



aseptium

Innovative Decontamination Solutions

VeriTest Process Challenge Devices

Instructions for Use

Included Products:

VeriTest Blue

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

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User assistance

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General warnings and cautions



Read and understand this manual before using VeriTest family products.



Always wear gloves when handling VeriTest Tags and VeriTest Blue Vials.



Always wear protective goggles when handling an open VeriTest Blue Vials.



VeriTest Tags contain raw animal blood and tissue.



VeriTest Blue contains Phosphorous Acid that is corrosive.



1. Purpose of the device



Fig 1. VeriTest Blue

VeriTest Blue is a protein detecting test for evaluation of residue contamination on VeriTest Tags after the cleaning process. VeriTest Blue is a part VeriTest Process Challenge Device Family are a family of process challenge devices (PCDs) created to help verify effectiveness of cleaning processes for medical devices.

VeriTest Blue allows not only to detect contamination but also to quantify it with the intensity of colour change. Colour changes from light green(brown) to blue.

VeriTest Blue is designed as a visual test that can be assessed by naked eye as well as automated devices.

2. Description of the device



Fig2.1 VeriTest Blue Vial

VeriTest Blue

VeriTest Blue are small transparent vials with removable caps that contain protein sensitive reagent. Once reagent is exposed to contamination containing proteins (bodily fluids, organic content) it changes colour. The intensity of the colour change is proportional to the quantity of contamination.

VeriTest Blue detects microgram level of contamination and is suitable for the most demanding cleaning challenges.



Fig2.1 VeriTest Tag

VeriTest Tag

VeriTest Blue are specially designed to assess contamination on VeriTest Tags. Vials size and shape were selected to minimise the amount of the reagent required to read the tag and this way increase the sensitivity of the test. The volume of the reagent is enough to submerge the entire Tag once it is inserted into the vial ensuring all surfaces are exposed to the reagent.

VeriTest Blue was designed to directly measure contamination left on VeriTest Tags.

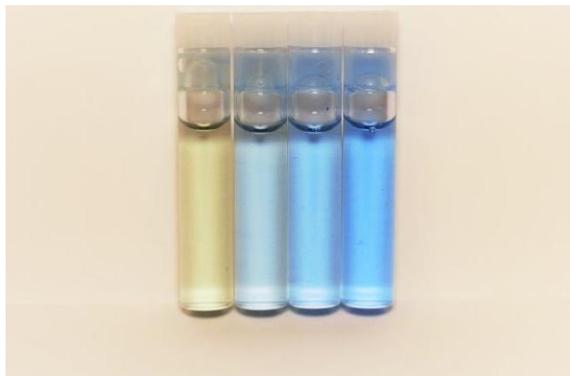


Fig2.2 VeriTest Blue BSA calibrated scale.

VeriTest Blue Reading Scale

Visual Inspection of contamination relies on assessing the magnitude of colour change. It can be done by comparison of the colour in the vial and assessing it against the printed scale. Scale is calibrated against the specific quantities of the Bovine Serum Albumin (BSA).

VeriTest Blue Scale was calibrated for residual contamination on VeriTest Tags and should not be used to assess contamination on other devices as it will not be accurate.

3. Environmental conditions that affect use

VeriTest Blue contains phosphoric acid that is corrosive and may cause damage to organic and inorganic matter. Consult the Material Safety Datasheet for details.

VeriTest Blue should be stored in a dry and dark place (ideally in pouches provided) as long term exposure to sunlight may affect the accuracy of the test. For best repeatability of the test keep VeriTest Blue refrigerated at between 2°C and 4°C during storage.

4. Setup instructions

Aseptium's VeriTest Blue is intended for use with VeriTest Tags only. Always wear protective gloves when handling VeriTest Tags. A pair of small forceps may be used to help with handling of the Tags.

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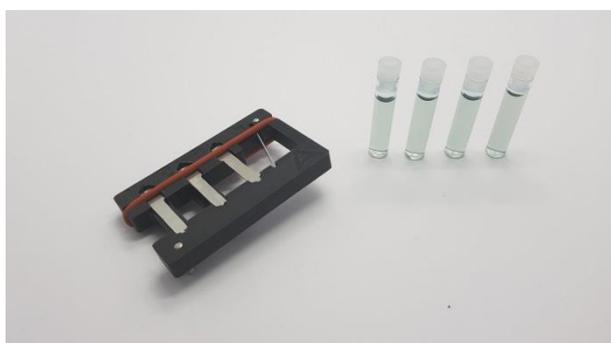


Fig 4. VeriTest Tags and Vials

1. Prepare a clean surface to work on (i.e. put a clean protective sheet of paper on the worktop surface)
2. Prepare a new VeriTest Blue Vial for each VeriTest Tags to be evaluated – Fig 4.
3. Ensure you wear appropriate personal equipment.
4. Pay attention not to further contaminate the VeriTest Tags in the process as test will be inaccurate.



