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Validation of Lung EpiCheck, a novel methylation-based blood assay, for the detection of lung cancer in European and Chinese high-risk individuals

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Lung EpiCheck, a simple blood test, detected 85% of early-stage lung cancers with specificity of 64% in high-risk population, reaching AUC of 0.942 when combined with risk factors. This could improve efficiency of implementing lung cancer screening. https://bit.ly/3jWhLOn

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ABSTRACT
Aim: Lung cancer screening reduces mortality. We aim to validate the performance of Lung EpiCheck, a six-marker panel methylation-based plasma test, in the detection of lung cancer in European and Chinese samples.
Methods: A case–control European training set (n=102 lung cancer cases, n=265 controls) was used to define the panel and algorithm. Two cut-offs were selected, low cut-off (LCO) for high sensitivity and high cut-off (HCO) for high specificity. The performance was validated in case–control European and Chinese validation sets (cases/controls 179/137 and 30/15, respectively).
Results: The European and Chinese validation sets achieved AUCs of 0.882 and 0.899, respectively. The

sensitivities/specificities with LCO were 87.2%/64.2% and 76.7%/93.3%, and with HCO they were 74.3%/90.5% and 56.7%/100.0%, respectively. Stage I nonsmall cell lung cancer (NSCLC) sensitivity in European and Chinese samples with LCO was 78.4% and 70.0% and with HCO was 62.2% and 30.0%, respectively. Small cell lung cancer (SCLC) was represented only in the European set and sensitivities with LCO and HCO were 100.0% and 93.3%, respectively. In multivariable analyses of the European validation set, the assay's ability to predict lung cancer was independent of established risk factors (age, smoking, COPD), and overall AUC was 0.942.

Conclusions: Lung EpiCheck demonstrated strong performance in lung cancer prediction in case–control European and Chinese samples, detecting high proportions of early-stage NSCLC and SCLC and significantly improving predictive accuracy when added to established risk factors. Prospective studies are required to confirm these findings. Utilising such a simple and inexpensive blood test has the potential to improve compliance and broaden access to screening for at-risk populations.