

## **ONCOblot Consistently Detects Stage 0 and Stage I Cancers and Correctly Identifies the Tissue of Origin**

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**MorNuCo, Inc. continues its monthly report for participating physicians and health professionals in order to answer common questions relating to the ONCOblot<sup>®</sup> Tissue of Origin (Cancer) Test.**

ONCOblot<sup>®</sup> differs from early detection strategies based on circulating tumor cells (CTC Tests) that require the cancer to have progressed to the extent that cancer cells are in the blood. ONCOblot<sup>®</sup> detection is based on the presence of cancer-specific cell surface ENOX2 proteins shed from cancer cells. All that is required is that the cancer has a blood supply.

### **Stage 0/Stage I Defined**

Stage 0 cancers are characterized by abnormal cells that are exclusively confined to the tissue of origin (1).

Similarly for stage I, the cancer has not yet spread outside the tissue of origin or to lymph nodes. Stage I solid tumors are usually less than 2 cm in diameter (1).

Sometimes referred to as carcinoma *in situ*, stage 0 and stage I cancers are usually amenable to surgical intervention.

### **Methods**

Sera from stage 0 patients were purchased from Asterand Bioscience, Detroit, MI.

Sera from stage I patients were collected by MorNuCo, Inc. Stage and tissue of origin were confirmed by biopsy for all participants using IRB approved protocols.

### **Results**

Sera from twenty-five stage 0 cancer patients and twenty-five stage I cancer patients confirmed by biopsy (Table 1) were analyzed by ONCOblot<sup>®</sup>. For all 25 patients in each category, early cancers were detected by ONCOblot<sup>®</sup> and correctly identified as to tissue of origin.

With a sample size of 25, values for each of the cancers fell within the pre-determined ranges of values for the characteristic ENOX2 transcript variant(s). Thus, the positive percent agreement observed was 100% (90% confidence interval, 88.7-100%).

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**Table 1.** The tissue of origin of stage 0 and stage I cancers analyzed

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<b><u>Stage 0 Cancers</u></b>	<b><u>n</u></b>	<b><u>Stage I Cancers</u></b>	<b><u>n</u></b>
Bladder	2	Bladder	1
Blood Cell	3	Blood Cell	2
Breast	6	Breast	16
Cervix	3	Colorectal	5
Colorectal	3	Lung	1
Hepatocellular (Ampullary)	1		
Lung	1		
Melanoma	1		
Renal Cell	2		
Squamous Cell (Vulvar)	2		
Uterine	1		

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### **Discussion**

ONCOblot<sup>®</sup> detects solid and blood cell cancers at both stage 0 and stage I (and beyond) making it possible to determine the tissue of origin of a cancer even if the patient is not showing physical symptoms associated with cancer.

By detecting stage 0 and stage I cancer, in most cases, treatment can be initiated before metastases occur.

#### **DCIS. A Common Example of Stage 0**

With breast cancer, ductal carcinoma *in situ* (DCIS), is stage 0 and has not spread outside a breast duct or into the surrounding breast tissue. Not all DCIS progress to become metastatic disease (2). Some never leave the duct. Never-the-less, most specialists recommend that all DCIS be treated with surgery often followed by radiation and hormone therapy (3).

Without mammography, DCIS would be a rare diagnosis. Even if it does not present as a lump, DCIS is frequently detected by the presence of microcalcifications, clusters of white specs of calcium, on the mammogram (4). Currently there appears to be no cancer tests, including ONCOblot<sup>®</sup>, that can predict with certainty, the risk of development of an

invasive cancer from DCIS although this remains an area of active investigation (3).

### **Summary**

The ONCOblot<sup>®</sup> Tissue of Origin Cancer Test reliably determines the presence and tissue of origin of 26 different cancers based on circulating ENOX2 transcript variants of differing molecular weights and isoelectric points in serum. The test correctly identified cancers as to tissue of origin with both stage 0 and stage I cancers. Often referred to as cancer *in situ*, with stage 0 and stage I cancers, disease has not spread beyond the tissue of origin. Thus, the ONCOblot<sup>®</sup> Cancer Test may signal cancer earlier than CTC (Circulating Tumor Cell) tests that detect only cancer cells present in the blood.

### **References**

1. Cancer Facts and Figures. 2014. How is cancer staged? Amer. Cancer Soc., pp. 2-3.
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4. Evans A. 2003. The diagnosis and management of pre-invasive breast disease: radiological diagnosis. Breast Cancer Res. 5:250-253.