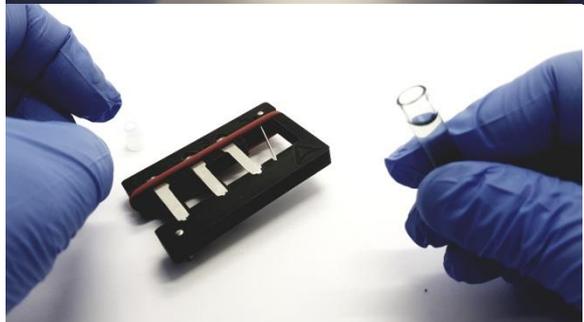
4.1 Operating Instructions

VeriTest Blue allow to quickly evaluate residual contamination after the cleaning process.

In order to evaluate the contamination on surfaces after cleaning follow below instructions:



1. Open a vial.



2. Put the cap upside down to protect the part of the cap that gets in contact with the protein sensitive reagent from contamination.



3. Holding the tag by the wider end or by the sides carefully insert the tag into the vial.



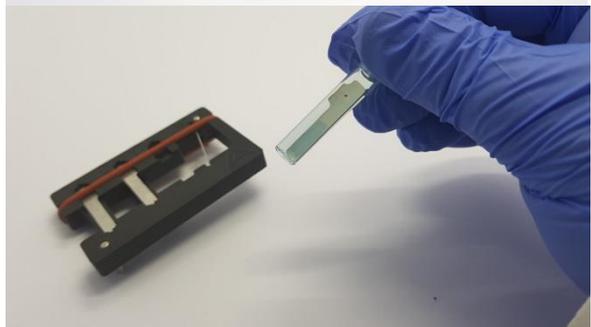
4. Put the cap back onto the vial and seal it.



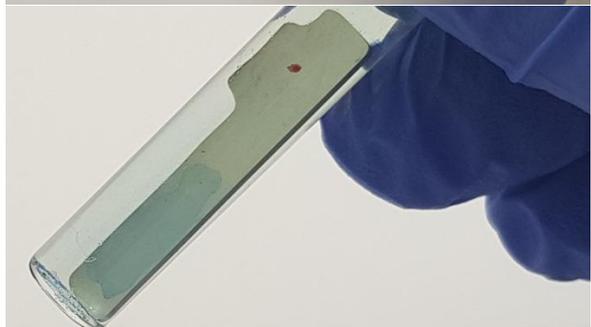
5. Shake the vial vigorously for 30 seconds.



6. Rest the Vial for 5 minutes



7. Evaluate the colour change of the fluid or blue residue on the surface of the tag.



8. Roll the Vial in your fingers to observe the tag under different angles. Contamination may dissolve in the reagent or stay on the surface of the tag as a blue residue.

- If any change is observed the tag cannot be considered clean.
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9. Record the results.

- For best results use one of Aseptium's testing schedule forms.





5. Cleaning process Evaluation – Interpretation of Results

What has to be considered is that surface contamination is evaluated on the surface of VeriTest Tags after the cleaning process. During the cleaning process contamination gets exposed to different types of cleaning chemicals and processes and therefore can react differently to the reagent. In some cases proteins can be still strongly stuck to the surface and after exposure to the protein detecting reagent will form a blue residue on the surface of the Tag without a significant change of the reagent colour – Fig 5.a. In other cases contamination may dissolve in the reagent and change the colour of the solution to light blue – Fig 5.b.

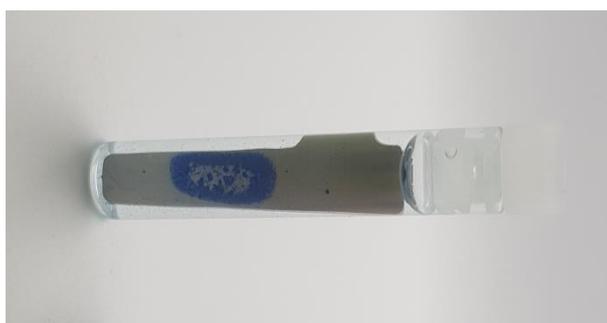


Fig 5.a. Blue residue - Surface contamination detected.

