

NeoDiagnostix Inc. Announces Issuance of US Patents

Company Expands IP Portfolio Covering Test Methods to Identify Chromosomal Abnormalities including 3q (TERC) and 5p (TERT) in Cervical Cells

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NeoDiagnostix announced today that the United States Patent and Trademark Office has granted two new patents owned by the company (US Patent No. 8,748,099 and 8,852,865) covering the detection of chromosomal abnormalities in cervical samples. The recently issued patents cover methods for identifying chromosomal abnormalities at multiple sites of the genome, including loci 3q, 5p, 20q and/or 1q, in a plurality of cells from a cervical sample. The issuance of these two patents both complements and augments NeoDiagnostix's previously issued patents (US Patent No. 8,603,746 and 8,603,747) covering such methods.

"We are extremely pleased with the issuance of these two patents", said Richard M. Pinnola, President and CEO of NeoDiagnostix. "We believe that our intellectual property assets are a significant value driver for the company and with a total of four (4) US patents we feel well positioned in this area of testing. This important milestone not only validates the company's valuable contributions toward chromosomal enumeration in cervical samples, but demonstrates our commitment to our customers and collaborators toward protecting the innovation and commercial opportunity of the Cervical DNA Dtex® test. The Cervical DNA Dtex® test provides novel insights into the key genomic mechanisms that drive cervical carcinogenesis."

"FISH-based testing in cervical cells offers unique advantages in the assessment and management of women presenting with mild cytological abnormalities and/or high-risk HPV infection", stated Gregory A. Endress, Chief Science Officer of NeoDiagnostix. "Whereas the infection and integration of HPV into epithelial cells are key steps in the development of cervical dysplasia, their predictive value remains insufficient in large numbers of women. Clinical research indicates the involvement of certain genes, most notably TERC and TERT, in the development of cervical carcinogenesis. It is believed that the gain of additional copies of these genes confer a growth advantage over normal cells thus leading to a marked increase in developing pre-cancerous lesions. Clinical studies have shown that increased copy number at loci 3q and 5p, where the TERC and TERT genes are located, correlates with high grade pre-cancerous lesions and cancer."

About NeoDiagnostix, Inc.

NeoDiagnostix is a privately-held company located in Gaithersburg, MD. The company is a leading provider of fluorescent in situ hybridization (FISH) testing for cervical cancer. Identification of chromosomal abnormalities in clinical samples has long been associated with

the development and progression of various cancers. The company's flagship test, the Cervical DNA Dtex® test, identifies the permanent and irreversible damage to cervical cells as the result of persistent HPV infection. The Cervical DNA Dtex® test is a fluorescence in situ hybridization (FISH) test that identifies chromosomal abnormalities as defined by multiple copies of 3q and/or 5p in cervical cells, a hallmark of carcinoma. Normal cervical cells have 2 copies of chromosomal regions 3q and 5p. Persistent HPV infection leads to genomic instability and the gain of extra copies at regions 3q and/or 5p. Mild abnormalities, such as the presence of cervical intraepithelial neoplasia (CIN2), include a few extra copies of these chromosomes in the DNA of the cervical cells. As the disease progresses toward carcinoma, more serious abnormalities occur and can result in dozens of extra copies of 3q and 5p.

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