



VeriTest Blue

Instructions for Use

Included Products:

VeriTest Blue

VeriTest Tags

VeriTest Blue Reading Scale

Included Processes:

Setup Instructions

Operating Instructions

Interpretation of Results

VeriTest Blue Troubleshooting

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

IFU NO 014

Release 01.002

Date 02.09.2020

Copyright Aseptium Limited 2020



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.



VeriTest Blue contains Phosphoric Acid that is corrosive.

To access the VeriTest Blue MSDS [click here](#).

User Assistance

Aseptium Limited Address:

Solasta House
8 Inverness Campus
Inverness
IV2 5NA
Scotland
UK

Telephone: +447853200379

Email: info@aseptium.com

Storage and Shelf Life

1. VeriTest devices should be stored in a dry place at temperatures between 5oC and 25oC.
2. 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.

VeriTest Blue should be kept away from light. For this reason it is packaged in a resealable packet.

3. VeriTest Blue has a shelf life of 12 months from the date of manufacturing. Please consult the label on the resealable packaging. Any vials of VeriTest Blue that have past their "Use by Date" should be disposed of appropriately.

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: Wash mouth with plenty of water. Seek medical attention.

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



For a detailed guide on the safety of VeriTest Blue, please refer to the Material Safety Data Sheet (MSDS) located at the following link: [click here](#).

1. Purpose of the Device



VeriTest Blue is a protein detection method designed specifically for use with VeriTest Tags. VeriTest Blue changes colour from light yellow/green to varying intensities of blue in the presence of protein.

The VeriTest Blue reagent has been meticulously designed to allow quantification of protein residue (μg) when used with the accompanying colour-change scale.

VeriTest Blue should be used on tags with low levels of residual protein as described in IFU 007 "Universal Scale of Contamination".

Results from VeriTest Blue can be used to determine whether the cleaning process has sufficiently removed protein to the specified amounts described in local/national guidelines.



2. Description of the Device

VeriTest 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 (left) – designed to test automatic washers as well as ultrasonic washer and their wash cycles.

Total Process Control (middle) – designed to assess the entire cleaning process.

FlexE (right) – designed to be used with accompanying FlexE capsule and tube to test the cleaning of flexible endoscope channels/lumen.

Each of these tags is compatible with VeriTest Blue.

VeriTest Blue



VeriTest Blue consists of a chemical reagent designed at Aseptium which presents a colour change when in contact with protein molecules.

Specifically designed to work with our range of VeriTest Tags according to their size and the quantity of protein present on each Tag.

Detects protein residue between 0µg - 20µg.

Colour change from light green/yellow to blue.

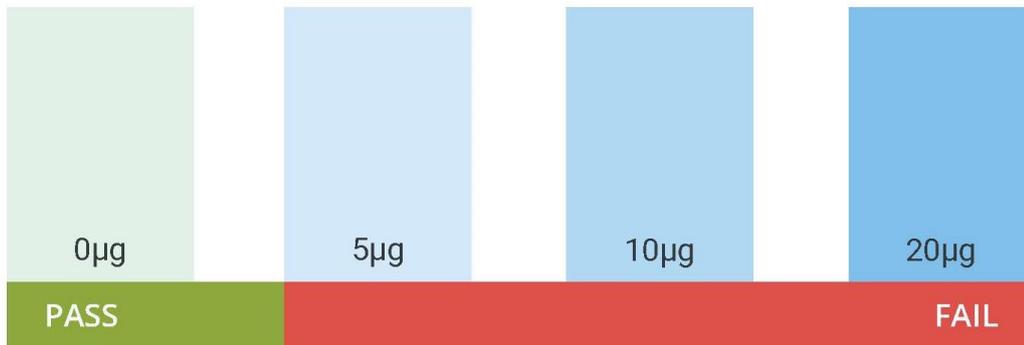
Intensity of blue colour strengthens as protein residue levels increase.

To be used with the accompanying VeriTest Blue Colour Scale.



Description of the Device, continued.

VeriTest Blue Colour Scale



- The accompanying colour scale allows the user to compare their VeriTest Blue vial containing the cleaned tag and match the colour of the reagent.
- This gives a semi-quantification of residual protein levels and can indicate whether the cleaning process has removed protein to an acceptable level.*

*The level of residual protein that is deemed acceptable varies depending on local/national regulations. Some countries may not require detail on residual protein levels. Please consult the relevant guidelines/regulations that set out your local/national requirements.



