



(86) Date de dépôt PCT/PCT Filing Date: 2005/07/29
 (87) Date publication PCT/PCT Publication Date: 2006/03/09
 (85) Entrée phase nationale/National Entry: 2007/01/26
 (86) N° demande PCT/PCT Application No.: US 2005/027183
 (87) N° publication PCT/PCT Publication No.: 2006/026020
 (30) Priorités/Priorities: 2004/07/30 (US60/592,825);
 2004/07/30 (US60/592,824); 2004/07/30 (US60/592,803);
 2004/07/30 (US60/592,823); 2004/07/30 (US60/592,804)

(51) Cl.Int./Int.Cl. *G01N 33/574* (2006.01),
A61K 39/395 (2006.01), *A61K 47/48* (2006.01),
C07K 16/18 (2006.01), *C07K 16/32* (2006.01),
C12Q 1/68 (2006.01), *G01N 33/483* (2006.01),
G01N 33/50 (2006.01), *G01N 33/53* (2006.01),
G01N 33/543 (2006.01), *C07K 14/78* (2006.01)

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(54) Titre : FIBRONECTINE ONCOFOETALE EN TANT QUE MARQUEUR DE MALADIES ET D'AUTRES CONDITIONS
 ET PROCEDES POUR LA DETECTION DE LA FIBRONECTINE ONCOFOETALE
 (54) Title: ONCOFETAL FIBRONECTIN AS A MARKER FOR DISEASE AND OTHER CONDITIONS AND METHODS
 FOR DETECTION OF ONCOFETAL FIBRONECTIN

(57) Abrégé/Abstract:

Methods and products for the detection of oncofetal fibronectin indicating molecules in samples are provided. Methods for imaging of oncofetal fibronectin are provided. In some methods provided herein, the sample is treated with a reagent and/or contacted with a non-specific binder. Provided are methods for testing subjects to ascertain health and disease status and to assess the risk of developing a disease or condition. Methods for detecting the presence of oncofetal fibronectin indicating molecules by a variety of methods such as immunoassays and mass spectrometry also are provided. Methods and products for detection of oncofetal fibronectin for selection of concepti are provided.

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(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

CORRECTED VERSION

(19) World Intellectual Property Organization
International Bureau(43) International Publication Date
9 March 2006 (09.03.2006)

PCT

(10) International Publication Number
WO 2006/026020 A2

(51) International Patent Classification: Not classified

(21) International Application Number:
PCT/US2005/027183

(22) International Filing Date: 29 July 2005 (29.07.2005)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

60/592,803	30 July 2004 (30.07.2004)	US
60/592,804	30 July 2004 (30.07.2004)	US
60/592,823	30 July 2004 (30.07.2004)	US
60/592,824	30 July 2004 (30.07.2004)	US
60/592,825	30 July 2004 (30.07.2004)	US

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(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declaration under Rule 4.17:

— as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))

Published:

— without international search report and to be republished upon receipt of that report

(48) Date of publication of this corrected version:

6 July 2006

(15) Information about Correction:

see PCT Gazette No. 27/2006 of 6 July 2006

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: ONCOFETAL FIBRONECTIN AS A MARKER FOR DISEASE AND OTHER CONDITIONS AND METHODS FOR DETECTION OF ONCOFETAL FIBRONECTIN

(57) Abstract: Methods and products for the detection of oncofetal fibronectin indicating molecules in samples are provided. Methods for imaging of oncofetal fibronectin are provided. In some methods provided herein, the sample is treated with a reagent and/or contacted with anon-specific binder. Provided are methods for testing subjects to ascertain health and disease status and to assess the risk of developing a disease or condition. Methods for detecting the presence of oncofetal fibronectin indicating molecules by a variety of methods such as immunoassays and mass spectrometry also are provided. Methods and products for detection of oncofetal fibronectin for selection of concepti are provided.

WO 2006/026020 A2

- 437 -

WHAT IS CLAIMED IS:

1. A method for detecting the presence of an oncofetal fibronectin indicating molecule in a sample, comprising:
 - contacting the sample with a substance that reduces non-specific binding of
5 background material to a fibronectin or oncofetal fibronectin binding partner;
contacting the sample with a fibronectin or oncofetal fibronectin binding partner; and
detecting any complex formed between an oncofetal fibronectin indicating molecule and the fibronectin or oncofetal fibronectin binding partner, whereby
10 detection of complex is indicative of the presence of oncofetal fibronectin indicating molecule in the sample.
 2. The method of any one of claims 1, wherein:
the fibronectin or oncofetal fibronectin binding partner is a fibronectin or oncofetal fibronectin binding protein; and
15 the oncofetal fibronectin indicating molecule is an oncofetal fibronectin protein or fragment thereof.
 3. The method of claim 1, wherein the substance is in a liquid mixture or immobilized on a solid support.
 4. The method of any one of claims 1-3, further comprising contacting the
20 sample with a second fibronectin or oncofetal fibronectin binding partner, wherein:
the second fibronectin or oncofetal fibronectin binding partner is conjugated to a detectable or bindable moiety or is immobilized on a solid support; and
detecting includes detecting complexes of the first binding partner, the second binding partner and the oncofetal fibronectin indicating molecule.
 - 25 5. The method of any one of claims 1-4, wherein:
the sample is selected from among urine, lymph, blood, plasma, serum, saliva, seminal fluid, lavages, cervical fluid, labial fluid, lower vaginal fluid, cervicovaginal fluid, vaginal fluid, breast fluid, breast milk, synovial fluid, semen, seminal fluid, stool, sputum, cerebral spinal fluid, tears, mucus, interstitial fluid, follicular fluid,
30 amniotic fluid, aqueous humor, vitreous humor, peritoneal fluid, ascites, sweat,

- 438 -

lymphatic fluid, lung sputum and a fraction or component of any of the preceding samples.

6. The method of any one of claims 1-5, wherein:
the sample is selected from among urine, lavage, breast milk, a labial swab, a
5 cervicovaginal swab, saliva, serum, plasma, blood and interstitial fluid.

7. The method of claim 6, wherein:
the sample is urine; and
the urine is neat or frozen.

8. The method of claim 1, wherein:
10 the substance that reduces non-specific binding of background material to a fibronectin or oncofetal fibronectin binding partner is a non-specific binding compound.

9. The method of claim 8, wherein:
the non-specific binding compound is selected from among albumin, casein,
15 fetal calf serum, gelatin, and an antibody that does not specifically bind an oncofetal fibronectin indicating molecule.

10. The method of claim 4, wherein the second binding partner is immobilized to the solid support of a test strip.

11. The method of claim 10, wherein:
20 the second binding partner is immobilized to a first region of the test strip;
the non-specific binding compound is immobilized to a second region of the test strip; and

the first region is downstream of the sample fluid flow pathway relative to the second region.

12. The method of any one of claims 1-11, further comprising:
normalizing the amount of oncofetal fibronectin indicating molecule in the
sample according to the concentration of one or more normalization analytes in the
sample.

13. The method of claim 12, wherein the normalization analyte is
30 creatinine.

14. The method of claim 8, further comprising:

- 439 -

separating the sample from the non-specific binding compound; and
contacting the separated sample with a solid support whereby one or more
components of the sample are immobilized on the solid support; and
contacting the solid support with a fibronectin or oncofetal fibronectin binding
5 partner.

15. The method of claim 14, wherein the one or more components are
selected from among a protein component, a nucleic acid component and a
combination thereof.

16. The method of claim 1, wherein the non-specific binder is immobilized
10 on a solid support.

17. The method of any one of claims 1-16, wherein a sample positive for
oncofetal fibronectin identifies the subject from whom the sample was collected as
having cancerous cells or pre-cancerous cells.

18. The method of claim 17, wherein the cancerous cells originate from an
15 organ selected from among breast, bladder, kidney, prostate, cervix and ovary.

19. The method of any one of claims 1-16, wherein:
a sample positive for oncofetal fibronectin identifies the subject from whom
the sample was collected as having an increased risk of imminent or preterm delivery.

20. The method of any one of claims 1-16, wherein:
20 a sample positive for oncofetal fibronectin identifies the subject from whom
the sample was collected as one for whom induction of labor is likely to be successful.

21. The method of any one of claims 1-16, wherein the fibronectin or
oncofetal fibronectin binding partner is detectably labeled.

22. The method of claim 21, wherein:
25 detectable label is selected from among a colloidal metal, a photodetectable
latex bead, a chromophore, a fluorescent moiety, a quantum dot and a detectable
enzyme.

