

Practical Application of AllerSnap™ and Detection Limits

AllerSnap is a simple, high sensitivity test device for the detection of protein residues, intended to be used as a rapid verification of surface cleanliness in practical industrial applications. The test result is dependent on the sample size, time and temperature. Allowances need to be made for variation in sample collection by swabbing (surface type, swab area and user), and visual color assessment. AllerSnap is not intended to be used as a precise determination of protein content. The chemistry of the AllerSnap test produces a visible color change from green to purple which is dependent on both time and temperature. Grey coloration is the earliest visible sign of a weak positive reaction. Increasing both time and temperature increases the sensitivity of the test to detect lower amounts of protein. At very low levels of protein i.e. 3 microgram (μg), the technology is operating at its limits where the color intensity (grey) is very weak and hence the interpretation of results is more subjective causing reduced precision and accuracy. A negative control test sample (i.e., the absence of protein) if left for extended time periods (>90 minutes at 37°C) will produce a color change that would be interpreted as a positive. Accordingly, caution needs to be exercised when interpreting results from samples with low protein content.

Detection Limits

The table below demonstrates the comparable performance and detection limits of AllerSnap at different times and temperatures when conducted under controlled laboratory conditions with reproducible known amounts of protein applied directly to the test device to avoid sample variation.

Protein content (μg BSA)	Time at 37°C				Time at 55°C
	5	10	15	30	15
10	✓	✓	✓	✓	✓
5	X	✓	✓	✓	✓
3	X	X	X	✓	✓

X Not Detected ✓ Detected

Accordingly under controlled laboratory conditions, the limit of detection of AllerSnap is calculated.

- 3 μg protein when incubated at 37°C for 30 minutes or 55°C for 15 minutes.

Practical Considerations

For the routine assessment of surface cleanliness, there is little difference in swab test performance when conducted at 37°C for 15 or 30 minutes, or 55°C for 15 minutes because of sample variation due to swabbing and the poor precision / color interpretation at very low protein levels of 3 μg .