3. Setup Instructions



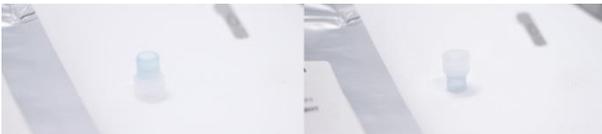
1. Wear PPE before handling VeriTest Blue or VeriTest tags. Fresh gloves should always be used.
2. Prepare your work surface with either a protective mat or paper as VeriTest Blue may stain surfaces if spilt. If spilling does occur, use an absorbent and dab the affected area. Any stains can be removed with isopropyl alcohol or any alcohol based cleaner.
3. Use a separate VeriTest Blue Vial for each VeriTest Tag to be analysed.
4. VeriTest Blue is for use on tags that have been cleaned but may still possess residual protein. Consult IFU 007 for details on what type of tag to analyse using VeriTest Blue.
5. When handling cleaned VeriTest Tags, take care not to contaminate the Tags as this will lead to inaccurate results. Tags should be removed from the respective holder using forceps and placed directly into an opened VeriTest Blue Vial.
6. When retrieving the necessary amount of VeriTest Blue Vials, inspect for any leakages, damaged vials or noticeable differences in volume of reagent. Any defects should be reported back to Aseptium.



4. How to Use VeriTest Blue



1. Carefully open the VeriTest Blue vial using your thumb and forefinger.



2. Place the cap upside-down on a clean surface to avoid contamination, as the inner side will be in contact with the reagent.



3. Using either your gloved hands or forceps, grasp the wider end of the VeriTest Tag and place it into the open vial.



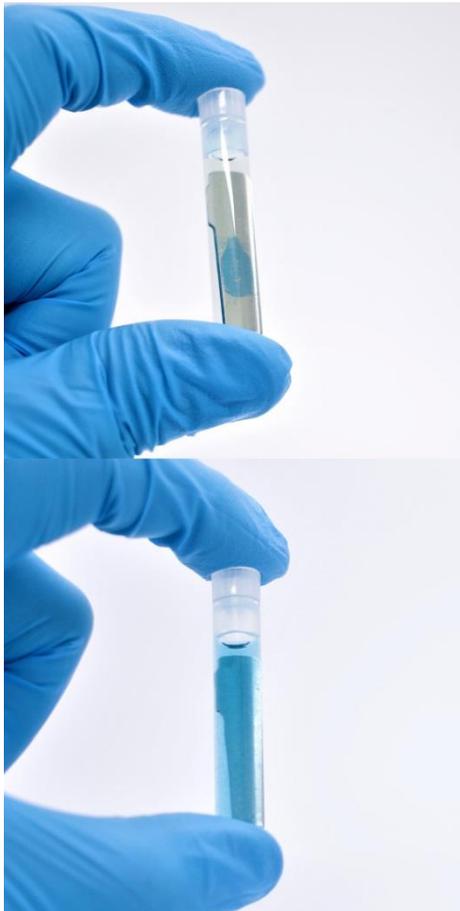
4. Place the cap back on the vial and seal it. It should “click” shut.



5. Shake the vial vigorously for 30 seconds



6. Allow the vial to rest for at least 5 minutes.

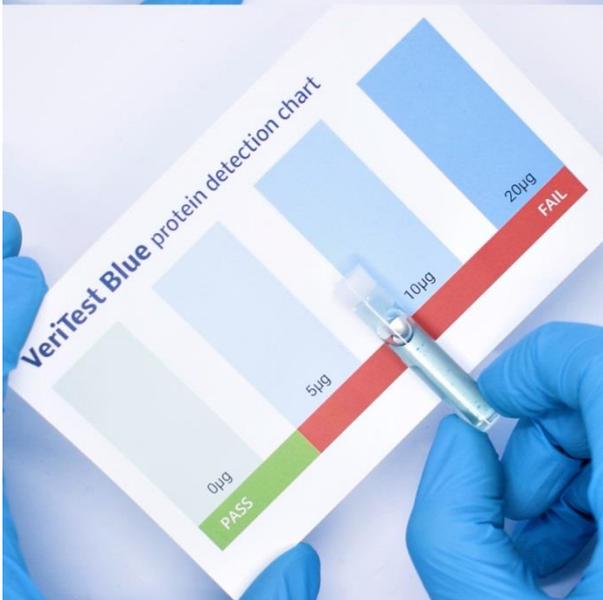
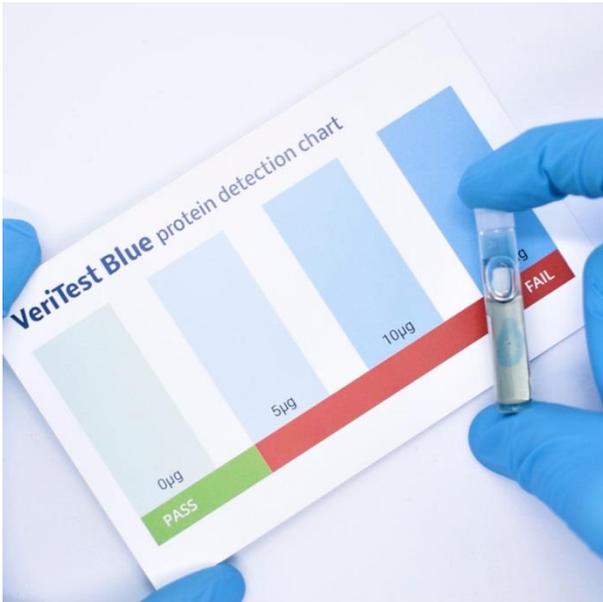


7. Inspect the VeriTest Blue for a colour change.

Protein may dissolve out into the solution, causing the liquid within the vial to change to blue.