23. The method of any one of claims 4-22, wherein:
complexes are detected by determining if any first binding partner is in spatial
30 proximity to the second binding partner, whereby detection of any first and second

- 440 -

binding partners in spatial proximity indicates presence of an oncofetal fibronectin indicating molecule in a sample.

24. The method of any one of claims 1-23, wherein presence of an oncofetal fibronectin indicating molecule equal to or above a threshold amount
5 classifies the sample as oncofetal fibronectin positive.

25. The method of any one of claims 1-24, wherein the amount of oncofetal fibronectin detected is compared to two or more thresholds; and
the sample is classified according to the highest threshold that is less than or equal to the detected amount of oncofetal fibronectin indicating molecule, whereby
10 the subject from whom the sample is collected is pregnant, and the two or more threshold amounts are a function of pregnancy gestational duration.

26. The method of any one of claims 1-25, wherein the fibronectin or oncofetal fibronectin binding partner is selected from among an anti-oncofetal fibronectin antibody or antigen-binding fragment thereof and an anti-fibronectin
15 antibody or antigen-binding fragment thereof.

27. The method of claim 4-26 wherein the second binding partner is an anti-fibronectin antibody or fragment thereof.

28. The method of any one of claims 1-27, wherein:
the oncofetal fibronectin indicating molecule is selected from among an
20 oncofetal fibronectin protein or a fragment indicative of an oncofetal fibronectin protein, a nucleic acid molecule encoding oncofetal fibronectin or a fragment indicative of an oncofetal fibronectin protein, a nucleic acid molecule complementary to a nucleic acid molecule encoding oncofetal fibronectin or a fragment indicative of an oncofetal fibronectin protein, autoantibody for oncofetal fibronectin protein or a
25 fragment indicative of an oncofetal fibronectin protein, and an autoantibody for a nucleic acid molecule encoding oncofetal fibronectin or a fragment indicative of an oncofetal fibronectin protein.

29. The method of any one of claims 1-28, wherein:
presence of an oncofetal fibronectin indicating molecule below a threshold
30 amount classifies the sample as oncofetal fibronectin negative.

30. The method of any one of claims 1-23, wherein:

- 441 -

the complex is detected by measuring the oncofetal fibronectin indicating molecule that bound to the fibronectin or oncofetal fibronectin binding partner, or a fragment of the oncofetal fibronectin indicating molecule that bound to the fibronectin or oncofetal fibronectin binding partner.

5 31. The method of any one of claims 1-30, wherein the oncofetal fibronectin indicating molecule is detected by a molecular weight of the molecule or a fragment thereof.

 32. The method of claim 31, wherein the indicating molecule is detected by mass spectrometry or gel electrophoresis.

10 33. The method of any one of claims 1-32, wherein at least one fibronectin or oncofetal fibronectin binding partner is immobilized to a test strip.

 34. A method of detecting an oncofetal fibronectin indicating molecule in tissue or cells of a subject, comprising:

 administering to a subject a fibronectin or oncofetal fibronectin binding
15 partner conjugated to an imaging moiety, whereby the conjugate localizes to tissue or cells in the subject containing an oncofetal fibronectin indicating molecule; and
 detecting the localization of the conjugate within the subject,
 thereby detecting the oncofetal fibronectin indicating molecule in tissue or cells of the subject, wherein detection is indicative of cancer or a disease state
20 characterized by the presence of oncofetal fibronectin.

 35. The method of claim 34, wherein the tissues or cells are cervical tissues or cells.

 36. The method of claim 34, further comprising contacting the sample with a substance that reduces non-specific binding of background material to the
25 fibronectin or oncofetal fibronectin binding partner.

 37. A method for detecting the presence of an oncofetal fibronectin indicating molecule in a urine sample, comprising:

 determining the amount of oncofetal fibronectin indicating molecule present in a buffer-treated urine sample, wherein:

- 442 -

600 ng/ml or more, or about 60 ng/ml or more of oncofetal fibronectin indicating molecule present in the sample identifies the sample as positive for oncofetal fibronectin.

38. The method of claim 37, further comprising:

5 contacting the sample with a first fibronectin or oncofetal fibronectin binding partner;

contacting the sample with a second fibronectin or oncofetal fibronectin binding partner, wherein: the second fibronectin or oncofetal fibronectin binding partner is conjugated to a detectable or bindable moiety, or is immobilized on a solid
10 support; and

detecting complexes of the first binding partner, oncofetal fibronectin indicating molecule and the second binding partner.

39. The method of claim 37 or 38, further comprising contacting the sample with a non-specific binding compound.

15 40. The method of any one of claims 37-39, wherein a sample positive for oncofetal fibronectin identifies the subject from whom the sample was collected as having cancerous cells or precancerous cells.

41. The method of claim 40, wherein the cancerous cells originate from an organ selected from among endometrium, uterus, breast, bladder, kidney, prostate,
20 cervix and ovary.

42. A method for determining the presence of an oncofetal fibronectin indicating molecule in a sample, comprising:

collecting the sample,
treating the sample under conditions for fragmentation of an oncofetal
25 fibronectin indicating molecule; and

detecting one or more fragments of the oncofetal fibronectin indicating molecule in the sample; whereby detection of oncofetal fibronectin indicating molecule fragments is indicative of the presence of oncofetal fibronectin indicating molecule in the sample.

30 43. The method of claim 42, wherein an amount of oncofetal fibronectin indicating molecule in the sample is determined.

- 443 -

44. The method of claim 42,
wherein the sample is selected from among urine, lymph, blood, plasma,
serum, saliva, seminal fluid, lavages, cervical fluid, labial fluid, lower vaginal fluid,
cervicovaginal fluid, vaginal fluid, breast fluid, breast milk, a labial swab, a
5 cervicovaginal swab, saliva, serum, plasma, blood, interstitial fluid, synovial fluid,
semen, seminal fluid, stool, sputum, cerebral spinal fluid, tears, mucus, interstitial
fluid, follicular fluid, amniotic fluid, aqueous humor, vitreous humor, peritoneal fluid,
ascites, sweat, lymphatic fluid, lung sputum and a fraction or component of any of the
preceding samples.
- 10 45. The method of any of claims 42-44, wherein the fragment is identified
or detected by mass spectrometry
46. The method of any of claims 42-44, wherein the fragment is captured
by an oncofetal fibronectin binding partner immobilized on a probe prior to mass
spectrometric analysis.
- 15 47. The method of any of claims 42-44, wherein prior to fragmentation, the
oncofetal fibronectin is captured by an oncofetal fibronectin binding partner
immobilized on a probe for mass spectrometric analysis.
48. A method for detecting the presence of an oncofetal fibronectin
indicating molecule in a sample, comprising:
- 20 contacting the sample with a fibronectin or oncofetal fibronectin binding
partner; and
- detecting any complex formed between an oncofetal fibronectin indicating
molecule and the fibronectin or oncofetal fibronectin binding partner, whereby
detection of complex is indicative of the presence of oncofetal fibronectin indicating
25 molecule in the sample, wherein
- the sample is selected from among lymph, blood, plasma, serum, saliva,
seminal fluid, lavages, cervical fluid, labial fluid, lower vaginal fluid, vaginal fluid,
breast fluid, breast milk, synovial fluid, semen, seminal fluid, stool, sputum, cerebral
spinal fluid, tears, mucus, interstitial fluid, follicular fluid, amniotic fluid, aqueous
30 humor, vitreous humor, peritoneal fluid, ascites, sweat, lymphatic fluid, lung sputum
and a fraction or component of any of the preceding samples.

- 444 -

49. The method of claim 48, wherein the presence of an oncofetal fibronectin indicating molecule or its presence above a threshold level is indicative of cancer.

50. A method for assessing whether a subject has an increased likelihood
5 of imminent or preterm delivery, comprising:

detecting an oncofetal fibronectin indicating molecule in a sample from a pregnant subject, wherein:

the sample is selected from among serum, plasma, blood, urine, a body tissue, lavage and cervical vaginal fluid sampled from among cervical canal, cervical os,
10 ectocervix, transition zone on the cervix between squamous and columnar cells, posterior fornix, a portion of the vagina below the posterior fornix, lower third of the vagina, labia and cervical interstitial fluid; and

the presence of the oncofetal fibronectin indicating molecule in the sample indicates that the subject has an increased likelihood of imminent or preterm delivery.

15 51. The method of claim 50, wherein the sample is urine.

52. The method of claim 50 or 51, wherein the amount of oncofetal fibronectin detected is correlated with the likelihood of imminent or preterm delivery.

