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United States Patent [19]

Koski

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[54] **METHODS AND COMPOSITIONS FOR DETERMINING HER-2/NEU EXPRESSION USING MONOCLONAL ANTIBODIES**

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[52] **U.S. Cl.** **435/7.23**; 435/330; 435/331; 435/344.1; 435/346; 435/40.5; 435/40.51; 435/40.52; 530/387.3; 530/387.7; 530/387.9; 530/388.8; 530/388.85; 530/391.3

[58] **Field of Search** 435/240.27, 7.23, 435/330, 331, 344.1, 346, 40.5, 40.52, 40.51; 530/387.7, 387.3, 391.3, 387.9, 388.8, 388.85

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[57] **ABSTRACT**

Anti-p185$^{HER-2/neu}$ antibodies which are useful in the detection of HER-2/neu oncogene overexpression in biological samples are described. The antibodies are accurate and reliable in immunocytochemical or immunohistochemical assays of cell and tissue samples. Also described are methods for detecting HER-2/neu oncogene expression in a biological sample using the antibodies of the invention and a diagnostic kit comprising the antibodies. The reagents provide an accurate means of identifying certain cancer patients who have the greatest probability of relapse and/or the least likelihood of survival.

13 Claims, 6 Drawing Sheets

FIG.1A

```
        10         20         30         40         50         60
         150-1                          150-3
TCTAGAAGGAGGAATAACATATGCTCCAGCGTCTGCGTATTGTACGTGGTACCCAGCTCT
AGATCTTCCTCCTTATTGTATACGAGGTCGCAGACGCATAACATGCACCATGGGTCGAGA
              150-2                          150-4


        70         80         90        100        110        120
        150-5                          150-7
TCGAAGATAACTACGCACTGGCTGTACTGGACAACGGTGATCCTCTGAACAACACCACTC
AGCTTCTATTGATGCGTGACCGACATGACCTGTTGCCACTAGGAGACTTGTTGTGGTGAG
            150-6                          150-8


       130        140        150        160        170        180
        150-9                       150-11
CGGTAACTGGTGCTTCTCCTGGCGGTCTGCGTGAACTGCAGCTCCGTAGCTTGACTGAAA
GCCATTGACCACGAAGAGGACCGCCAGACGCACTTGACGTCGAGGCATCGAACTGACTTT
           150-10                       150-12


       190        200        210        220        230        240
      150-13              150-15                   150-17
TCCTCAAAGGTGGCGTACTGATCCAGCGTAACCCTCAGCTGTGCTATCAGGATACTATCC
AGGAGTTTCCACCGCATGACTAGGTCGCATTGGGAGTCGACACGATAGTCCTATGATAGG
          150-14                  150-16                  150-18


       250        260        270        280        290        300
        150-19                     150-21                150-23
TGTGGAAAGACATCTTCCACAAGAACAACCAGCTGGCTCTGACTCTGATCGACACCAACC
ACACCTTTCTGTAGAAGGTGTTCTTGTTGGTCGACCGAGACTGAGACTAGCTGTGGTTGG
             150-20                    150-22                150-24


       310        320
GTTCTCGAGCTTAATAGGATCC
CAAGAGCTCGAATTATCCTAGG
```

