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## **Significant Lung Cancer Screening Study Published in the American Cancer Society Journal, *Cancer Cytopathology***

**–Two newly published articles demonstrate potential for lung cancer screening using sputum –**

**PHOENIX, Ariz. – July 7, 2015** – VisionGate Inc., a new generation biotech company that has developed a revolutionary, non-invasive test for the early detection of lung cancer today commented on two articles describing significant progress toward life-saving lung cancer screening. The studies were published this week in *Cancer Cytopathology*, a peer-reviewed journal of the American Cancer Society.

The multi-center, international study demonstrates that VisionGate's LuCED® test, providing automated three-dimensional morphological analysis of lung cells in sputum, is highly sensitive (91.8%) and highly specific (95%) for detection of early lung cancer. The test therefore has significant value as an adjunctive test following a suspicious low-dose CT (LDCT) scan or as a primary screening test to better inform next steps in lung cancer early detection, diagnosis and treatment. In this particular issue of *Cancer Cytopathology*, one article describes LuCED's clinical performance and a second article focuses on the LuCED technology which incorporates VisionGate's breakthrough three-dimensional cell-imaging platform, the Cell-CT®.

VisionGate issued the following statement regarding the study:

As the number of lung cancer screening programs in the U.S. surges following the Centers for Medicare & Medicaid (CMS) decision to provide coverage for a very high-risk patient population, important real-time data emerges to demonstrate a complementary test that could be utilized to confirm positives or suspicious nodules found by LDCT while dramatically reducing the burden of false positives. Moreover, the new test could serve as an alternative test for lung cancer among the broader patient population.

In the new study, sputa from 91 patients (49 with confirmed lung cancer and 42 with no known malignancy) were evaluated using the non-invasive LuCED test. Moderate/severe dysplasia or cancer cells were found in 45 of the 49 abnormal patients, and showed consistent performance across all tumor types, stages, sizes and locations.

VisionGate believes the results of the study support the clinical utility that LuCED can help aid physicians in lowering the risk to patients being sent unnecessarily for follow-up from false positive LDCT scans, thus drastically decreasing the cost of a lung cancer screening program and extending lung cancer testing to additional patient populations such as current and former smokers below age 55, or COPD patients.

"At a time when great strides have been made in the fight against lung cancer over recent years, we need to leverage this momentum toward higher detection sensitivity and reduction of false positives to advance screening effectiveness and improve the healthcare economics," said VisionGate CEO Dr. Alan Nelson. "Now, there is an even greater need for a non-invasive, non-radiation test with exquisite efficacy – we think that's LuCED."

VisionGate is committed to improving survival for lung cancer victims, which means finding the cancer earlier. Its LuCED test is designed to reduce false negatives and false positives, providing physicians with the confidence to identify lung cancer patients and minimize unnecessary interventions. For more information, please visit [www.visiongate3d.com](http://www.visiongate3d.com)

Web links and citations for the articles are:

LuCED clinical performance:

<http://onlinelibrary.wiley.com/doi/10.1002/cncy.21565/full>

Wilbur DC, Meyer MG, Presley C, et al. Automated 3-dimensional morphologic analysis of sputum specimens for lung cancer detection: Performance characteristics support use in lung cancer screening. *Cancer Cytopathology*. 2015. doi: 10.1002/cncy.21565

LuCED technology:

<http://onlinelibrary.wiley.com/doi/10.1002/cncy.21576/full>

Meyer MG, Hayenga JW, Neumann T, et al. The cell-CT 3-dimensional cell imaging technology platform enables the detection of lung cancer using the noninvasive LuCED sputum test. *Cancer Cytopathology*. 2015. doi: 10.1002/cncy.21576

### **About VisionGate**

VisionGate, Inc. is led by Dr. Alan Nelson, physicist, bioengineer and entrepreneur who developed the world's first and only automated screening test to detect cervical cancer, marketed today as FocalPoint by Becton Dickinson. VisionGate produces the first automated 3D cell imaging platform, the Cell-CT, which computes high-resolution 3D biosignatures from intact cells. The company's first product is the LuCED test, which incorporates the Cell-CT, and is initially being deployed as a CLIA lab developed test (LDT) for adjunctive use with low dose x-ray computed tomography (LDCT) screening. Adjunctive use of LuCED to better manage the high rate of false positive results in LDCT screening could increase the utility and cost effectiveness of the approach, which has been shown to decrease lung cancer deaths in high-risk patients. VisionGate is headquartered in Phoenix, Arizona, and has a research and development facility in Seattle, Washington. It currently holds 124 issued patents.

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