With particularly sticky proteins, the residue may stay on the surface of the tag resulting in a blue presence on the surface.

Refer to the colour change sheet for information on both types of colour change.



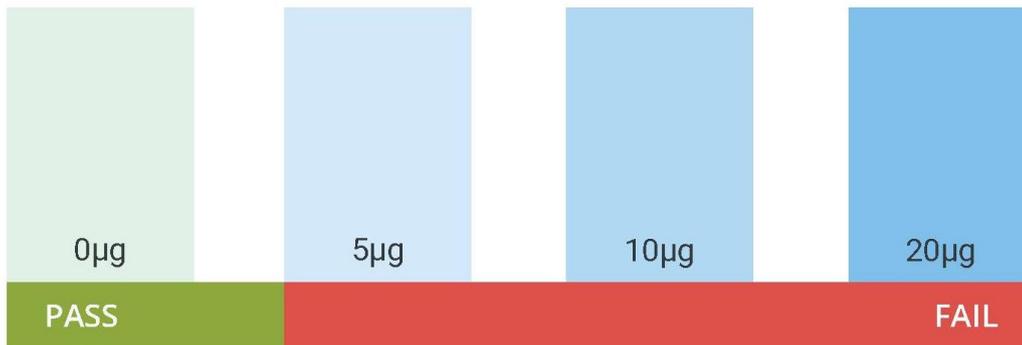
8. Evaluate using the VeriTest Blue Colour Meter and record results using the relevant result sheet IFU. See section 5. "Recording Results" below for detailed information on results.

(See IFUs 003 – 006)

The images on the left show different examples of results that can be expected from wash cycles that do not remove sufficient levels of protein.



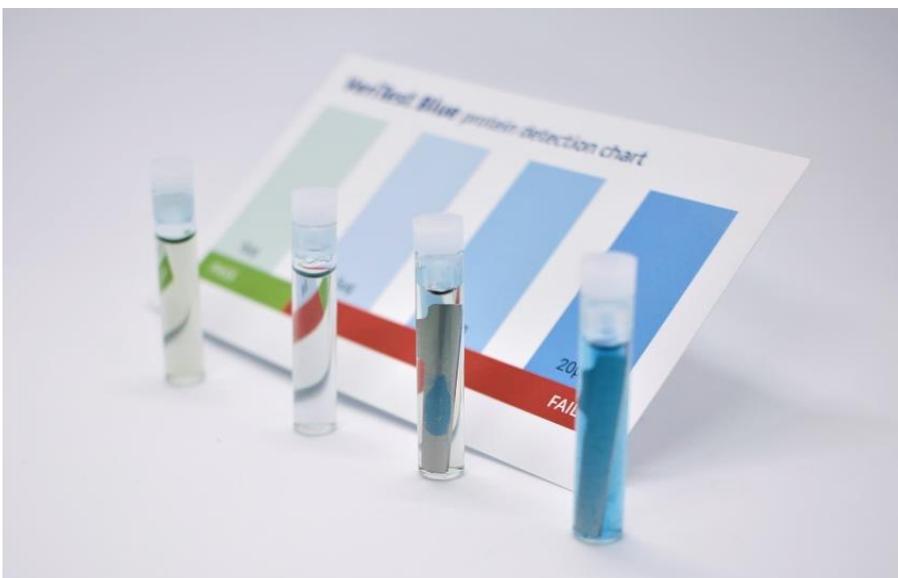
5. Recording Results



1. Firstly inspect the VeriTest Blue Vial after leaving the Tag to rest in the reagent for 5 minutes as instructed.
2. The colour change may present itself either as dissolved protein, with the reagent changing colour from yellow/green to blue, or as surface protein, where sticky proteins are still adhered to the surface. These proteins will turn blue also.
3. If there is a considerable amount of surface protein, consider the result as a FAIL.
4. If the proteins have dissolved into the reagent, check against the provided VeriTest Blue Colour Meter and determine the best match. Score the process accordingly.
5. Results can be recorded as ether a PASS/FAIL or by indicating the estimated level of protein residue in micrograms on any of the relevant IFUs* under the "Results" column

*Result Document IFUs include IFU 003, 004, 005 and 006.

Choose the IFU that represents the type of washer and VeriTest Multi used (360/Basic).





6. VeriTest Blue Troubleshooting

1. If a vial of VeriTest Blue is coloured blue straight out of the packet then compare with other vials from the pack. If there is a difference in colour, do not use. Please report any faults directly to Aseptium.
2. If there is a significant difference in volume between vials, check for leaks/damage and report back to Aseptium. Do not use any vials that have significantly less VeriTest Blue reagent as this may lead to inaccurate results.
3. Always use VeriTest Blue within the "Use By Date" indicated on the front of the packaging.