53. The method of any one of claims 50-52, wherein presence of an amount of oncofetal fibronectin indicating molecule at or above a threshold level
20 indicates that the subject has an increased likelihood of imminent or preterm delivery.

54. The method of any one of claims 50-53, wherein:

the amount of oncofetal fibronectin indicating molecule detected is compared to two or more thresholds; and

the sample is classified according to the highest threshold that is less than or
25 equal to the detected amount of oncofetal fibronectin indicating molecule, whereby classification of oncofetal fibronectin indicating molecule in the sample according to the highest threshold indicates that the subject has an increased likelihood of imminent or preterm delivery.

55. The method of any one of claims 50-54, wherein:

30 the oncofetal fibronectin indicating molecule is selected from among an oncofetal fibronectin protein or a fragment thereof, a nucleic acid molecule encoding

- 445 -

oncofetal fibronectin or a fragment thereof, a nucleic acid molecule complementary to a nucleic acid molecule encoding oncofetal fibronectin or a fragment thereof, an autoantibody for oncofetal fibronectin protein or a fragment thereof and an autoantibody for a nucleic acid molecule encoding oncofetal fibronectin or a fragment thereof.

5 56. The method of any one of claims 50-55, wherein:
detecting the oncofetal fibronectin indicating molecule further comprises:
contacting the sample with a first oncofetal fibronectin binding partner; and
detecting complexes of the binding partner and oncofetal fibronectin, whereby
10 detection of a complex is indicative of the presence of oncofetal fibronectin indicating molecule in the sample.

 57. The method of claim 55 or 56, further comprising contacting a sample from the subject with a non-specific binding compound.

 58. The method of any one of claims 55-57, wherein the binding partner is
15 detectably labeled.

 59. The method of any one of claims 55-58, wherein:
detecting the oncofetal fibronectin indicating molecule further comprises:
contacting the sample with a first fibronectin or oncofetal fibronectin binding partner;
20 contacting the sample with a second fibronectin or oncofetal fibronectin binding partner, wherein:
the second fibronectin or oncofetal fibronectin binding partner is conjugated to a detectable or bindable moiety, or the second fibronectin or oncofetal fibronectin binding partner is immobilized to a solid support.

 60. The method of claim 56, wherein at least one binding partner is
25 detectably labeled.

 61. The method of any one of claims 50-60, wherein the oncofetal fibronectin indicating molecule is detected by its molecular weight or the weight of a fragment thereof.

 62. The method of claim 61, wherein the oncofetal fibronectin indicating molecule is detected by mass spectrometry or gel electrophoresis.

- 446 -

63. The method of any one of claims 50-62, wherein at least one fibronectin or oncofetal fibronectin binding partner is immobilized on a test strip.

64. A method for determining whether a subject is a candidate for successful induction of labor, comprising:

5 determining the amount of an oncofetal fibronectin indicating molecule in a sample from a pregnant subject; wherein

if the amount of oncofetal fibronectin indicating molecule is equal to or above a threshold level, the subject is identified as one likely to have a successful induction.

65. The method of claim 64, wherein a subject who has a successful
10 induction is an induction that results in vaginal delivery, shorter time to delivery or fewer administrations of induction or pre-induction agents compared to a subject that does not have a successful induction.

66. The method of claim 64 or 65, further comprising:

15 administering to the subject having an amount of oncofetal fibronectin indicating molecule equal to or above the threshold level a dose of an agent or procedure effective to induce labor.

67. The method of any one of claims 64-66, further comprising:

20 evaluating the effectiveness of induction by determining the amount of an oncofetal fibronectin indicating molecule in a sample from a pregnant subject undergoing an induction procedure; and

if the amount of oncofetal fibronectin indicating molecule is equal to or above threshold level, identifying the subject as one who is likely to have a successful induction.

68. The method of any one of claims 64-67, further comprising:

25 determining a second indicator of induction outcome for the subject, wherein:
if the amount of oncofetal fibronectin indicating molecule is above threshold level and the second indicator indicates favorable induction outcome, the subject is identified as one for whom induction is likely to be successful.

69. The method of claim 68, wherein the second indicator of induction
30 outcome is selected from among measurements or observations of the pregnant

- 447 -

subject, a measurement or observation of the fetus(es), and medical history of the pregnant subject.

70. The method of claim 69, wherein the second indicator is selected from among cervical length, Bishop score, effacement, parity, cervical dilation, gestational
5 age, body mass index, station, consistency, transvaginal ultrasound, and digital examination.

71. The method of any one of claims 68-70, further comprising:
identifying the subject as one for whom induction is likely to be successful;
and
10 administering an induction agent to a subject or subjecting the subject to a procedure.

72. The method of any one of claims 65-71, wherein the sample is collected with a swab selected from among a polyester swab, a cotton swab and a rayon swab.

15 73. The method of any one of claims 65-72, wherein the sample is contacted with a non-specific binding compound prior to determining the amount of the oncofetal fibronectin indicating molecule.

74. The method of any one of claims 65-73, wherein the oncofetal fibronectin indicating molecule or a fragment thereof is detected by mass spectrometry
20 or gel electrophoresis.

75. The method of any one of claims 65-74, wherein the complex is measured by detecting the fibronectin or oncofetal fibronectin binding partner.

76. The method of any one of claims 65-75, wherein at least one fibronectin or oncofetal fibronectin binding partner is immobilized on a test strip.

25 77. The method of any one of claims 64-76, wherein:
determining the amount of oncofetal fibronectin indicating molecule comprises:

contacting the sample with an immunoassay test strip.

78. The method of claim 77, wherein the test strip contains:

- 448 -

a mobilizable oncofetal fibronectin binding partner conjugated to a detectable moiety and a fibronectin or oncofetal fibronectin binding partner immobilized to the test strip; and

5 detecting complexes of the first binding partner, oncofetal fibronectin indicating molecule, and the second binding partner, whereby detection of a complex is indicative of the amount of oncofetal fibronectin indicating molecule in the sample.

79. A method for delivery date prediction, comprising:

measuring an oncofetal fibronectin indicating molecule in a sample from a pregnant subject, wherein:

10 an amount of oncofetal fibronectin indicating molecule in the sample at or above a threshold level indicates an increased likelihood that the subject will deliver within a particular time period.

80. The method of claim 79, wherein:

15 the particular time period is selected from among 3 weeks or less, 2 weeks or less, 10 days or less, 1 week or less, 6 days or less, 5 days or less, 4 days or less, 3 days or less, 2 days or less, or 1 day or less.

81. A method of detecting the presence of cancerous or pre-cancerous cervical cells in a subject, comprising:

20 testing for an oncofetal fibronectin indicating molecule in a sample from a subject, wherein:

the sample is selected from among urine, cervical interstitial fluid, blood, plasma and serum; and

an oncofetal fibronectin positive sample indicates the presence of cancerous or pre-cancerous cervical cells in the subject.

25 82. The method of claim 81, wherein the sample is collected with a swab selected from among a polyester swab, a cotton swab and a rayon swab.

83. The method of claim 81 or 82, wherein an amount of oncofetal fibronectin indicating molecule in the sample at or above a threshold identifies the sample as oncofetal fibronectin positive.

- 449 -

84. The method of claim 81 or 82, wherein an amount of oncofetal fibronectin indicating molecule in the sample below a threshold identifies the sample as oncofetal fibronectin negative.

85. The method of any one of claims 81-84, wherein testing further
5 comprises:

contacting the sample with a first fibronectin or oncofetal fibronectin binding partner; and

detecting complexes of the binding partner and oncofetal fibronectin indicating molecule.

10 86. The method of claim 85, wherein:

testing further comprises contacting the sample with a second fibronectin or oncofetal fibronectin binding partner, wherein: the second fibronectin or oncofetal fibronectin binding partner is conjugated to a detectable or bindable moiety, or the second fibronectin or oncofetal fibronectin binding partner is immobilized to a solid

15 support; and

detecting complexes of the first binding partner, the second binding partner, and the oncofetal fibronectin indicating molecule.

87. The method of claim 85 or 86, further comprising:

20 contacting the sample with a non-specific binding compound prior to detecting complexes.

88. The method of claim 85, wherein:

the first binding partner is conjugated to a detectable moiety.

89. The method of claim 85, further comprising:

25 contacting the sample with a detectable compound that specifically binds the first binder after contacting the first binding partner and sample.

90. The method of claim 89, wherein the detectable compound is an antibody conjugate or a nucleic acid conjugate.

91. The method of any one of claims 81-90, wherein the first binding partner is an anti-fibronectin antibody, or a fragment thereof.

