

**Detection of pepsin in sputum and exhaled breath condensate: could it be a useful marker for reflux-related respiratory disease?**

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**Background:** Extra-oesophageal reflux (EOR) is a common cause of unexplained chronic cough. A non-invasive diagnostic test in the form of a rapid lateral flow (LF) *in vitro* diagnostic device specific for human pepsin has been shown to be of benefit in the diagnosis of EOR<sup>1</sup>. This test is able to detect pepsin, as a marker of prior reflux, in a range of clinical specimens. We present data utilising sputum/saliva or exhaled breath condensate (EBC) of patients with chronic cough with and without recent symptoms.

**Methods:** Samples were obtained from patients who were clinically suspected to have reflux associated cough. Sputum/saliva was obtained by requesting the patient to cough up and spit into a tube containing 0.1 M citric acid. After centrifugation (to remove insoluble material) the supernatant was retained for analysis. The device for collecting EBC consisted of polypropylene tubing connected to a dreschel flask immersed in crushed ice. Unidirectional tidal breathing for approximately 10 minutes led to the collection of 1-2mls of EBC. 30 µl of the fluid collected was tested for the presence of pepsin using a novel LF *in vitro* diagnostic device with two unique monoclonal antibodies to human pepsin 3.

**Results:** Sputum/saliva was obtained from 12 patients (males 2, mean age 47 years) after recent symptoms (n=15) or when asymptomatic (n=7). 93% of symptomatic samples were positive for pepsin while only 1 (14%) of the asymptomatic samples was positive (p<0.001). EBC was obtained from 4 patients (males 2, mean age 50 years). Pepsin assay was positive in 2 patients who had recent symptoms and negative in the 2 who did not have recent symptoms.

**Conclusion:**

Pepsin LF *in vitro* diagnostic test performed on a variety of non-invasively obtained samples is able to confirm that symptoms are a consequence of reflux. This is the first demonstration that EBC, a common non-invasive sampling technique, can be used to collect refluxate into the upper airways and detect pepsin within recent experience of symptoms. This test could prove to be a highly valuable investigatory tool in the diagnosis of reflux associated cough.

**References**

- 1: Strugala *et al.* 2007 Gastroenterology 132(4Suppl1):A99-A100