FIG.1B

Met Leu Gln Arg Leu Arg Ile Val Arg Gly Thr Gln Leu Phe

Glu Asp Asn Tyr Ala Leu Ala Val Leu Asp Asn Gly Asp Pro

Leu Asn Asn Thr Thr Pro Val Thr Gly Ala Ser Pro Gly Gly

Leu Arg Glu Leu Gln Leu Arg Ser Leu Thr Glu Ile Leu Lys

Gly Gly Val Leu Ile Gln Arg Asn Pro Gln Leu Cys Tyr Gln

Asp Thr Ile Leu Trp Lys Asp Ile Phe His Lys Asn Asn Gln

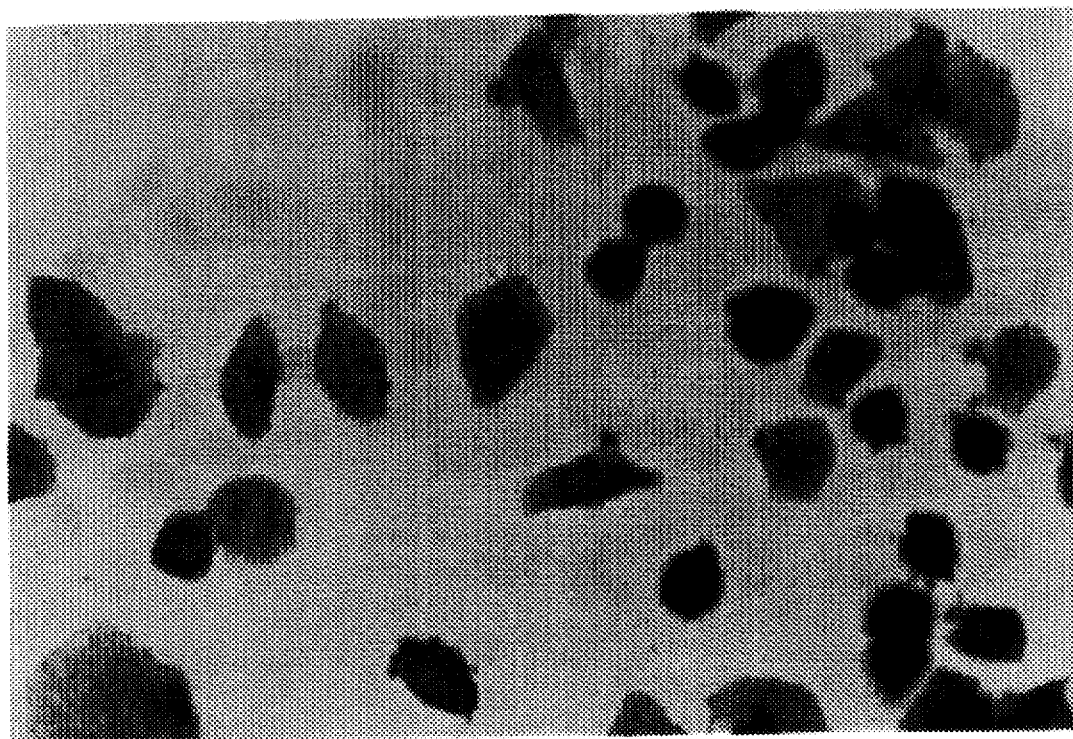Leu Ala Leu Thr Leu Ile Asp Thr Asn Arg Ser Arg Ala
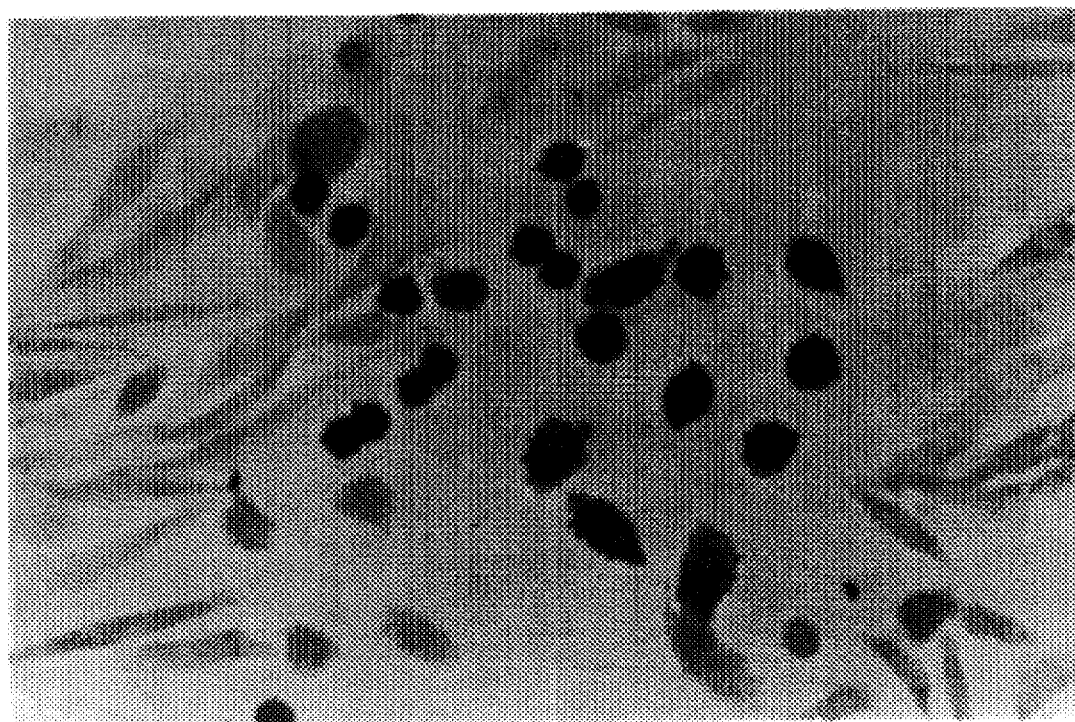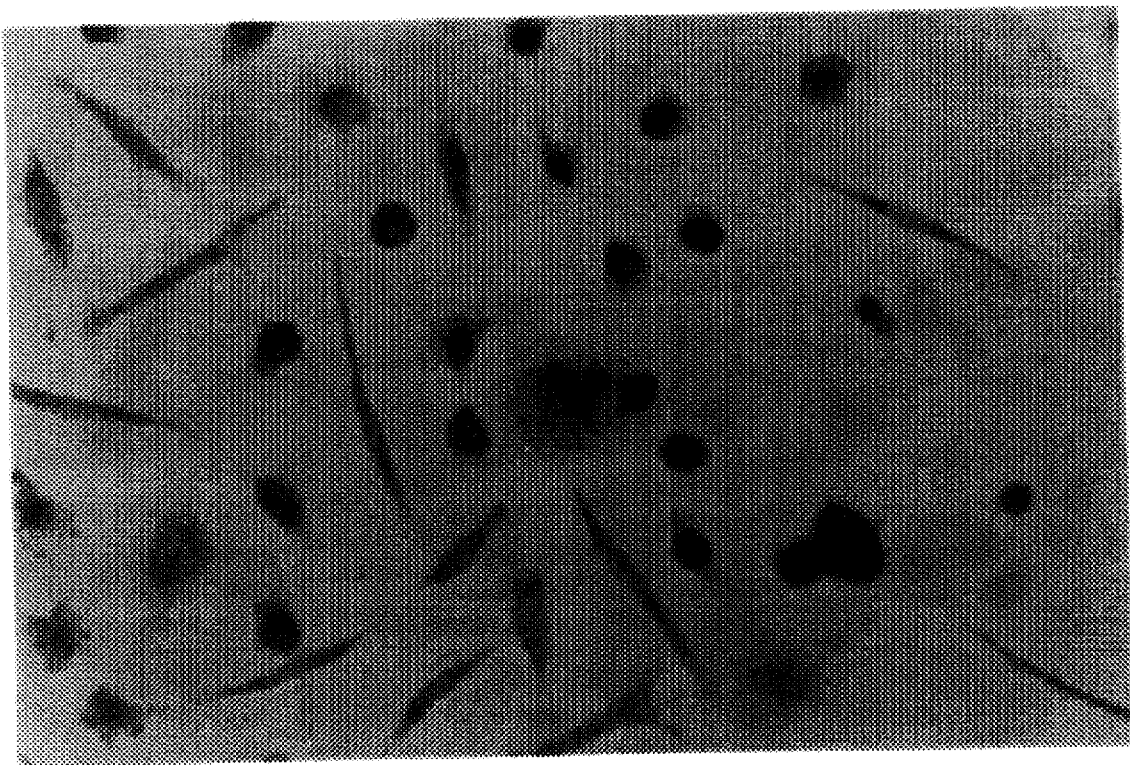
FIG.2A

FIG.2B

FIG.2C

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