30 92. The method of any one of claims 86-91, wherein the second binding partner is an anti-fibronectin antibody, or a fragment thereof.

- 450 -

93. The method of any one of claims 81-92, wherein the sample is contacted with a non-specific binding compound.

94. The method of any one of claims 81-93, wherein:
the amount of oncofetal fibronectin indicating molecule detected is compared
5 to two or more thresholds; and

the sample is classified according to the highest threshold that is less than or equal to the detected amount of oncofetal fibronectin indicating molecule, whereby classification of oncofetal fibronectin indicating molecule in the sample according to the highest threshold identifies an indication selected from among a risk of the subject
10 developing cancerous cells, a likelihood of a subject developing cancerous cells and aggressiveness of cancerous cells.

95. The method of any one of claims 85-94, wherein:
the complex is detected by measuring the oncofetal fibronectin indicating molecule that is bound to the fibronectin or oncofetal fibronectin binding partner, or a
15 fragment of the oncofetal fibronectin indicating molecule that binds to the fibronectin or oncofetal fibronectin binding partner.

96. The method of claim 95, wherein the oncofetal fibronectin indicating molecule is detected by mass spectrometry or gel electrophoresis.

97. The method of any one of claims 85-96, wherein:
20 the complex is detected by detecting the molecular weight of compounds bound to the fibronectin or oncofetal fibronectin binding partner; wherein a molecular weight that corresponds to an oncofetal fibronectin indicating molecule indicates the presence of the oncofetal fibronectin indicating molecule in the sample.

98. The method of claim 97, wherein the oncofetal fibronectin indicating
25 molecule or fragment thereof is detected by mass spectrometry or gel electrophoresis.

99. The method of any one of claims 85-94, wherein the complex is detected by detecting the fibronectin or oncofetal fibronectin binding partner bound to the oncofetal fibronectin indicating molecule.

100. The method of any one of claims 86-94, wherein:
30 the fibronectin or oncofetal fibronectin binding partner is detected by detecting the label.

- 451 -

101. The method of any one of claims 86-100, wherein at least one fibronectin or oncofetal fibronectin binding partner is immobilized to a test strip.

102. The method of any one of claims 81-101, wherein the cells are hyperplastic, neoplastic or malignant.

5 103. A method of treating tumorous tissue in a subject, comprising topically administering to a subject a fibronectin or oncofetal fibronectin binding partner, whereby the binding partner localizes to surfaces on the subject containing an oncofetal fibronectin indicating molecule, whereby the localized binding partner causes cell death or inhibits cell growth, whereby the cell death or cell growth
10 inhibition caused by the binding partner inhibits tumor proliferation in the subject.

104. A method for inhibiting the recurrence of neoplastic disease in a subject, comprising:

treating a subject for neoplastic disease; and

15 administering to the treated subject a fibronectin or oncofetal fibronectin binding partner, whereby recurrence of neoplastic disease is inhibited.

105. The method claim 104, wherein the neoplastic, malignant or metastatic cells are cells selected from among lung, breast, ovary, stomach, pancreas, larynx, esophagus, testes, liver, parotid, biliary tract, colon, rectum, cervix, uterus, endometrium, kidney, bladder, prostate, thyroid, pituitary, eye, brain, oral, skin, head
20 and neck cancer, lymphoma, leukemia, squamous cell carcinoma, adenocarcinoma, small cell carcinoma, melanoma, glioma, sarcoma and neuroblastoma.

106. A method of determining the overall health state of a subject, comprising testing for the presence of an oncofetal fibronectin indicating molecule in a sample from a subject, wherein:

25 the presence of oncofetal fibronectin indicating molecule in the sample indicates that the subject has a disease characterized by the presence of oncofetal fibronectin; and

the absence of oncofetal fibronectin indicating molecule indicates that the subject is free of a disease characterized by oncofetal fibronectin.

30 107. The method of claim 106, wherein the presence and absence are relative to a threshold level.

- 452 -

108. The method of claim 106 or 107, wherein the disease is selected from among neoplastic disease, arthritis, diabetic retinopathy and Dupuytren's contracture.

109. The method of any one of claims 106-108, further comprising performing one or more additional tests to identify the disease.

5 110. A method for detecting an oncofetal fibronectin indicating molecule or fragment thereof in a sample, comprising:

treating a sample under conditions that separate one or more first sample components from one or more second sample components, wherein an oncofetal fibronectin indicating molecule or fragment thereof, if present, is among the one or
10 more first sample components; and

detecting the oncofetal fibronectin indicating molecule or fragment thereof by its molecular weight.

111. The method of claim 110, wherein:

treating further comprises contacting the sample with a fibronectin or
15 oncofetal fibronectin binding partner immobilized on a solid support to form a complex thereof;

treating the solid support to release oncofetal fibronectin indicating molecule or fragment thereof from the complex; and

20 detecting further comprises detecting the released oncofetal fibronectin indicating molecule or fragment thereof by its molecular weight.

112. The method of claim 110 or 111, further comprising:

calculating the molecular weight of the detected oncofetal fibronectin indicating molecule or fragment thereof.

113. The method of any one of claims 110-112, wherein:

25 detecting further comprises comparing the detected first sample components to one or more references, wherein a reference that matches a detected first sample component corresponds to a fibronectin indicating molecule or fragment thereof.

114. The method of claim 111, further comprising:

30 prior to treating the solid support to release oncofetal fibronectin indicating molecule or fragment thereof from the binding partner, treating the solid support

- 453 -

under conditions that separate the solid support from sample components not specifically bound to the binding partner.

115. The method of any one of claims 111-114, wherein:

5 prior to detecting, and subsequent to, contacting the sample with a fibronectin or oncofetal fibronectin binding partner, the method further comprises contacting the sample with a fragmentation reagent.

116. The method of claim 115, wherein the fragmentation reagent is a protease or a nuclease.

117. The method of claim 115 or 116, wherein the fragmentation reagent is
10 immobilized onto a second solid support; and

contacting the sample with a fragmentation reagent further comprises contacting the sample with the second solid support.

118. The method of any one of claims 115-117, wherein:

15 prior to detecting, and subsequent to, contacting the sample with a fragmentation reagent, the method further comprises treating the sample under conditions whereby the oncofetal fibronectin indicating molecule or fragment thereof is released from the second solid support.

119. The method of any one of claims 115-118, wherein:

20 release of the oncofetal fibronectin indicating molecule or fragment thereof from the second solid support is accomplished by matrix-assisted laser desorption or electrospray desorption.

120. The method of claim 110-119, further comprising separating DNA from RNA in a sample.

121. The method of claim 120, further comprising:

25 contacting the RNA sample with a primer complementary to an oncofetal fibronectin-encoding nucleotide sequence; and

treating the sample with one or more nucleic acid synthesis steps.

122. The method of claim 121, wherein the primer is complementary to mRNA encoding oncofetal fibronectin.

30 123. The method of claim 122, wherein a first nucleic acid synthesis step includes nucleic acid synthesis by reverse transcriptase.

- 454 -

124. The method of any one of claims 110-123, wherein the oncofetal fibronectin indicating molecule is selected from among an oncofetal fibronectin protein or fragment thereof, a nucleic acid molecule encoding oncofetal fibronectin or fragment thereof, a nucleic acid molecule complementary to a nucleic acid molecule
5 encoding oncofetal fibronectin a fragment thereof, an autoantibody for oncofetal fibronectin protein or fragment thereof, and an autoantibody for a nucleic acid molecule encoding oncofetal fibronectin or fragment thereof.

125. The method of any one of claims 111-124, wherein the complex is detected by measuring products of a nucleic acid synthesis reaction.

10 126. The method of claim 110, wherein the sample comprises a sample selected from among a tissue sample, a cell sample and a liquid sample.

127. The method of claim 125, wherein:

the tissue or cell sample is selected from among: lung, breast, ovary, stomach, pancreas, larynx, esophagus, testes, liver, parotid, biliary tract, colon, rectum, cervix,
15 uterus, endometrium, kidney, bladder, prostate, thyroid, pituitary, eye, brain, oral, skin, head and neck cancer, lymphoma, leukemia, squamous cell carcinoma, adenocarcinoma, small cell carcinoma, melanoma, glioma, sarcoma neuroblastoma, semen, stool and a fraction or component thereof.

