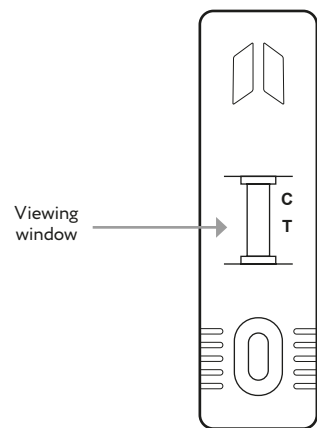




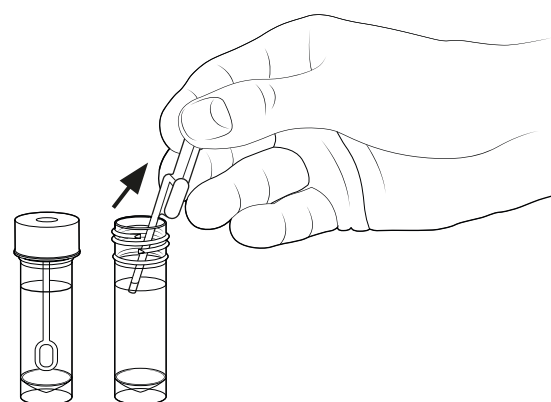
## 6. TESTING PROCEDURE (cont)

### Performing the test

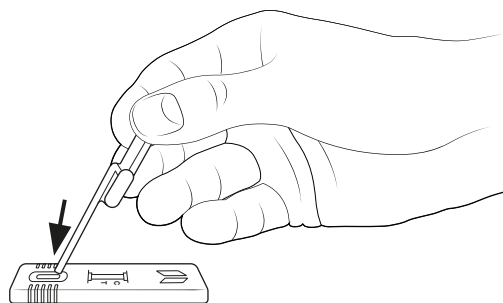
- Remove NEATstik® from the foil packaging and place on a level surface with the viewing window upwards.



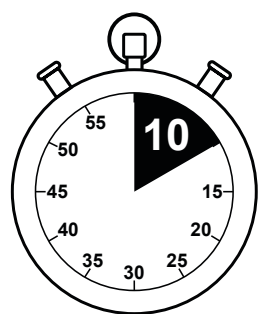
- Remove the lid from the sputum dilution pot.
- Use the dual bulb pipette to draw up a sample of the diluted sputum. Try to ensure solution only – no ‘lumps’ of sputum.



- Apply the sample to the oval shaped sample port on NEATstik®.

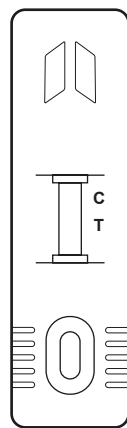


- Wait for 10 minutes (use a timer) before reading the result.

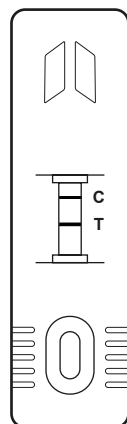


### Reading the result and Quality Control

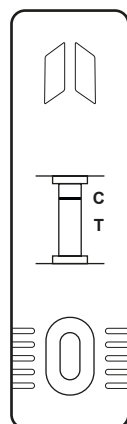
If the test has been performed successfully, the CONTROL (C) line will be visible as a red line (colour intensity may vary). If the CONTROL (C) line is not visible, the results are invalid and the test should be repeated with a new sample and a fresh test kit.



If the TEST (T) line is visible, this confirms the presence of active NE greater than the pre-set threshold, in the sputum sample.



If the TEST (T) line is not visible, any active NE present in the sputum sample does not exceed the pre-set threshold.



## 7. PERFORMANCE CHARACTERISTICS

The performance of NEATstik® test was assessed using 58 frozen sputum samples. Active NE was quantified using a ProteaseTag® Active NE Immunoassay (ProAxis Ltd).

- 42 samples had sputum NE concentrations <8 µg/mL = negative
- 16 samples had sputum NE concentrations >8 µg/mL = positive

The test gave a positive result for 16 of the 16 sputum samples with NE quantified above 8 µg/mL (100% sensitivity), and a negative result for 36 of the 42 sputum samples with NE quantified below 8 µg/mL (86% specificity).

## 8. LIMITATIONS OF USE

- For use with diluted sputum samples only
- For accurate results, please follow the instructions provided
- NEATstik® does not quantify active NE in sputum samples.

## 9. QUANTIFYING ACTIVE NEUTROPHIL ELASTASE

To measure the concentration of active NE in a sputum sample, use of ProteaseTag® Active Neutrophil Elastase Immunoassay is recommended (available from ProAxis Ltd).

## 10. TROUBLESHOOTING

### The CONTROL (C) line does not appear

The test is invalid. Repeat with new kit.

### Some of the test kit components are damaged

If any of the test kit is damaged or missing please contact ProAxis Ltd on +44 (0) 2890 730 445 or [info@proaxis.com](mailto:info@proaxis.com)

## 11. WARNINGS AND PRECAUTIONS

- Do not use components past their expiry dates
- Do not mix components from different kits lots
- The test is for single use only. Do not reuse
- Suitable protective clothing should be worn when handling sputum samples and while performing the test.

## 12. STORAGE

Store the kit at room temperature.

Each test kit may be used until the expiration date printed on the label if it remains in original packaging under recommended storage conditions.

NEATstik® lateral flow test should be used immediately after removal from the sealed pouch.

NEATstik® sample dilution buffer should be used immediately after bottle opening.

## 13. DISPOSAL

Sputum samples and used test components are potentially biohazardous. Dispose of used test kits and sputum samples appropriately in line with local clinical waste guidelines.

## 14. REFERENCES

- Pham, C. (2008) *International Journal of Biochemistry & Cell Biology*, 40 (6-7), 1317-1333.
- Sandhaus, R. & Turino, G. (2013) *COPD*, 10(S1):60–63.
- Sagel, S. et al (2012) *American Journal of Respiratory and Critical Care Medicine*, 186 (9): 857-865
- Mayer-Hamblett, N. et al (2007) *American Journal of Respiratory and Critical Care Medicine*, 175: 822-828
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## SYMBOLS USED

	EC Declaration of Conformity
	Research Use Only
	Catalogue Number
	Lot Number
	Consult Instructions
	Manufactured By
	Expiry Date
	Storage Temperature Limitations
	Single Use Only DO NOT Re-use

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