

Practical application of AllerSnap and detection limits

AllerSnap is a simple, high sensitivity test device for the detection of protein residues.

AllerSnap is 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 colour assessment.

AllerSnap is not intended to be used as a precise determination of protein content.

The chemistry of the AllerSnap test produces a visible colour change from green to purple which is dependent on both time and temperature. Grey colouration 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. 1 microgram (μg), the technology is operating at its limits where the colour 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 mins at 37°C) will produce a colour change that would be interpreted as a positive.

Accordingly caution needs to be exercised when interpreting results from samples with low protein content, and negative controls should always be conducted.

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 (mins) | | | | 55°C for 15 mins |
|---|----------------------|----|----|----|---------------------|
| | 5 | 10 | 15 | 30 | |
| 10 | ✓ | ✓ | ✓ | ✓ | ✓ |
| 5 | ✗ | ✓ | ✓ | ✓ | ✓ |
| 3 | ✗ | ✗ | ✓ | ✓ | ✓ |
| 1 | ✗ | ✗ | ✗ | ✓ | ✓ |

✗ Not Detected

✓ Detected (weak positive i.e. grey colour)

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

- 3 μg protein when incubated at 37°C for 15 mins
- 1 μg protein when incubated at 37°C for 30 mins
- 1 μg protein when incubated at 55°C for 15 mins

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 mins, or 55°C for 15 mins because of sample variation due to swabbing and the poor precision / colour interpretation at very low protein levels of 1 – 3 μg .

Ref: MCE 0312