

Explanation of ONCOblot® Laboratory Report Form (General)

*Tissue-specific isoforms of the ENOX2 protein have been shown to be produced by malignant cells. The ONCOblot® test is a blood serum test that detects ENOX2 proteins that have been shed into circulation. The results of the ONCOblot test will first indicate if one or more ENOX2 proteins are detectable in a human serum sample (yes or no). If yes, the results will indicate the molecular weight (MW) and isoelectric point (pI) of each ENOX2 protein detected. The properties (MW and pI) of each ENOX2 protein detected within a serum sample are then compared to a database of ENOX2 proteins identified within serum samples drawn from clinically-confirmed cancer patients. Through this comparison, the Tissue of Origin that is most consistent with the detected pattern of ENOX2 proteins within a serum sample is reported. The results of the ONCOblot® test **do not** distinguish between localized and metastatic disease, nor do the results indicate cancer stage or provide a measure of tumor burden.*

Patient Identifier: Matches unique identifier found on patient Requisition Form.

ONCOblot® Number: Internal coding provided by ONCOblot® Laboratories.

ENOX2: Enzyme that aids unregulated cell growth and has been shown to be produced by malignant cells.

ENOX2 present (no): Indicates that no ENOX2 proteins were detected within a serum sample.

ENOX2 present (yes): Indicates that one or more ENOX2 proteins were detected within a serum sample.

Molecular Weight (MW): A measure of the total size of a protein, reported in kilodaltons (kDa).

Isoelectric Point (pI): An isoelectric point is the pH value at which a protein has an overall net zero charge. This value is directly related to the ratio of acidic and basic amino acids that make up a particular protein.

Tissue of Origin: If one or more ENOX2 proteins are detected, then the properties (MW and pI) of each protein are compared to a database of ENOX2 proteins detected within serum sample drawn from clinically-confirmed cancer patients. Based upon this comparison, the Tissue of Origin that is most consistent with a detected pattern of ENOX2 proteins is reported.

Generic/Non-specific ENOX2: Some malignant cells have been shown to produce a non-specific or fully processed form of ENOX2. These generic ENOX2 proteins may potentially be produced by malignant cells derived from any Tissue of Origin.

NIDB (Not in Database): The ONCOblot® Database currently includes examples of serum samples drawn from patients diagnosed with 24 common cancers. A result of "Not in Database" indicates that the detected pattern of ENOX2 proteins within a serum sample does not match a pattern within the ONCOblot® Database.

Control Validation: Serotransferrin and Alpha Fetuin are two proteins that are present in all human serum samples. These two proteins cross react with the ONCOblot® custom antibody. Their presence within pre-defined molecular weight and isoelectric point ranges serve as internal performance controls for each ONCOblot® test.

LABORATORY REPORT



PATIENT IDENTIFIER: 12345-DAL ONCOblot: 1234
DOB: 01/01/1955 GENDER: F DATE RECEIVED: 08/25/2014

ONCOblot® TEST RESULTS

ENOX2 proteins evident: Yes No

ENOX2	Molecular Weight (kDa)	Isoelectric Point (pH)	Tissue of Origin
Protein 1	67	4.5	Breast

Test Description: The ONCOblot® blood serum test reveals the presence of cancer-specific ENOX2 proteins to verify the tissue of origin of cancers as early as stage 0, identify the origin of metastasized cancers of unknown primary, and confirm cancer recurrence. Its utility for ENOX2 detection in the general population for cancer has not been determined. The ONCOblot® test results are provided to medical professionals for interpretation and are not intended to replace current standards of care.

Control Validation

Alpha Fetuin and Transferrin are reference proteins (controls) that validate that the ONCOblot® test performed to standards.

Reference proteins present and in range: Yes No

Comments

Results and report have been reviewed and are approved for communication to the requesting clinician.

Director of Laboratory

Date

Quality Assurance Officer

Date

ONCOblot® is a CLIA-approved and CAP accredited test performed at: MorNuCo's ONCOblot Laboratories.
ONCOblot® meets current FDA requirements as a laboratory developed test.

1201 Cumberland Ave Suite B • West Lafayette, IN 47906

Lab____

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LABORATORY REPORT



PATIENT IDENTIFIER: 54321-DAL ONCOblot: 4321
DOB: 05/20/1940 GENDER: M DATE RECEIVED: 09/20/2014

ONCOblot® TEST RESULTS

ENOX2 proteins evident: Yes No

ENOX2	Molecular Weight (kDa)	Isoelectric Point (pH)	Tissue of Origin
Protein 1	85	5.0	Colorectal
Protein 2	55	4.5	
Protein 3	40	4.2	

Test Description: The ONCOblot® blood serum test reveals the presence of cancer-specific ENOX2 proteins to verify the tissue of origin of cancers as early as stage 0, identify the origin of metastasized cancers of unknown primary, and confirm cancer recurrence. Its utility for ENOX2 detection in the general population for cancer has not been determined. The ONCOblot® test results are provided to medical professionals for interpretation and are not intended to replace current standards of care.

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LABORATORY REPORT



PATIENT IDENTIFIER: ABCD-1234 ONCOblot: 9876
DOB: 01/20/1934 GENDER: F DATE RECEIVED: 05/21/2014

ONCOblot® TEST RESULTS

ENOX2 proteins evident: Yes No

ENOX2	Molecular Weight (kDa)	Isoelectric Point (pH)	Tissue of Origin

Test Description: The ONCOblot® blood serum test reveals the presence of cancer-specific ENOX2 proteins to verify the tissue of origin of cancers as early as stage 0, identify the origin of metastasized cancers of unknown primary, and confirm cancer recurrence. Its utility for ENOX2 detection in the general population for cancer has not been determined. The ONCOblot® test results are provided to medical professionals for interpretation and are not intended to replace current standards of care.

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