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## Detection and diagnosis of lung cancer by electronic nose analysis of exhaled breath: A multi-center prospective observational study

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### Background

An accurate diagnosis at an early disease stage is crucial to improve prognosis and management of patients with lung cancer. Exhaled breath analysis by electronic nose (eNose) may aid for this purpose. We aimed to (1) validate the eNose model for detection of lung cancer in COPD patients developed by *De Vries et al.* (sensitivity 86%, specificity 89%, ROC-AUC of 0.90) (*CHEST, 2023*) at a 86% and 95% sensitivity level, and (2) develop a new eNose model able to identify lung cancer at a 95% sensitivity level in a more general population of individuals suspected of having lung cancer.

### Methods

We performed a prospective observational multi-center study in 318 adult individuals who were suspected of having lung cancer and were referred to thoracic oncology outpatient clinics for further diagnosis (final diagnosis: benign n=105, lung cancer n=213). Breath profiles were collected using a cloud-connected eNose (SpiroNose®). Firstly, we validated the model developed by *De Vries et al.* in included individuals with COPD (n=121). Secondly, we developed a new eNose model for all included individuals (training cohort n=212, validation cohort n=106). Data analyses involved signal processing and statistics based on Independent Samples T-test and Linear Discriminant Analysis (LDA) followed by ROC analysis.

### Results

The model developed by *De Vries et al.* achieved a ROC-AUC of 0.93 for detecting lung cancer in COPD patients. Selecting a sensitivity of 86% and 95%, it yielded a specificity of 78% and 74%, respectively. The new eNose model reached a comparable specificity of 71% at a 95% sensitivity level and ROC-AUC of 0.90 in the training cohort. These results were confirmed in the validation cohort with a specificity of 74% at a 95% sensitivity level and ROC-AUC of 0.87. Subanalyses showed no influence of tumour location, size, disease stage, or diagnostics clinic on the ability to detect lung cancer.

### Conclusions

eNose analysis of exhaled breath allows for non-invasive, accurate detection and diagnosis of lung cancer irrespective of tumour location, size, disease stage, or diagnostics clinic. Implementation of eNose analysis could help identify those individuals for whom additional diagnostics are necessary.

### Legal entity responsible for the study

Radboudumc (Department of Respiratory Diseases) and UMCG (Department of Respiratory Diseases).

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### Disclosure

R. De Vries: Financial Interests, Personal, Officer, Chief Executive Officer: Breathomix. All other authors have declared no conflicts of interest.

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