Gender: Age: 38
Social Security Number: XXX-XX-1111
Patient ID/Case Number: ABC123

Date of Collection: 3/8/2019
Date Received: 3/12/2019

CBLPath QA Account
Z, Z
760 Westchester Ave
Rye Brook, NY 10573
(877) 225-7284

CBLPATH
A Sonic Healthcare Company

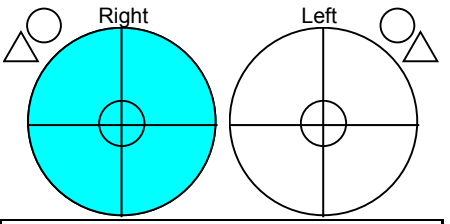
ADDENDUM Breast Pathology Report

RESULTS

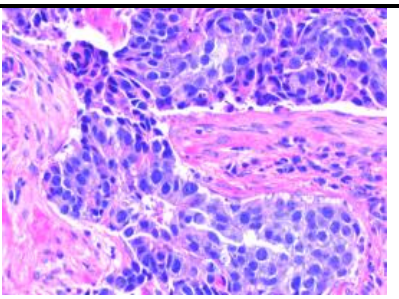
1: Diagnosis

Right Breast1:00: ***Poorly differentiated invasive ductal carcinoma (tubule formation 3/3, nuclear pleomorphism 3/3, mitotic rate 2/3), measuring 1.9 cm in maximal length in this material.***

Gross Description: The specimen is received in formalin labeled with the patient's name and "Right Breast1:00". The specimen consists of multiple light tan to yellow tan soft tissue fragments measuring 2.1 x 1.2 x 0.3 cm in aggregate. The entire specimen is submitted in 1 cassette(s) labeled "1A". Specimen radiograph is attached / performed. Ischemic time: hrs: min; fixation time: hrs: min. /Test



PHOTOMICROGRAPH



Specimen 1: *Right Breast1:00*

Comments

PREDICTIVE/PROGNOSTIC MARKERS

The invasive carcinoma demonstrates*:
Estrogen receptor (ER): NEGATIVE, 0% nuclear staining;
Progesterone receptor (PgR): NEGATIVE, 0% nuclear staining;
HER-2 neu score: NEGATIVE (0 staining).

Case reviewed in departmental conference.
The results were verbally communicated to the requesting physician.

*PD-L1 SP142 (Tecentriq™) assay to aid in the evaluation of patient eligibility for anti-PDL1 cancer immunotherapy treatment is available at CBLPath and may be performed upon request.

ER clone (SP1) ultraview DAB detection; computer assisted quantitative IHC.
PR clone (1E2) ultraview DAB detection; computer assisted quantitative IHC.
Ventana Pathway HER2 neu/4B5 ultraview DAB detection.

Negative and positive (internal if applicable) controls show appropriate results.
This evaluation is performed according to guidelines issued by CAP/ASCO.

Addendum

Ventana PD-L1 SP142 (Tecentriq™)Assay Result: Positive

Ventana PD-L1 SP142 IHC Score: >1% Immune Cell staining

Interpretive information for PD-L1 SP142 (Tecentriq™)
PD-L1 status is determined by the presence of discernible PD-L1 staining of any intensity in tumor-infiltrating immune cells covering > or = 1% of tumor area occupied by tumor cells, associated intratumoral, and contiguous peritumoral stroma.

VENTANA PD-L1 (SP142) Assay is a qualitative immunohistochemical assay using rabbit monoclonal anti-PD-L1 clone SP142 intended for use in the assessment of the programmed death-ligand 1 (PD-L1) protein in tumor cells and tumor infiltrating immune cells in the formalin-fixed, paraffin-embedded (FFPE) tissues indicated below stained with OptiView DAB IHC Detection Kit and OptiView Amplification Kit on a VENTANA BenchMark ULTRA instrument.
VENTANA PD-L1 (SP142) Assay2 as the first companion diagnostic to aid in identifying triple-negative breast cancer (TNBC) patients eligible for treatment with the Roche cancer immunotherapy Tecentriq®(atezolizumab)3 plus chemotherapy (Abraxane® [paclitaxel protein-bound particles for injectable suspension (albumin-bound); nab-paclitaxel]). Assessment of PD-L1 biomarker status on tumor-infiltrating immune cells with the assay is essential for identifying those patients most likely to benefit from the treatment.