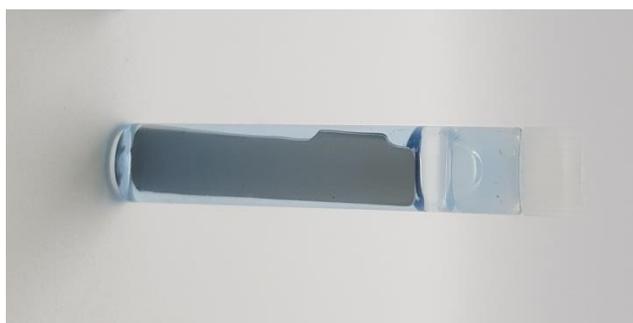


Fig 5.b. Dissolved contamination – reagent turns blue.

The magnitude of the colour change is linked to the amount of contamination on the Tag – the more intense the blue colour the more contaminated the sample. VeriTest Blue is designed as a visual test that helps to highlight contamination. It can be also read with automated readers and produce quantifiable results.

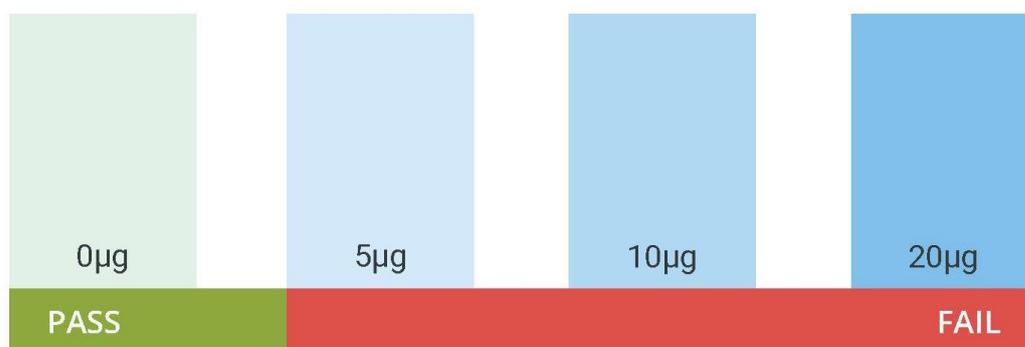


Fig 5.d. VeriTest Blue Protein detection chart.

VeriTest Blue are provided with a colour scale – Fig 5.d. This scale was calibrated in the laboratory (Fig 5.c) against specific amounts of Bovine Serum Albumin protein.

If contamination is dissolved in the reagent and it changed colour simply put it against the scale and find the closest match. Once the quantity is known compare it with the local guidelines.



6. Troubleshooting disclaimer

Cleaning cycles can be affected by multiple variables and random events. All troubleshooting contained within this document is presented as exemplary cases and these should not be the ultimate basis for any decision making. Aseptium does not accept any responsibility for following instructions contained in this document.

7. Storage

VeriTest Tags as well as accessories should be stored in a dry place at temperatures between 5°C and 25°C.

Please note that in the case of VeriTest Lumen the shelf life of these accessories is reduced to 6 months from the first use or 240 cycles.

Dispose of used/expired VeriTest Tags and Accessories into the medical waste bin. Packaging is widely recyclable.

8. VeriTest Blue Troubleshooting

If new VeriTest Blue liquid is blueish straight out of the packet compare with other vials from the pack and if the colour is different do not use.

If the volume of the reagent in the VeriTest Blue vial is significantly different from other unopened vials check for leaks on the cap and do not use.

Never open VeriTest Vials without gloves and eye protective equipment.

9. Accidental Exposure

Dermal exposure:	In case of contact, wash skin with soap and copious amounts of water for at least 15 minutes. Take off all contaminated clothing, and wash before reuse.
Eye exposure:	In case of contact, flush eyes with large amounts of water for at least 15 minutes. Consult a physician.
Inhalation exposure:	If directly inhaled, remove to fresh air, if breathing is difficult, provide oxygen if necessary. If not breathing, provide artificial respiration. Consult a physician.
Oral exposure:	If swallowed, wash mouth with water provided person is conscious. Consult a physician.

Please refer to the Material Safety Data Sheet for further instructions.