128. The method of claim 126, wherein:

20 the liquid sample comprises a body fluid selected from among: urine, blood, plasma, serum, saliva, lavage, cervical fluid, cervicovaginal fluid, vaginal fluid, breast fluid, breast milk, synovial fluid, seminal fluid, sputum, cerebral spinal fluid, tears, interstitial fluid, follicular fluid, amniotic fluid, aqueous humor, vitreous humor, peritoneal fluid, ascites, sweat, lymphatic fluid, and a fraction or component thereof.

25 129. The method of claim 128, wherein the sputum is lung sputum.

130. The method of any one of claims 111-129, further comprising:

removing sample components not bound to the binding partner prior to the step of removing the oncofetal fibronectin indicating molecule or fragment thereof from the complex.

30 131. The method of any one of claims 110-130, wherein the binding partner contains an energy absorbing moiety.

- 455 -

132. The method of claim 131, wherein:
removing is accomplished by a method selected from among ultraviolet
Matrix-Assisted Laser Desorption/Ionization, infrared Matrix-Assisted Laser
Desorption/Ionization, and electrospray ionization.
- 5 133. The method of claim 132, wherein:
the oncofetal fibronectin indicating molecule or fragment thereof is detected
by a mass spectrometry method selected from among time-of-flight, Fourier
transform, and magnetic sector/magnetic deflection.
134. The method of claim 133, further comprising enhancing a signal from
10 the oncofetal fibronectin indicating molecule bound to the binding partner.
135. The method of claim 134, further comprising quantitating the amount
of oncofetal fibronectin indicating molecule in the sample.
136. The method of any one of claims 110-135, wherein:
presence of the oncofetal fibronectin indicating molecule in a sample
15 determines a risk or identifies a health problem associated with oncofetal fibronectin.
137. The method of any one of claims 110-136, wherein:
presence of the oncofetal fibronectin indicating molecule in a sample indicates
an increased risk of imminent or preterm delivery.
138. The method of any one of claims 110-137, wherein:
20 the oncofetal fibronectin indicating molecule is autoantibodies specific for
oncofetal fibronectin; and
the presence of anti-oncofetal fibronectin autoantibodies in the sample
indicates the presence of an oncofetal fibronectin-associated health problem in the
subject.
- 25 139. The method of any one of claims 110-138, wherein:
the oncofetal fibronectin indicating molecule is autoantibodies specific for
oncofetal fibronectin; and
the presence of anti-oncofetal fibronectin autoantibodies in the sample
indicates the presence of an oncofetal fibronectin in the sample.
- 30 140. The method of claim 139, wherein:

- 456 -

detecting further comprises contacting the sample with an anti-oncofetal fibronectin autoantibody binding partner; and

detecting complexes formed between the binding partner and an anti-oncofetal fibronectin autoantibody.

5 141. The method of any one of claims 111-140, further comprising:
contacting the sample with a binding partner that specifically binds the first fibronectin or oncofetal fibronectin binding partner.

142. The method of claim 141, wherein:
the binding partner that specifically binds the first fibronectin or oncofetal
10 fibronectin binding partner is selected from among an antibody and a nucleic acid molecule.

143. The method of claim 142, wherein:
the fibronectin or oncofetal fibronectin binding partner is an anti-fibronectin antibody, or antigen-binding fragment thereof.

15 144. The method of any one of claims 110-143, wherein presence of an oncofetal fibronectin indicating molecule equal to or above a threshold level classifies the sample as oncofetal fibronectin positive.

145. The method of claim 144, wherein:
the amount of oncofetal fibronectin indicating molecule detected is compared
20 to one or more thresholds, wherein the sample is classified according to the highest threshold that is less than or equal to the detected amount of oncofetal fibronectin indicating molecule.

146. The method of claim 145, wherein:
the subject from whom the sample is collected is pregnant and the one or more
25 threshold levels correspond to increasing likelihood of imminent pregnancy termination.

147. The method of any one of claims 110-146, wherein:
the complex between the oncofetal fibronectin indicating molecule and the fibronectin or oncofetal fibronectin binding partner is measured by detecting the
30 oncofetal fibronectin indicating molecule or a fragment thereof.

148. The method of any one of claims 110-147, wherein:

- 457 -

the oncofetal fibronectin indicating molecule is detected by mass spectrometry or gel electrophoresis.

149. The method of any one of claims 111-148, wherein:

5 the complex between the oncofetal fibronectin indicating molecule and the fibronectin or oncofetal fibronectin binding partner is measured by detecting the fibronectin or oncofetal fibronectin binding partner.

150. A method for indicating oncofetal fibronectin in a subject comprising: detecting the presence of autoantibodies specific for oncofetal fibronectin in a sample from a subject, wherein:

10 the presence of anti-oncofetal fibronectin autoantibodies in the sample indicates the presence oncofetal fibronectin in the subject.

151. The method of claim 150, wherein:

detecting further comprises contacting the sample with an anti-oncofetal fibronectin autoantibody binding partner; and

15 detecting complexes formed between the binding partner and an anti-oncofetal fibronectin autoantibody.

152. The method of claim 150 or 151, wherein,:

20 the presence of autoantibodies specific for oncofetal fibronectin in a sample from a subject indicates the presence of an oncofetal fibronectin-associated health problem in the subject.

153. The method of any one of claims 150-152, further comprising:

contacting a sample with a solution that reduces non-specific binding of background material to a fibronectin or oncofetal fibronectin binding partner.

154. The method of any one of claims 150-153, wherein:

25 the sample is selected from among urine, lavage, breast milk, cervicovaginal swab, saliva, serum, plasma, blood and interstitial fluid.

155. The method of claim 154, wherein the sample is urine and one or more filtering and/or non-specific binding steps is performed on the urine sample prior to the detecting step.

30 156. The method of claim 151-155, further comprising:

- 458 -

contacting the sample with a binding partner selected from among an antibody and a nucleic acid molecule that specifically binds the anti-oncofetal fibronectin autoantibody.

157. The method of any one of claims 150-156, wherein the oncofetal
5 fibronectin indicating molecule is selected from among an oncofetal fibronectin protein or fragment thereof, a nucleic acid molecule encoding oncofetal fibronectin or fragment thereof, a nucleic acid molecule complementary to a nucleic acid molecule encoding oncofetal fibronectin a fragment thereof, an autoantibody for oncofetal fibronectin protein or fragment thereof, and an autoantibody for a nucleic acid
10 molecule encoding oncofetal fibronectin or fragment thereof.

158. The method of any one of claims 150-157, wherein presence of an oncofetal fibronectin indicating molecule equal to or above a threshold level classifies the sample as oncofetal fibronectin positive.

159. The method of claim 158, wherein:
15 the amount of oncofetal fibronectin indicating molecule detected is compared to one or more thresholds; and

the sample is classified according to the highest threshold that is less than or equal to the detected amount of oncofetal fibronectin indicating molecule, whereby the subject from whom the sample is collected is pregnant and the one or more
20 threshold levels correspond to increasing likelihood of imminent pregnancy termination.

160. The method of any one of claims 150-159, wherein:
the complex between the oncofetal fibronectin indicating molecule and the fibronectin or oncofetal fibronectin binding partner is measured by detecting the
25 oncofetal fibronectin indicating molecule or a fragment thereof.

161. The method of claim 160, wherein:
the oncofetal fibronectin indicating molecule is detected by mass spectrometry or gel electrophoresis.

162. The method of any one of claims 151-161, wherein:

- 459 -

the complex between the oncofetal fibronectin indicating molecule and the fibronectin or oncofetal fibronectin binding partner is measured by detecting the fibronectin or oncofetal fibronectin binding partner.

5 163. A method for classifying the level of oncofetal fibronectin in a sample, comprising:

measuring the amount of an oncofetal fibronectin indicating molecule in a sample;

comparing the amount of oncofetal fibronectin indicating molecule in a sample to two or more threshold levels; and

10 classifying the amount of oncofetal fibronectin indicating molecule in a sample according to the highest threshold level that is less than or equal to amount of oncofetal fibronectin indicating molecule in the sample, whereby classification of oncofetal fibronectin indicating molecule in the sample according to the highest threshold identifies an indication selected from among a higher risk of preterm, 15 impending delivery, imminent delivery, increased ability to predict delivery date, decreased likelihood of maintaining pregnancy, increased benefit from using methods of preventing preterm delivery, increased likelihood of success in inducing delivery, increased likelihood of delivery within a predetermined time, presence of cancerous cells, an increased risk of developing cancer or recurrence of cancer, a faster 20 progression of cancer, a more aggressive cancer and a decreased efficacy of cancer therapy.

