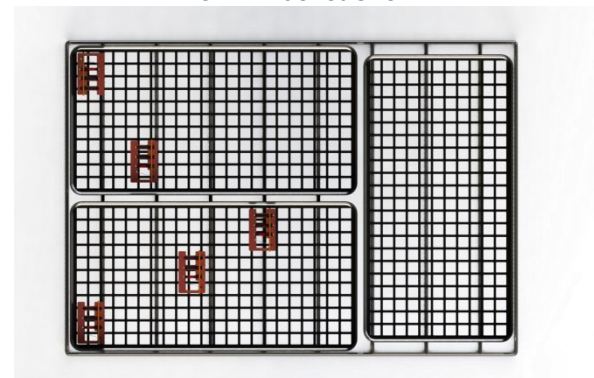
NOTE: IN CASES WHERE CARRIERS ARE ASYMMETRICAL, CARE SHOULD BE TAKEN TO PLACE VERITEST MULTI DEVICES IN ALL MAJOR LOCATIONS OF THE BASKET TO ENSURE COMPREHENSIVE COVERAGE AND ANALYSIS OF LOCATIONS.

Whether the Automatic Washer being evaluated accommodates two or three din baskets on each level, the same methodology should be used. Below are examples of how to arrange VeriTest Multi Devices in both instances.

2 Din Basket Shelf



3 Din Basket Shelf





Mapping of Automatic Washers: Setup & Assessment Guide

1. Remove VeriTest Tags from protective packaging and load into the required number of VeriTest Multi Basics as previously demonstrated. (For VeriTest Multi 360, simply remove from packaging – no assembly required).
 2. Position the Multi Devices as follows: 1 per shelf/level in a single location, with a different location for each shelf/level.
 3. For each shelf/level, record the level and position using the corresponding results document relating to the type of VeriTest Multi and washer being used (see IFUs 003 – 006).
 4. Run a wash cycle identical to what is used routinely on normal loads*.
 5. Starting at the bottom shelf/level, remove the carrier and carefully remove the individual VeriTest Multi Devices, ensuring their location within the washer is known and recorded.
 6. Using fresh gloves and, if required, forceps, remove the VeriTest Tags from the Multi Device and place on the corresponding result sheet relating to the type of VeriTest Multi and washer being used (see IFUs 003 – 006).
 7. Assess the level of contamination present using one of the following methods:
 - a) IFU 007 “Universal Scale of Contamination”
 - b) Protein Quantification method (VeriTest Blue, ProReveal etc.)
- Record the results in the “Results” column.
8. Repeat steps 4 to 6 for each VeriTest Multi Device on each shelf/level of the washer until every location has been assessed.
 9. Once all results have been recorded, dispose of used VeriTest Tags in an appropriate manner.
 10. Finally, consult IFU 008 “Cleaning Effectiveness Mapping Troubleshooting Guide – Automatic Washers” for a detailed analysis of results and identification of common issues that may impede cleaning.

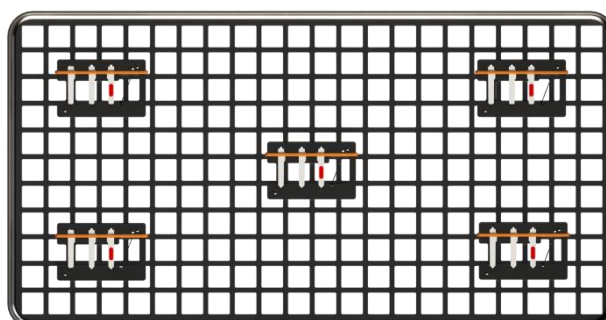
IMPORTANT: WHEN DONE CORRECTLY, THE MAPPING PROCESS WILL IDENTIFY THE AREA IN A WASHER WITH THE POOREST CLEANING PERFORMANCE. THIS LOCATION MUST BE RECORDED AND SHOULD BE USED FOR ROUTINE PROCESS MONITORING.

*If all VeriTest tags are completely clean, run the process again but instead of running a full wash cycle, stop the cycle halfway through the main wash (portion of the cycle where the chemical is administered).

Mapping of Ultrasonic Washers

In Ultrasonic Washers, it is important to assess every major location of the washer as the coverage of the Ultrasonic Transducers can vary throughout the bath. For this reason, each section of the basin should be assessed using the following set up.

For larger baths, simply split the bath into two halves and create the same five-multi-setup as seen in the image below in each of the two halves side by side.





Mapping of Ultrasonic Washers: Setup & Assessment Guide

1. Remove VeriTest Tags from protective packaging and load into the required number of VeriTest Multi Basics. (For VeriTest Multi 360, simply remove from packaging – no assembly required).
2. Position the Multis as seen in the above images.
3. For each VeriTest Multi Device, record the position using the corresponding results sheet relating to the type of VeriTest Multi and washer being used (see IFUs 003 – 006).
4. Run a wash cycle identical to what is used routinely on normal loads*.

