

CLAIMS

1. A method for the *in vitro* diagnosis of prostate cancer in a subject, comprising the steps of:
 - a) contacting said biological sample from said subject with at least one
5 progastrin-binding molecule,
 - b) detecting the binding of said progastrin-binding molecule to progastrin in said sample, wherein said binding indicates the presence of prostate cancer in said subject.
2. The method of claim 1, wherein step b) further comprises determining the
10 concentration of progastrin and wherein a concentration of progastrin at least 10 pM in said biological sample is indicative of the presence of prostate cancer in said subject.
3. The method of claim 2, comprising the further steps of:
 - c) determining a reference concentration of progastrin in a reference
15 sample,
 - d) comparing the concentration of progastrin in said biological sample with said reference concentration of progastrin,
 - e) determining, from the comparison of step d), the presence of prostate cancer.
- 20 4. The method of any one of claims 1 to 3, wherein said progastrin-binding molecule is an antibody, or an antigen-binding fragment thereof.
5. The method of any of claims 1 to 4, wherein said antibody, or antigen-binding fragment thereof, is selected among N-terminal anti-progastrin monoclonal antibodies and C-terminal anti-progastrin monoclonal antibodies.
- 25 6. The method of any of claims 1 to 5, wherein said antibody binding to progastrin is a monoclonal antibody chosen in the group consisting of:
 - A monoclonal antibody comprising a heavy chain comprising at least one, preferentially at least two, preferentially three, of CDR-H1, CDR-H2 and CDR-H3 of amino acid sequences SEQ ID N°4, 5 and 6, respectively, and a
30 light chain comprising at least one, preferentially at least two,

preferentially three, of CDR-L1, CDR-L2 and CDR-L3 of amino acid sequences SEQ ID N° 7, 8 and 9, respectively,

- 5 - A monoclonal antibody comprising a heavy chain comprising at least one, preferentially at least two, preferentially three, of CDR-H1, CDR-H2 and CDR-H3 of amino acid sequences SEQ ID N° 10, 11 and 12, respectively, and a light chain comprising at least one, preferentially at least two, preferentially three, of CDR-L1, CDR-L2 and CDR-L3 of amino acid sequences SEQ ID N° 13, 14 and 15, respectively,
- 10 - A monoclonal antibody comprising a heavy chain comprising at least one, preferentially at least two, preferentially three, of CDR-H1, CDR-H2 and CDR-H3 of amino acid sequences SEQ ID N° 16, 17 and 18, respectively, and a light chain comprising at least one, preferentially at least two, preferentially three, of CDR-L1, CDR-L2 and CDR-L3 of amino acid sequences SEQ ID N° 19, 20 and 21, respectively,
- 15 - A monoclonal antibody comprising a heavy chain comprising at least one, preferentially at least two, preferentially three, of CDR-H1, CDR-H2 and CDR-H3 of amino acid sequences SEQ ID N° 22, 23 and 24, respectively, and a light chain comprising at least one, preferentially at least two, preferentially three, of CDR-L1, CDR-L2 and CDR-L3 of amino acid sequences SEQ ID N° 25, 26 and 27, respectively,
- 20 - A monoclonal antibody comprising a heavy chain comprising at least one, preferentially at least two, preferentially three, of CDR-H1, CDR-H2 and CDR-H3 of amino acid sequences SEQ ID N° 28, 29 and 30, respectively, and a light chain comprising at least one, preferentially at least two, preferentially three, of CDR-L1, CDR-L2 and CDR-L3 of amino acid sequences SEQ ID N° 31, 32 and 33, respectively, and
- 25 - A monoclonal antibody comprising a heavy chain comprising at least one, preferentially at least two, preferentially three, of CDR-H1, CDR-H2 and CDR-H3 of amino acid sequences SEQ ID N° 34, 35 and 36, respectively, and a light chain comprising at least one, preferentially at least two, preferentially three, of CDR-L1, CDR-L2 and CDR-L3 of amino acid sequences SEQ ID N° 37, 38 and 39, respectively.
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7. The method of any one of claims 1 to 6, wherein said biological sample is contacted with a first molecule, which binds to a first part of progastrin, and with a second molecule, which binds to a second part of progastrin.
8. The method of any one of claim 1 to 7, wherein biological sample is chosen among: blood, serum and plasma.
9. The method of any one of claims 1 to 8, wherein said biological sample is plasma, and wherein a concentration of progastrin of at least 10 pM is indicative of the presence of prostate cancer in said subject.
10. Use of a progastrin-binding antibody, or an antigen-binding fragment thereof, as in any one of claims 1 to 6 for the in vitro diagnosis of prostate cancer.