advantageous for detecting and quantifying GPC-1 levels in persons undergoing diagnostic and/or prognostic tests.

Summary of the Invention

In one aspect, provided herein is an isolated epitope or epitope segment for an anti-glypican 1 (GPC-1) antibody located within a portion of the GPC-1 flexible loop defined by an amino acid sequence KVNPQGPGPEEK (**SEQ ID NO: 1**), wherein the isolated epitope or epitope segment consists of:

(i) KVNPQGPGPEEK (**SEQ ID NO: 1**);

(ii) a fragment of KVNPQGPGPEEK (**SEQ ID NO: 1**) consisting of VNPQGPGPEEK (**SEQ ID NO: 2**), VNPQGPGPEE (**SEQ ID NO: 3**), NPQGPGPEE (**SEQ ID NO: 4**), KVNPQGPGPE (**SEQ ID NO: 5**) or KVNPQGPGP (**SEQ ID NO: 6**);

(iii) a variant of **SEQ ID NO: 3** with a substitution at any one of:

position 1, wherein V (val) is substituted with any other amino acid,

position 2, wherein N (asn) is substituted with any other amino acid,

position 3, wherein P (pro) is substituted with any other amino acid,

position 4, wherein Q (gln) is substituted with any one of Y (tyr), A (ala), E (glu), V (val), M (met), F (phe), L (leu), I (ile), T (thr), or R (arg),

position 5, wherein G (gly) is substituted with A (ala), S (ser), T (thr), H (his), W (trp), Y (tyr), F (phe), or M (met),

position 8, wherein P (pro) is substituted with any other amino acid, or

position 10, wherein E (glu) is substituted with Q (gln), D (asp), F (phe), H (his) or M (met),

(iv) a variant of **SEQ ID NO: 4** with a substitution at any one of:

position 1, wherein N (asn) is substituted with H (his),

position 2, wherein P (pro) is substituted with any other amino acid,

position 3, wherein Q (gln) is substituted with any one of N (asn), M (met), T (thr), S (ser), or R (arg),

position 5, wherein P (pro) is substituted with A (ala),

position 7, wherein P (pro) is substituted with any one of A (ala), D (asp), C (cys), E (glu), Z (glx), G (gly), H (his), K (lys), M (met), F (phe), P (pro), S (ser), T (thr), W (trp), or Y (tyr), or

position 9, wherein E (glu) is substituted with any other amino acid; or

(v) a variant of **SEQ ID NO: 5** or **SEQ ID NO: 6** with a substitution only at any one of:

position 1, wherein K (lys) is substituted with any one of W (trp), R (arg), L (lys), Y (tyr) or F (phe);

position 3, wherein N (asn) is substituted with any one of H (his), P (pro) or D (asp);

position 4, wherein P (pro) is substituted with any one of R (arg), K (lys), W (trp), S (ser), H (his) or N (asn);

position 8, wherein G (gly) is substituted with any one of D (asp), E (glu), N (asn), Q (gln), K (lys), R (arg) or A (ala); or

position 9, wherein P (pro) is substituted with any one of M (met), A (ala), I (ile), K (lys), R (arg), Q (gln), S (ser), T (thr), or Y (tyr).

In another aspect, provided herein is a nucleic acid encoding the epitope as described herein.

In another aspect, provided herein is a method for detecting prostate cancer in a subject, the method comprising detecting the presence of an epitope as described herein in a biological sample obtained from a subject, and determining that the subject has prostate cancer or an increased likelihood of developing prostate cancer based on amount of the epitope detected in the sample.

In another aspect, provided herein is fusion protein comprising the epitope as described herein.

In yet another aspect, provided herein is use of the epitope as described herein, or the fusion protein as described herein, as a positive control element in a method for detecting GPC-1.

The present inventors have determined that a series of epitopes within the GPC-1 protein are preferably targeted by binding entities including, but not limited to, antibodies.

Accordingly, the present invention relates to at least the following embodiments:

Embodiment 1: An epitope for an anti-glypican 1 (GPC-1) antibody located within a portion of the GPC-1 flexible loop defined by an amino acid sequence KVNPQGPGPEEK (**SEQ ID NO: 1**).

Embodiment 2: The epitope according to embodiment 1, wherein the epitope comprises a first segment comprising an amino acid sequence selected from:

(i) VNPQGPGPEEK (**SEQ ID NO: 2**); or

(ii) a variant of VNPQGPGPEEK (**SEQ ID NO: 2**), wherein the variant comprises a substituted amino acid residue only at:

any one or more of positions 2, 3, 7, 8, 9, 10 and/or 11; or

any one or more of positions 1, 2, 3, 4, 6, 8, 10 and/or 11; or

any one or more of positions 1, 2, 3, 4, 5, 8, 10 and/or 11.

Embodiment 3: The epitope according to embodiment 1 wherein the epitope comprises a first segment comprising an amino acid sequence selected from:

(i) KVNPQGPGP (**SEQ ID NO: 6**); or

(ii) a variant of KVNPQGPGP (**SEQ ID NO: 6**) comprising a substituted amino acid residue only at any one or more of positions 1, 3, 4, 8, and 9 of **SEQ ID NO: 6**.

Embodiment 4: The variant according to embodiment 3, comprising a substituted amino acid residue only at any one or more of positions 8 and 9 of **SEQ ID NO: 6**.

Embodiment 5: The epitope according to embodiment 1, wherein the epitope comprises a first segment comprising an amino acid sequence selected from:

(i) KVNPQGPGPE (**SEQ ID NO: 5**); or

(ii) a variant of KVNPQGPGPE (**SEQ ID NO: 5**) comprising a substituted amino acid residue only at any one or more of positions 1, 3, 4, 8, 9 and 10 of **SEQ ID NO: 5**.

Embodiment 6: The variant according to embodiment 5, comprising a substituted amino acid residue only at any one or more of positions 8, 9 and 10 of **SEQ ID NO: 6**.

Embodiment 7: The variant according to embodiment 5 or embodiment 6, wherein E (glu) at position 10 is substituted with any other amino acid.