

DIAGNOSTIC APPLICATION: Efficacy and safety of a new acoustic device, the Lung Flute[®], for sputum induction in healthy non-smokers and chronic bronchitis

CLINICAL RESULTS

In a clinical study entitled, “*Efficacy and Safety of a New Acoustic Device, The Lung Flute, for Sputum Induction in Healthy Non-smokers and Chronic Bronchitis,*” tested the hypothesis that expectorate samples obtained after induction with the Lung Flute would have characteristics of lower respiratory tract secretion and would be comparable to sputum samples obtained by induction with hypertonic saline. The researchers found that samples from 100% of the chronic bronchitis patients obtained with the Lung Flute contained lower respiratory secretions. Analysis also revealed that the samples obtained using the Lung Flute and through hypertonic saline induction were not statistically different. The most common adverse event associated with use of the Lung Flute was mild transient throat irritation. **The researchers concluded, “The Lung Flute presents a safe, effective, convenient and rapid method of sputum induction. Further investigation in its utility for diagnostic and therapeutic applications is warranted.”**

CELLULAR AND BIOCHEMICAL CHARACTERISTICS OF SAMPLES OBTAINED WITH LUNG FLUTE

The Lung Flute’s patented low frequency acoustic wave-producing technology (LFAW) compares favorably to current standard-of-care hypertonic saline induction used to collect diagnostic sputum samples in patients with reduced pulmonary function. In a clinical trial with 15 chronic bronchitic subjects, collected sample cell counts, neutrophils, macrophages, squamous cells and IL-8 were not statistically different for those collected by the Lung Flute than those inducted with hypertonic saline.

Parameter	Saliva Median	IQR	Lung Flute Median	IQR	Hypertonic Saline	IQR	P Value S vs F	P Value S vs H	P Value F vs H
Weight	0.37	0.342	1	1.36	4.5	6.415	0.3067	0.0001	0.0001
Cell Count (/mL)	50000	70000	247500	365000	280000	377500	0.0022	0.0019	0.81
Neutrophil (/mL)	19	403	98803	249566	178464	248701	0.0034	0.0005	0.64
Macrophages (/mL)	75	506	82385	130043	54926	70627	0.001	0.0005	0.18
Squamous Cells (/mL)	36000	60885	35219	70299	10950	34330	0.62	0.09	0.15
IL-8 (ng/mL)	0.38	0.78	1.61	1.56	1.46	1.6	0.008	0.01	0.81
Elastase (nM)	0.69	2.18	0.89	1.67	0.62	0.93	> 0.99	0.67	0.16
Fibrinogen (ng/mL)	661	1531	822	1837	1914	3219	0.31	0.07	0.53