NOTE: ULTRASONIC WASHERS MAY EFFECTIVELY REMOVE SOIL AND LEAVE IT SUSPENDED ABOVE THE VERITEST TAG. TO ENSURE NO SOIL REMAINS SUSPENDED ABOVE THE TAG, GENTLY AGITATE THE VERITEST MULTI DEVICE WHEN SUBMERGED IN WATER TO REMOVE ANY SUSPENDED SOIL.

5. Remove the carrier and carefully remove the individual VeriTest Multi Devices, ensuring their location within the washer is known and recorded.
6. Using fresh gloves and, if required, forceps, remove the VeriTest Tags from the Multi Device and place on the corresponding result sheet relating to the type of VeriTest Multi and washer being used (see IFUs 003 – 006).
7. Assess the level of contamination present using one of the following options:
 - a) IFU 007 “Universal Scale of Contamination”.
 - b) Protein Quantification method (VeriTest Blue, ProReveal, etc.)

Record the results in the “results” column.

8. Repeat steps 4 to 6 for each VeriTest Multi Device in the washer until every location has been assessed.
9. Once all results have been recorded, dispose of used VeriTest Tags in an appropriate manner.
10. Finally, consult IFU 009 “Cleaning Effectiveness Mapping Troubleshooting Guide – Ultrasonic Washers” for a detailed analysis of results and identification of common issues that may impede cleaning.

IMPORTANT: When done correctly, the mapping process will identify the area in a washer with the poorest cleaning performance. This location must be recorded and should be used for Routine Process Monitoring.

It is expected that Ultrasonic Coverage should be uniform. As such, this may result in negligible differences between location and cleaning performance. In this instance, any location can be used for routine monitoring. It is recommended however, that the same location be used throughout each Routine Monitoring process.

*If all VeriTest tags are completely clean, run the process again but instead of running a full wash cycle, stop the cycle halfway through the main wash (portion of the cycle where the chemical is administered).



6. Process Verification

When to Perform a Process Verification

It is recommended that departments perform a Process Verification under the following circumstances:

1. When the programmed wash cycle has been changed.
2. When a new chemical is being used.
3. When the washer has undergone a major repair/change.

Process Verification of Automatic Washers & Ultrasonic Washers

Process verification follows the same setup and steps as seen in section A. Cleaning Effectiveness Mapping for both Automatic Washers and Ultrasonic Washers, with one main difference.

The difference is that the process should be performed **alongside a regular load of instruments**, as this provides information on how the specific process will perform under normal circumstances.

Aseptium recommends repeating this process for a total of three times. Repeating the process reduces the risk of random errors and provides a more accurate analysis of the process being evaluated.

Following the guidelines in section A, the results should then be used with the following troubleshooting guide depending on the type of washer:

- Automatic Washers: IFU 010 "Process Verification Troubleshooting Guide – Automatic Washer"
- Ultrasonic Washers: IFU 011 "Process Verification Troubleshooting Guide – Ultrasonic Washer"



7. Routine Process Monitoring

When to perform Routine Process Monitoring

It is recommended that departments perform a Process Verification under the following circumstances:

1. As often as required by local/national guidelines
2. According to your department's specifications

NOTE: ASEPTIUM RECOMMENDS PERFORMING ROUTINE PROCESS MONITORING ON EACH WASHER EVERY WASH CYCLE TO ENSURE OPTIMAL PERFORMANCE AND TO IDENTIFY ANY ISSUES AS THEY APPEAR.

Routine Process Monitoring Overview

- Routine Process Monitoring should be performed alongside a normal load.
- Aseptium recommends using the location identified to have the poorest cleaning performance (identified using Cleaning Effectiveness Mapping) as the location to be used during Routine Process Monitoring, as this location is the best indicator of the process/washer's cleaning performance.
- The purpose of Routine Process Monitoring is to identify any issues with equipment and to ensure optimal levels of cleaning and to allow departments to comply with relevant regulations.

Routine Process Monitoring of Automatic Washers & Ultrasonic Washers: Setup & Assessment Guide

1. Remove VeriTest Tags from protective packaging and load into a single VeriTest Multi Basic Device (For VeriTest Multi 360, simply remove from packaging – no assembly required).
2. Position the VeriTest Multi Device into the washer – Aseptium recommends using the position identified to have the poorest cleaning performance determined using Cleaning Effectiveness Mapping.
3. Run a wash cycle identical to what is used routinely on normal loads until 100% completion.
4. Remove the VeriTest Multi Device from the washer.
5. Using fresh gloves and, if required, forceps, remove the VeriTest Tags from the Multi Device and place on the corresponding results sheet relating to the type of VeriTest Multi and washer being used (See IFUs 003 – 006).
6. Assess the level of contamination present using one of the following options:
 - a. IFU 007 "Universal Scale of Contamination"
 - b. Protein Quantification method (VeriTest Blue, ProReveal, etc.)

Record the results in the "Results" column.

7. Consult the troubleshooting guide that corresponds to the type of washer used to identify any issues:

- Automatic Washers: IFU 012 "Routine Process Monitoring Troubleshooting Guide – Automatic Washers".
- Ultrasonic Washers: IFU 013 "Routine Process Monitoring Troubleshooting Guide – Ultrasonic Washers".

8. Ensure all results are recorded appropriately.