Claims

1. A screening method for diagnosing growth hormone deficiency in pediatric patients by using macimorelin comprising:

(a) providing one to five blood samples, taken from a subject within a range from about 15 to about 100 minutes following an administration of an amount of macimorelin effective for inducing growth hormone secretion;

(b) measuring the growth hormone level of each blood sample provided in step (a);

(c) comparing the measured growth hormone level obtained in step (b) with a single threshold value, wherein the single threshold value is 10.0 ng/mL or higher;

(d) determining the subject, whose highest growth hormone level in the blood samples obtained in step (b) is lower than the single threshold value, as having growth hormone deficiency, and determining the subject, whose highest growth hormone level in the blood samples obtained in step (b) is no lower than the single threshold value, as having no growth hormone deficiency.

2. The method according to claim 1, wherein the single threshold value is within a range from about 10.0 to about 25.0 ng/mL.

3. The method according to claim 1 or 2, wherein in step (a) one to four blood samples are provided.

4. The method according to claim 1 or 2 wherein in step (a) one to three blood samples are provided.

5. The method according to any of claims 1 to 4, wherein in step (a) about 0.8 mg to about 1.2 mg per kg subject body weight of macimorelin is to be administered.

6. The method according to any of claims 1 to 5, wherein the subject is a human child from the age of 2 to less than 18 years.

7. The method according to any of claims 1 to 4, wherein the subject is a human child from the age of 4 to less than 18 years

8. The method according to any of claims 1 to 7, wherein the method is a stand-alone test and does not need to be repeated and no alternative growth hormone stimulation test is required to reliably diagnose growth hormone deficiency in pediatric patients.

9. The method according to any of claims 1 to 8, wherein determining the subject as having or not having growth hormone deficiency according to step (d) is exclusively based on the growth hormone level induction by a single macimorelin administration.

10. The substance macimorelin when used in diagnosing growth hormone deficiency in pediatric patients wherein

(a) one to five blood samples are provided, taken from a subject within a range from about 15 to about 100 minutes following an administration of an amount of macimorelin effective for inducing growth hormone secretion;

(b) the growth hormone level of each blood sample provided in step (a) is measured;

(c) the measured growth hormone level obtained in step (b) is compared with a single threshold value, wherein the single threshold value is 10.0 ng/mL or higher;

(d) the subject, whose highest growth hormone level in the blood samples obtained in step (b) is lower than the single threshold value, is determined as having growth hormone deficiency, and the subject, whose highest growth hormone level in the blood samples obtained in step (b) is no lower

than the single threshold value, is determined as having no growth hormone deficiency.

11. The use of substance macimorelin according to claim 10, wherein the single threshold value is within a range from about 10.0 to about 25.0 ng/mL.

12. The use of substance macimorelin according to claim 10 or 11, wherein in step (a) one to four blood samples are provided.

13. The use of substance macimorelin according to claim 10 or 11, wherein in step (a) one to three blood samples are provided.

14. The use of substance macimorelin according to any of claims 10 to 13, wherein in step (a) about 0.8 mg to about 1.2 mg per kg subject body weight of macimorelin is to be administered.

15. The use of substance macimorelin according to any of claims 10 to 14, wherein the subject is a human child from the age of 2 to less than 18 years.

16. The use of substance macimorelin according to any of claims 10 to 14, wherein the subject is a human child from the age of 4 to less than 18 years.

17. The use of substance macimorelin according to any of claims 10 to 16, wherein the substance is used in a stand-alone test and does not need to be repeated and no alternative growth hormone stimulation test is required to reliably diagnose growth hormone deficiency in pediatric patients.

18. The use of substance macimorelin according to any of claims 10 to 17, wherein determining the subject as having or not having growth hormone deficiency according to step (d) is exclusively based on the growth hormone level induction by a single macimorelin administration.

19. A screening method for diagnosing growth hormone deficiency in pediatric patients by using macimorelin comprising:

(a) providing at least one blood sample, taken from a subject within a range from about 15 to about 100 minutes following an administration of an amount of macimorelin effective for inducing growth hormone secretion;

(b) measuring the growth hormone level of each blood sample;

(c) comparing each of the measured growth hormone level with a single threshold value, wherein the single threshold value is within a range from about 10.0 to about 25.0 ng/mL;

(d) diagnosing whether the subject suffers from growth hormone deficiency or not based on the comparison of growth hormone level measured in step (b) with said single threshold value in said at least one blood sample; wherein determining the subject as having or not having growth hormone deficiency is exclusively based on the growth hormone level induction by a single macimorelin administration.

20. The method according to claim 19, wherein the subject is a human child from the age of 2 to less than 18 years.