Addendum Sign-Out
3/22/2019 - Addendum Issued By: Magalis Vuolo M.D.

Electronically signed out by:

Dr. Magalis Vuolo (877) 258-9310 Report Date: 3/22/2019

End of Report

Gender: Age: 38
Social Security Number: XXX-XX-1111
Patient ID/Case Number: ABC123
Hospital/Lab ID: S19-1224-B
Date of Collection: 3/8/2019
Date Received: 3/12/2019

CBLPath QA Account
Z, Z
760 Westchester Ave
Rye Brook, NY 10573
(877) 225-7284

CBLPATH
A Sonic Healthcare Company

Immunohistochemical (IHC) Report

Date/Time of Sample Collection: 3/8/2019 11:59:56 PM

Date/Time Sample Received: 3/12/2019 11:20:56 AM

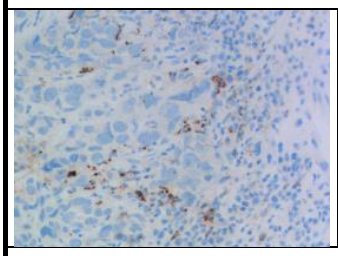
Hospital/Laboratory ID#: 123-456-789

Submitted Diagnosis / Diagnosis Under Consideration:

Specimen Type: Paraffin Embedded Tissue **Specimen Site:** Left Breast 12:00

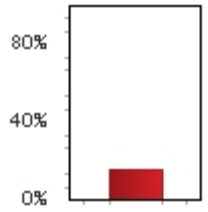
Immunohistochemical (IHC) Results:

Antibodies	Clone	Results/Comments
PD-L1 (SP142) Tecentriq	**SP142**	**Positive**



PD-L1 (SP142) Tecentriq

Percentage: 15%



POSITIVE

Gross Description: Received 1 block labeled S19-1224-B. Forwarded to IHC for special stains PD-L1 (SP142) Tecentriq.

Comments

Ventana PD-L1 SP142 (Tecentriq™) Assay Result: Positive

Ventana PD-L1 SP142 IHC Score: 15% Immune Cell staining

Interpretive information for PD-L1 SP142 (Tecentriq™)
PD-L1 status is determined by the presence of discernible PD-L1 staining of any intensity in tumor-infiltrating immune cells > or = 1% of tumor area occupied by tumor cells, associated intratumoral, and contiguous peritumoral stroma.

VENTANA PD-L1 (SP142) Assay is a qualitative immunohistochemical assay using rabbit monoclonal anti-PD-L1 clone SP142 intended for use in the assessment of the programmed death-ligand 1 (PD-L1) protein in tumor cells and tumor infiltrating immune cells in the formalin-fixed, paraffin-embedded (FFPE) tissues indicated below stained with OptiView DAB IHC Detection Kit and OptiView Amplification Kit on a VENTANA BenchMark ULTRA instrument.
VENTANA PD-L1 (SP142) Assay2 as the first companion diagnostic to aid in identifying triple-negative breast cancer (TNBC) patients eligible for treatment with the Roche cancer immunotherapy Tecentriq®(atezolizumab)3 plus chemotherapy (Abraxane® [paclitaxel protein-bound particles for injectable suspension (albumin-bound); nab-paclitaxel]). Assessment of PD-L1 biomarker status on tumor-infiltrating immune cells with the assay is essential for identifying those patients most likely to benefit from the treatment.

Electronically signed out by:
Dr. Magalis Vuolo (877) 258-9310

Report Date:
3/25/2019

End of Report