164. A method for classifying a sample as oncofetal fibronectin positive or negative, comprising:

25 measuring the amount of an oncofetal fibronectin indicating molecule in a sample;

comparing the measured sample oncofetal fibronectin indicating molecule amount to a threshold level of 150 ng/ml;

30 classifying the sample as oncofetal fibronectin positive if the amount of oncofetal fibronectin indicating molecule is equal to or greater than the threshold level; and

- 460 -

classifying the sample as oncofetal fibronectin negative if the amount of oncofetal fibronectin indicating molecule is equal to or less than the threshold level

165. A method for detecting the presence of an oncofetal fibronectin indicating molecule or analog thereof in a sample, comprising:

5 contacting a sample with a first fibronectin or oncofetal fibronectin binding partner and a second fibronectin or oncofetal fibronectin binding partner; and
 measuring formation of a complex of oncofetal fibronectin, the first binding partner and the second binding partner by detecting fluorescence from non-radioactive energy transfer selected from among fluorescence energy transfer (FET), fluorescence resonance energy transfer (FRET), or homogeneous time-resolved fluorescence (HTRF).
10

166. The method of claim 165, wherein a binding partner is conjugated to a fluorescent dye or a quantum dot.

167. The method of claim 165 or 166, wherein:

15 the oncofetal fibronectin indicating molecule or analog thereof is conjugated to a fluorescent dye or a quantum dot; and
 signal dissipation or change indicates complex formation of a sample oncofetal fibronectin indicating molecule and the binding partner.

168. A method for detecting the presence of an oncofetal fibronectin indicating molecule in a sample, comprising:

20 contacting a sample with a fibronectin or oncofetal fibronectin binding partner;
 measuring formation of a complex of an oncofetal fibronectin indicating molecule and the binding partner by detecting fluorescence polarization indicative of complex formation.

25 169. The method of claim 168, wherein:

 the fluorescence polarization measurement indicates the mass of the complex;
 and

 the binding partner is conjugated to a fluorescent dye or a quantum dot.

30 170. A method for detecting an oncofetal fibronectin indicating molecule in a sample, comprising:

- 461 -

detecting the molecular weight of an oncofetal fibronectin indicating molecule or fragment thereof by mass spectrometry to thereby detect the presence of an oncofetal fibronectin indicating molecule.

171. A method for selecting concepti for implantation, comprising:
5 testing one or more conceptus samples to detect an oncofetal fibronectin indicating molecule; and

selecting a conceptus or concepti for implantation that yielded an oncofetal fibronectin positive sample.

172. The method of claim 171, wherein the oncofetal fibronectin indicating
10 molecule is selected from among a fibronectin III connecting segment (III CS), an extra-domain A (EDA), an extra-domain B (EDB) segment and an autoantibody that specifically binds to III CS, EDA or EDB.

173. The method of claim 171 or 172, wherein an amount of oncofetal
15 fibronectin indicating molecule in the sample equal to or greater than a predetermined threshold level identifies the sample as oncofetal fibronectin positive.

174. The method of claim 173, wherein the threshold level is a level predetermined to indicate that the conceptus will implant.

175. The method of claim 173 or 174, wherein samples from two or more
20 concepti are assayed, and the conceptus that yields a sample containing a higher level of oncofetal fibronectin indicating molecule is selected for implantation.

176. The method of any one of claims 171-175, further comprising
assessing the rate of increase of oncofetal fibronectin, wherein the rate is assessed by:
testing a second conceptus sample from the same conceptus to detect an
oncofetal fibronectin indicating molecule, wherein a conceptus for which the second
25 sample contains more oncofetal fibronectin indicating molecule than the first sample is suitable for implantation.

177. The method of claim 176, wherein two or more samples from each of
two or more concepti are assayed and the conceptus that exhibits the highest rate of
increase of oncofetal fibronectin is selected for implantation.

30 178. The method of any one of claims 171-177, wherein the conceptus sample is selected from among conceptus extract, sample from outside of the

- 462 -

conceptus, culture fluid bathing the conceptus and an extract of a cell from the conceptus.

179. The method of any one of claims 171-178, wherein the sample is treated with a reagent and/or fractionated prior to the step of testing for an oncofetal
5 fibronectin indicating molecule in a conceptus sample.

180. The method of 178, wherein a sample from outside the conceptus is an extract of culture medium in which a single conceptus has been cultured.

181. The method of any one of claims 171-180, further comprising determining an additional maternal or conceptus marker that is predetermined to be
10 marker for successful implantation.

182. The method of claim 181, wherein the additional marker is detected in a conceptus sample or is determined by visual inspection of the conceptus or is detected in a maternal sample.

183. The method of claim 181 or 182, wherein the additional marker is
15 selected from among genetic composition of the conceptus, gene expression of the conceptus and morphology of the conceptus.

184. The method of any one of claims 181-183, wherein one additional marker is morphology of the conceptus, and the morphology of the conceptus is graded according to factors selected from among cell number, degree of
20 fragmentation, cell regularity, symmetry, pronuclear morphology, follicle size, follicular fluid volume, multi-nucleation, presence of vacuoles, granularity, and combinations thereof.

185. A test strip for detecting the presence of an oncofetal fibronectin indicating molecule in a sample, comprising:

25 a non-specific binding region; and

an analyte binding region containing a first fibronectin or oncofetal fibronectin binding partner immobilized thereon;

wherein the analyte binding region is downstream of the sample fluid flow pathway relative to the non-specific binding region.

30 186. The test strip of claim 185, further comprising:

a conjugate pad, which serves as a sample application component;

- 463 -

an absorbent pad, which serves to draw liquid continuously through the device, wherein the materials of the membrane system form a single fluid flow pathway; and

a porous or bibulous member in fluid communication with the absorbent pad and conjugate pad, which porous or bibulous member accommodates a liquid sample and contains the analyte binding region.

187. The test strip of claim 185 or 186, further comprising:

a mobilization region containing a second fibronectin or oncofetal fibronectin binding partner, wherein:

the second fibronectin or oncofetal fibronectin binding partner is mobilized upon contact with the sample; and

the mobilization region is upstream of the analyte binding region.

188. The test strip of any one of claims 185-187, further comprising:

a control region containing a biomolecule that specifically binds the second fibronectin or oncofetal fibronectin binding partner, wherein:

the control region is downstream of the analyte binding region.

189. The test strip of any one of claims 185-188, wherein the first fibronectin or oncofetal fibronectin binding partner binds oncofetal fibronectin in preference to fibronectin.

190. The test strip of any one of claims 185-189, wherein:

the non-specific binding region contains a non-specific binding protein immobilized thereon; and

the non-specific binding protein is selected from among BSA, methylated BSA, W632 and mouse IgG.

191. A combination, comprising: a fibronectin or oncofetal fibronectin binding partner and a non-specific binder.

192. The combination of claim 191, wherein:

the non-specific binder is a non-specific binding compound or a non-specific binding surface of a solid support.

193. The combination of claim 192, wherein the solid support contains a non-specific binding surface.

- 464 -

194. The combination of claim 192 or 193, wherein the solid support is a test strip with the non-specific binding compound immobilized thereto.

195. The combination of any one of claims 191-194, further comprising a sample collection device.

5 196. A combination, comprising a fibronectin or oncofetal fibronectin binding partner and a solid support containing a non-specific binding surface.

197. The combination of claim 196, wherein:
the solid support is a test strip with a non-specific binding compound immobilized thereto.

10 198. The combination of claim 197, further comprising:
a test strip reader configured to indicate a positive result when the amount of oncofetal fibronectin indicating molecule in the sample is above a threshold level.

199. The combination of any one of claims 196-198, further comprising a sample collection device.

15 200. A kit comprising the combination of any one of claims 191-199, and optionally instructions for use.

201. The kit of claim 200, wherein the combination further contains a sample collection device.

20 202. The kit of claim 201, wherein:
the sample collection device is selected from among a urine collection device, a dipstick, a swab and a passive cervicovaginal fluid collection device; and
optionally one or more of instructions for collecting and/or measuring the oncofetal fibronectin indicating molecule, and reagents therefor.

25 203. The kit of any one of claims 200-202, further comprising a system for classifying the subject with respect to multiple thresholds.

204. The kit of any one of claims 200-203, wherein:
the combination further comprises a test strip with a non-specific binding compound immobilized thereto; and

30 the test strip reader is configured to indicate a positive result when the amount of oncofetal fibronectin indicating molecule in the sample is above one or more thresholds.

- 465 -

205. A combination, comprising a sample collection device and a fibronectin or oncofetal fibronectin binding partner.

206. The combination of claim 205, wherein:
the sample collection device is selected from among a urine collection device,
5 a dipstick, a swab and a passive cervicovaginal fluid collection device.

