

ADJUNCTIVE LUNG CANCER SCREENING TOOL BASED ON CELLULAR IMAGING

Lung cancer is the world's leading cause of cancer-related deaths. The disease is expected to claim more than 164,000 lives this year in the US alone, which accounts for more deaths than the total number of deaths due to breast cancer, prostate cancer, and ovarian cancer combined. Of those diagnosed with lung cancer, only 15% of them are projected to survive beyond five years, while the survival prospects for the remaining 85% are extremely low, attributable to late stage diagnosis. Early detection is critical to reverse this trend.

Today, patients typically undergo X-ray or computerized axial tomography (CAT) scans or CT scans to detect abnormal growths in the lungs. While a CAT scan can pick up lumps, it fails to differentially diagnose malignant lesions, as has been reported by a landmark study conducted by the National Cancer Institute (NCI) in 53,000 high-risk patients who were subjected to low-dose CAT scans. Despite an overall reduction in cancer deaths, researchers reported that more than 96% of the positive results over three rounds of testing turned out to be false positive. Such high rates of false positives result in extensive follow up care and added costs for patients in the form of additional scans or invasive biopsies. These drawbacks could eventually jeopardize the feasibility of implementing mass screening programs for millions of patients at high risk for lung cancer.

VisionGate, based out of Phoenix, Arizona, has developed a novel solution to address this problem. The company's Lung Cell Evaluation Device (LuCED)--an automated 3D cell analysis system based on its Cell-CT optical tomography platform technology has emerged as an ideal modality to be used as an adjunctive screening test to CAT scans for diagnosing lung cancers early. The test, which is based on the tried and tested method of cytological analysis, has the potential to significantly improve the current rates of lung cancer detection.

Contrary to its name, Cell-CT does not use X-rays, but uses light sources typical of standard microscope. The suspension of cells isolated from a human sputum sample is passed through a rotating glass capillary tube, and in the process, each cell is imaged by the microscope at multiple angles. These individual images are then automatically reconstructed using computerized tomography, to generate high-resolution 3D images of cells for diagnosing cancerous abnormalities.

The unique feature of this technology lies in its ability to diagnose lung cancers early in a non-invasive manner and its unparalleled ability to detect

malignancy among the lumps picked up by the CAT. Another unique feature of the technology is its capability to rapidly handle data-intensive processes such as image construction, processing, and analysis by performing a fast paced tomographic reconstruction of the 2D digital images taken at 500 different angles.

VisionGate expects the LuCED test's specificity rate to be as high as 99.9%, which means there are hardly any false positives with LuCED. With regards to sensitivity, VisionGate expects LuCED to exceed 75% per test, and because the patients can undergo routine yearly screening, the company expects to achieve a sensitivity reaching 95% after multiple annual tests.

VisionGate's Cell-CT technology has already garnered the support of the National Institutes of Health (NIH) in the form of a \$2.6 million grant, which goes to prove the Institute's confidence about the impact of this break through technology on cancer screening procedures. With this milestone achievement combined with the demand for early lung cancer screening, and the need for an adjunct to CAT scan to eliminate false positives, VisionGate expects that LuCED will be favorably reviewed by the US Food and Drug Administration (FDA).

VisionGate has already developed a second-generation prototype. VisionGate plans to have it fully automated by December 2011, and ready for market launch before the end of 2012. The company is looking for strategic partnerships for manufacturing and clinical trials.

The impact that the Cell-CT-based LuCED test will have on early lung cancer diagnosis is likely to be phenomenal, as it would enable early-stage lung cancer diagnosis in pre-symptomatic patients in particular. For the radiologist, who has already found a suspicious lung lesion through CAT, the LuCED test proves to be a diagnostic tool that offers value-addition by being able to true-up the true positives as the otherwise high-false positive rate is a perpetual problem with the CAT scans. Also, by giving a 'yes' or 'no' result within a day, the test gives the physician a total patient picture. LuCED testing thereby saves huge amounts of time and unwanted costs for the patients.

Further, the Cell-CT technology has multiple applications. In addition to applications in lung cancer, the Cell-CT as a platform technology could also enable a host of diagnostic and scientific research applications. For example, the Cell-CT platform could be extended for diagnosis of bladder cancer, esophageal cancer, and oral cancer. VisionGate is also developing a Cell-CT-based test for gastro-esophageal reflux disease (GERD) and for monitoring treatment success. By allowing cellular

imaging with superior clarity at submicrometer imaging, Cell-CT has the potential to reveal for physicians, a whole new range of biosignatures, with which they will be able to diagnose all kinds of diseases much earlier for better therapeutic outcomes for patients. Furthermore, the LuCED test could also serve as a potential tool for selecting the right patients and for drug response monitoring during lung cancer therapy.

VisionGate has also patented its technology in over 13 countries spanning North America, Europe, and Asia with a vision to launch the product globally. With a novel, patented technology in hand that addresses a global health issue, VisionGate is soon to emerge as the trend setter in the early detection of lung cancer.

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