|          | 2005                        | Diagnostic<br>Pathology<br>Medical<br>Group, inc. | MAF | RKE | CER PROG<br>R REPORT |                                | 3301 C Street Ste 200E<br>Sacramento,CA 95816<br>(916) 446-0424<br>Fax: (916) 446-9330<br>www.dpmginc.com |  |
|----------|-----------------------------|---|-----|-----|----------------------|--------------------------------|---|--|
| Patient: | TEST, P                     | ATIENT  | Ą   | ge: | 68 (01/01/47)        | Pathology #                    | <sup>#:</sup> IHC-16-01234  |  |
| Acct#:   |                             |   | Se  | ex: | FEMALE               |                                |   |  |
| Doctor:  | Test Doctor<br>1234 Test st |   |     |     |                      | Date Obtained<br>Date Received | 00/20/2010  |  |
|          |                             |   | CC: |     |                      |                                | 3161L   |  |

## **SPECIMEN:** BREAST TUMOR PROFILE (ER, PR & HER-2NEU ) - DPS-16-05694

## Immunohistochemistry Evaluation

| Test                  | Interpretation | Intensity | % Tumor Staining | Comment   |
|-----------------------|----------------|-----------|------------------|-----------|
| Estrogen Receptor     | Positive       | 2-3+      | 90               | Favorable |
| Progesterone Receptor | Positive       | 2-3+      | 100              | Favorable |
| HER-2/Neu HercepTest  | Negative       | 1+        | 40               | Favorable |

\*\*Grading: Immunohistochemical reactivity/intensity for ER/PR is graded 0-3+. 0 is no staining. 1+ is weak staining intensity. 2+ is moderate staining intensity. 3+ is strong staining intensity. Nuclear staining in less than 1% of tumor cells is scored as negative.

Immunohistochemical reactivity for Her-2/Neu is graded positive for Her-2/Neu (overexpression) is 3+ staining defined as uniform intense uninterrupted membrane staining of > 10% of invasive tumor cells.

Equivocal or indeterminate for Her-2/Neu is 2+ staining defined as weak to moderate uninterrupted membrane staining in at least 10% of invasive tumor cells or 3+ staining in < 10% of invasive tumor cells. All equivocal staining cases are reflexed for FISH analysis.

Negative for Her-2/Neu is 0 or 1+ staining defined as either no staining or weak incomplete membrane staining in any proportion of invasive tumor cells.

Antibody: Estrogen Receptor Antibody - Ventana Clone SP1

Progesterone Receptor Antibody - Ventana Clone 1E2 HER-2/Neu Antibody - Ventana Clone 4B5

Detection system: ultraView DAB Detection System (for ER&PgR) ultraView DAB Pathway (for HER2/neu)

Specimen: 10% neutral buffered formalin fixed paraffin embedded tissue. Tissue cold ischemic time < 1 hour. Fixation time 14 hours.

Control, external: Satisfactory. Internal control positive for ER and PR.

Comment:

The ER and PR immunoperoxidase tests were developed and their performance characteristics determined by DPMG. These tests have not been cleared or approved by the U.S. Food and Drug Administration. The FDA has determined that such clearance or approval is not necessary. These tests are used for clinical purposes and should not be regarded as investigational or research. This laboratory is regulated under the Clinical Laboratory Amendment (CLIA) of 1998 as qualified to perform high complexity clinical testing.

ultraView DAB Pathway is FDA approved for diagnostic evaluation of HER-2/neu overexpression as an aid in the assessment of patients for when Herceptin (Trastuzumab) treatment is being considered.

\*\*Wolff AC, Hammond ME, Hicks, DG, et al. American Society of Clinical Oncology/College of American Pathologists guideline recommendations for human epidermal growth factor receptor 2 testing in breast cancer. Arch Pathol Lab Med 2014,138:241-256.

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