207. The combination of claim 206, wherein the swab is long enough to insert into the vagina, but not long enough to contact the cervix.

208. The combination of claim 206 or 207, wherein the fibronectin or oncofetal fibronectin binding partner is immobilized onto the sample collection
10 device.

209. The combination of claim 205-208, further comprising a second fibronectin or oncofetal fibronectin binding partner.

210. The combination of claim 209, wherein the second fibronectin or oncofetal fibronectin binding partner is detectably labeled.

211. The combination of any one of claims 205-210, which is configured to indicate a positive result when the amount of oncofetal fibronectin indicating
15 molecule in the sample is above a threshold level.

212. A kit comprising the combination of any one of claims 205-211, and optionally instructions for use.

213. The kit of any one of claims 205-212, wherein:
the sample collection device is selected from among a urine collection device,
20 a dipstick, a swab and a passive cervicovaginal fluid collection device; and
and optionally one or more of instructions for collecting and/or measuring the oncofetal fibronectin indicating molecule, and reagents therefor.

214. The kit of any one of claims 205-213, further comprising a system for classifying the subject with respect to multiple thresholds.

215. The kit of any one of claims 205-214, wherein:
the combination further comprises a test strip with a non-specific binding
25 compound immobilized thereto; and

- 466 -

the test strip reader is configured to indicate a positive result when the amount of oncofetal fibronectin indicating molecule in the sample is above one or more thresholds.

216. A probe for detecting an oncofetal fibronectin indicating molecule,
5 comprising
a mass spectrometry substrate; and
a fibronectin or oncofetal fibronectin binding partner immobilized on the mass spectrometry substrate.

217. The probe of claim 216, wherein:
10 the substrate contains a substance selected from among glass, metal, ceramic, Teflon coated magnetic material, organic polymer, biopolymer and inorganic polymer.

218. The probe of claim 216 or 217, wherein the molecular weight of the oncofetal fibronectin indicating molecule is detected by mass spectrometry.

219. A conjugate, comprising a fibronectin or oncofetal fibronectin binding
15 partner linked directly or via a linker to a therapeutic agent selected from among a cytokine, a photosensitizing agent, a toxin, an anticancer antibiotic, a chemotherapeutic compound, a radionuclide, an angiogenesis inhibitor, a signaling modulator and a bioluminescent compound or to a detectable moiety selected from
among a fluorescent moiety, a radionuclide, a magnetically detectable isotope or
20 compound, a sonographic imaging agent, a chromophore, a latex microsphere, or a quantum dot.

220. The conjugate of claim 219, wherein the therapeutic agent is an angiogenesis inhibitor.

221. The conjugate of claim 219, wherein the therapeutic agent is a
25 signaling modulator.

222. The conjugate of claim 221, wherein the signaling modulator is selected from among an inhibitor of macrophage inhibitory factor, a toll-like receptor agonist and a stat 3 inhibitor.

223. The conjugate of any one of claims 219-222, wherein binding partner
30 is an antibody selected from among FDC-6, BC-1, ME4C and L19.

224. A combination, comprising:

- 467 -

a fibronectin or oncofetal fibronectin binding partner and a parturifacient.

225. The combination of claim 224, further comprising a non-specific binding compound.

226. A kit, comprising the combination of claim 224 or 225, and optionally
5 instructions for use of the binding partner and parturifacient for assessing whether a subject has an increased likelihood of imminent or preterm delivery.

227. A kit, comprising:
a fibronectin or oncofetal fibronectin binding partner,
a parturifacient, and
10 a system for classifying the sample according to one or more threshold levels.

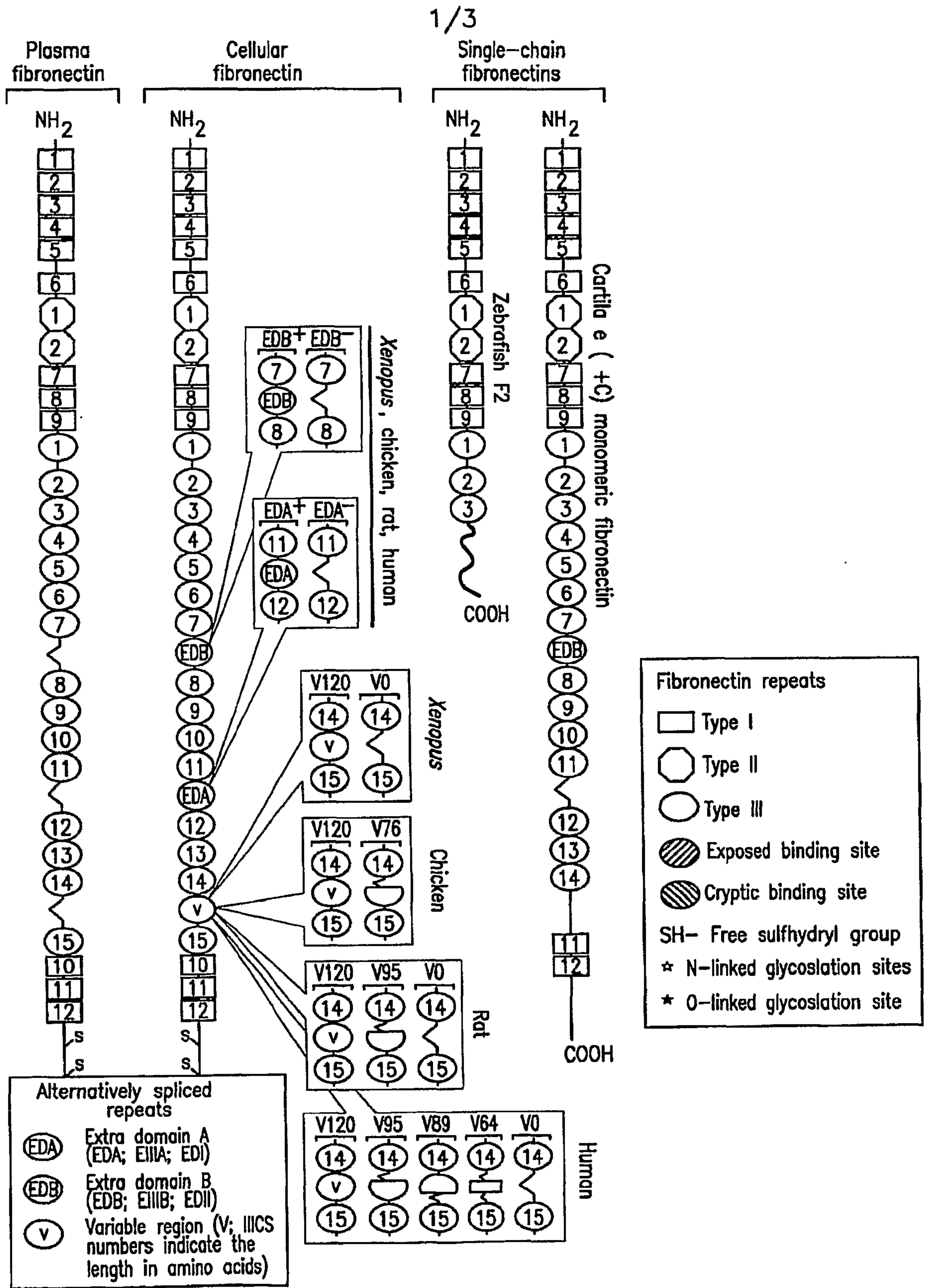
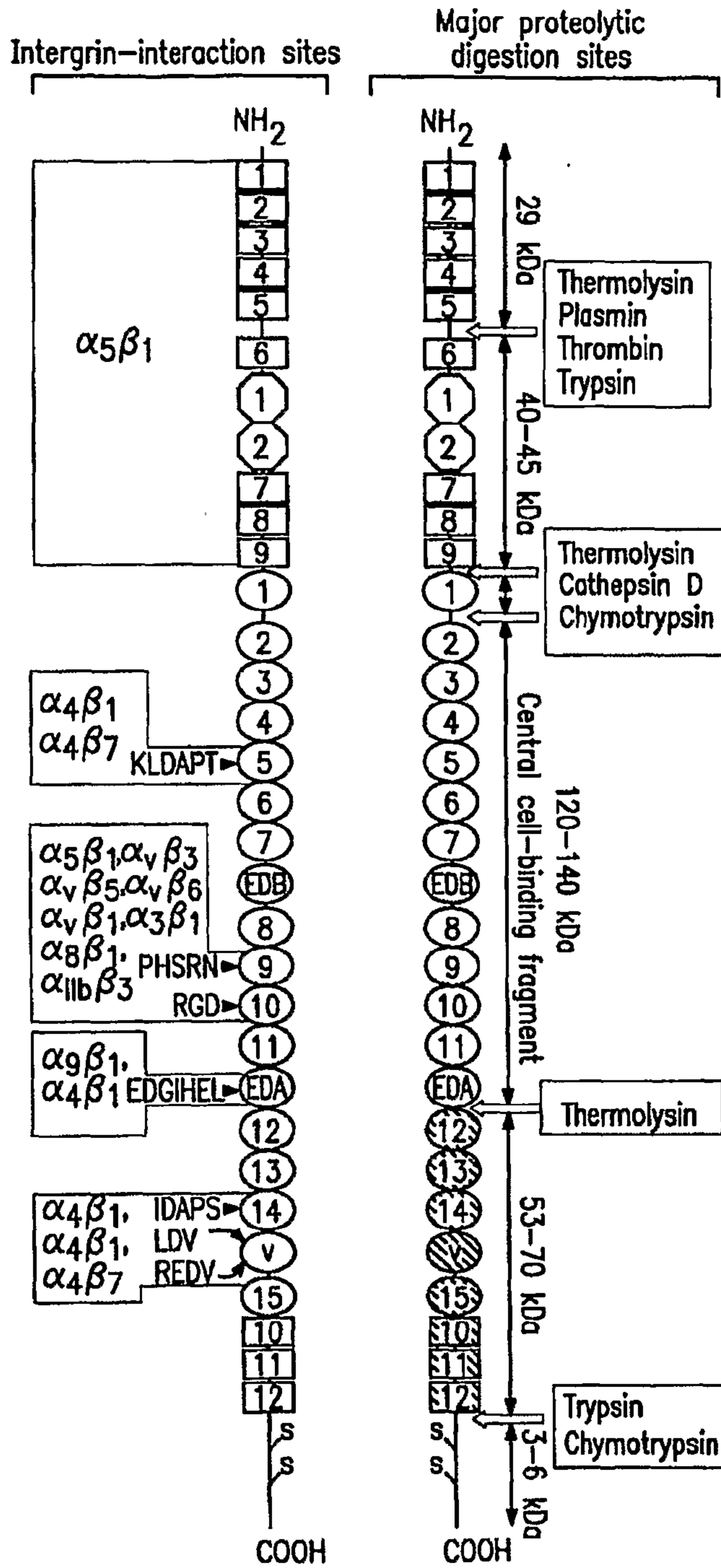


FIG. 1A

2/3



Fibronectin repeats			SH- Free sulfhydryl group
□ Type I	⬡ Type II	○ Type III	☆ N-linked glycosylation sites
▨ Exposed binding site	▩ Cryptic binding site	☆ O-linked glycosylation site	

FIG. 1B

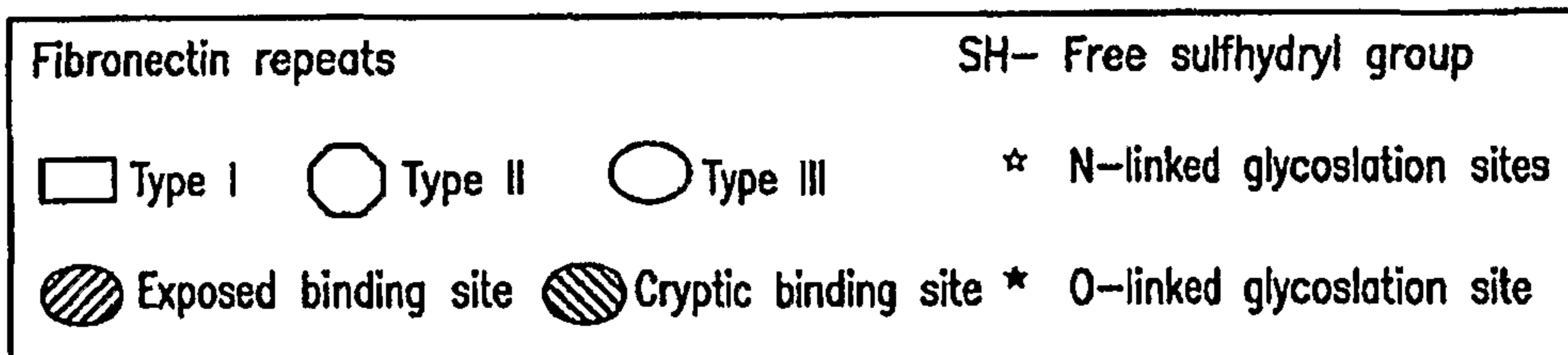
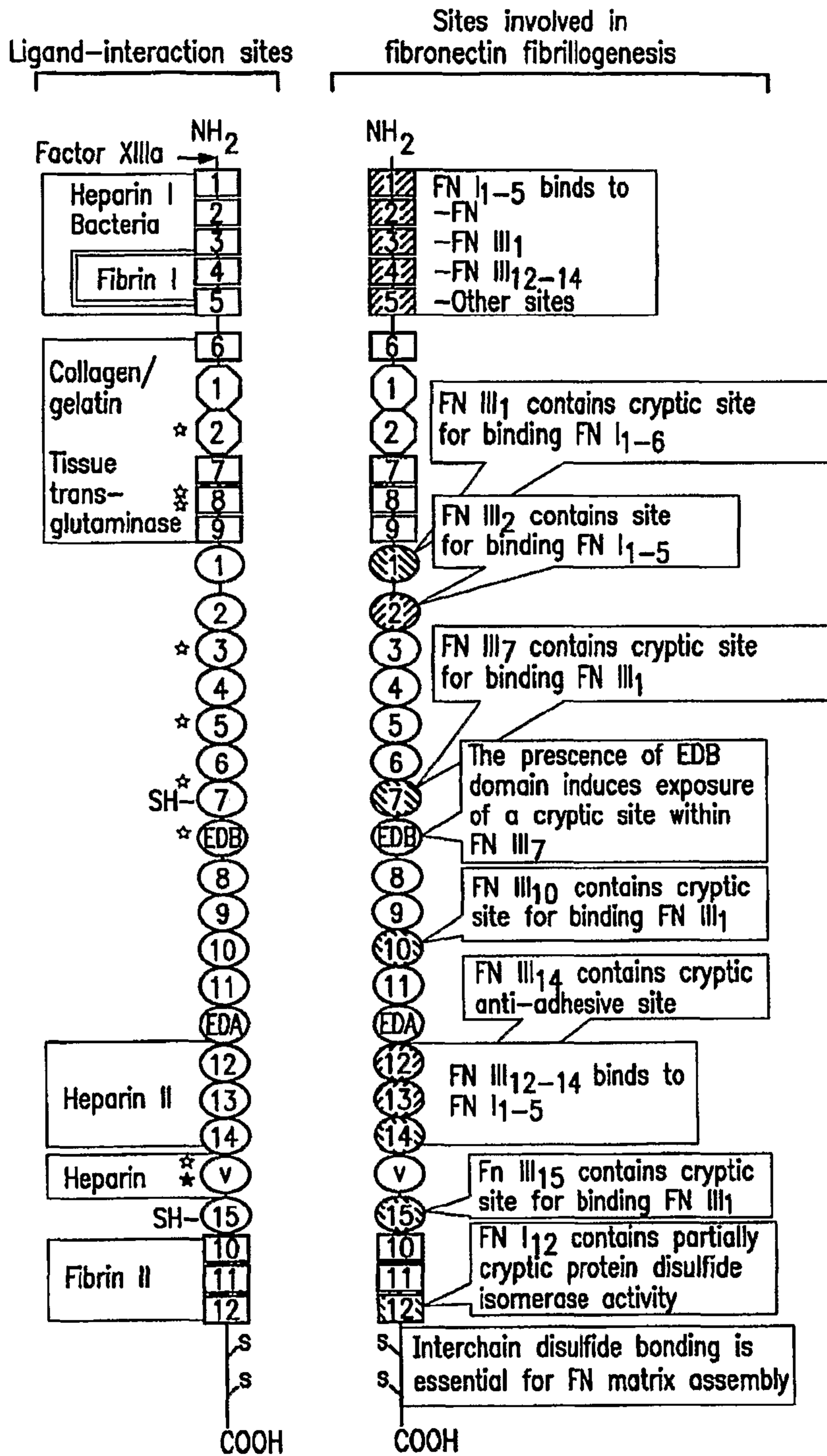


FIG. 1C