Prolactin

infinosis™

Prolactin (FIA)

REF: IN027705 Σ 25

Intended use
The infinosis™ Prolactin is a fluorescence immunoassay (FIA) for the in vitro quantitative determination of prolactin in Human serum or plasma. For professional use only.

Summary
References[1-2]
Prolactin is synthesized in the anterior pituitary and is secreted in episodes. The hormone is made up of 198 amino acids and has a molecular weight of approx. 22-23 kD. Prolactin appears in serum in three different forms. The biologically and immunologically active monomeric ("little") form predominates (approx. 80 %), 5-20 % is present as the biologically inactive dimeric ("big") form and 0.5-5 % is present as the tetrameric ("big-big") form having low biological activity. The target organ for prolactin is the mammary gland, the development and differentiation of which is promoted by this hormone. High concentrations of prolactin have an inhibiting action on steroidogenesis of the ovaries and on hypophyseal gonadotropin production and secretion. During pregnancy the concentration of prolactin rises under the influence of elevated estrogen and progesterone production. The stimulating action of prolactin on the mammary gland leads post partum to lactation.
Hyperprolactinemia (in men and women) is the main cause of fertility disorders. The determination of prolactin is utilized in the diagnosis of anovular cycles, hyperprolactinemic amenorrhea and galactorrhea, gynecomastia and azoospermia. Prolactin is also determined when breast cancer and pituitary tumors are suspected.

Test principle
Sandwich principle. Total duration of assay: **15 minutes**
Sample is added to the sample well of the test, then the fluorescence-labeled detector anti-PRL antibody binds to PRL antigen in blood specimen. As the sample mixture migrates on the nitrocellulose matrix of test strip by capillary action, the complexes of detector antibody and PRL are captured to anti-PRL antibody that has been immobilized on test strip.
The more PRL antigen is in blood specimen, the more complexes are accumulated on test strip. Signal intensity of fluorescence of detector antibody reflects amount of PRL captured and instrument for infinosis™ tests shows PRL concentrations in blood specimen.

Reagents
Materials provided
- **Test Cartridge**, 25 pcs, individually packaged
- **ID Chip** or **QR code of Calibration Curve**, 1 pcs
- **Sample Buffer,** 25 vials
- **IFU**, 1 copy

Materials required (but not provided)
- infinosis™ FIA analyzer
- Prolactin control (DiaSino control is recommended)
- Transfer pipette set (100 µL size)
- Centrifuge (for plasma and serum only)
- Timer

Precautions and warnings
- For in vitro diagnostic use only.
- Carefully follow the instructions and procedures described in this instructions before testing.
- The test cartridge should remain in its original sealed pouch until ready to use. Do not use it if the pouch is damaged or the seal is broken.
- Do not use reagents beyond the labeled expiry date.
- Do not mix or use components from kits with different Lots.
- Don't use Test Cartridge if its Lot does not match with ID Chip that is inserted onto the instrument.
- The infinosis™ PRL should be used only in conjunction with the instrument for infinosis™ tests.
- The tests should be applied by professionally trained staff working in certified laboratories at some remove from the patient and clinic at which the sample is taken by qualified medical personnel.
- infinosis™ PRL assay is single use only. Do not reuse it.
- The Test Cartridge and instrument for infinosis™ tests should be used away from vibration and magnetic field. During normal usage, the Test Cartridge may generate slight vibration, which should be regarded as normal.
- Use separate clean pipette tips and buffer tubes for different specimens. The pipette tips and detector buffer tubes should be used for one specimen only.
- Do not smoke, eat, or drink in areas in which specimens or kit reagents are handled.
- Blood specimens, used test cartridges, pipette tips and sample buffer tubes are potentially infectious. Proper laboratory safety techniques, handing and disposal methods should be followed in accordance with standard procedures and relevant regulations observed by microbiological hazard materials.
- The results should be interpreted by the physician along with clinical findings and other laboratory test results.

Incident report
Any suspected serious incidents related to this assay shall be immediately reported to DiaSino, DiaSino's Authorized Representative in the EU, and the national competent authorities of the Member States where the users and/or patients are located.

Storage and stability
- Store the test kit at 2-30°C, the stability is up to the expiration date printed on package.
- Test cartridge and sample buffer should be used within 1 hour after opening the pack.

Specimen collection and preparation
- The test can be performed with either serum or plasma.
- Collect serum samples in accordance with correct medical practices.
- Using standard phlebotomy procedure, collect a venipuncture whole blood specimen using a blood collection tube. If collecting plasma use a blood collection tube containing suitable anticoagulant (EDTA recommended).
- Separate the serum/plasma from blood as soon as possible to avoid hemolysis.
- Test should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 3 days. For long-term storage, specimens should be kept below -20°C.

Quality control
- Quality control tests are a part of the good testing practice to confirm the expected results and validity of the assay and should be performed at regular intervals.
- The control tests should be performed immediately after opening a new test lot to ensure the test performance is not altered.
- Quality control tests should also be performed whenever there is any question concerning the validity of the test results.
- Control materials are provided on demand with infinosis™ tests. For more information regarding obtaining the control materials, contact DiaSino Laboratories Co., Ltd for assistance.

Test setup
- Ensure that the lot number of the cartridge matches that of the sample buffer, and the ID Chip.
- If the sealed cartridge and sample buffer have been stored in refrigerator, place them at room temperature (18-25 °C) at least 30 minutes before measurement.
- Turn on the instrument for infinosis™ tests.
  Refer to the *'instrument for infinosis™ tests Operation Manual'* for the complete information and operating instructions.

Test procedure
1. Insert ID Chip into the instrument for infinosis™ tests or Scan the QR code to read the calibration curve.
2. Using a pipette to transfer **50 µL** of sample (Human plasma/serum) to the **sample buffer tube** provided in the kit.
3. Close the lid of the sample mixing tube and mix the sample thoroughly for **5-10 seconds** by tapping or inverting the tube.
4. Pipette out **100 µL** of **sample mixture** and load it onto the sample well on the cartridge.
5. Leave the sample-loaded cartridge at room temperature for **15 minutes.**
6. Insert the sample-loaded cartridge into the cartridge holder of instrument for infinosis™ tests.
   Ensure proper orientation of the cartridge before pushing it all the way inside the cartridge holder.
7. Press **"Test"** button on the instrument for infinosis™ tests.
8. Instrument for infinosis™ tests will start scanning the sample-loaded cartridge immediately.

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9. Read the test result on the display screen of the instrument for infinosis™ tests.
10. Print out the testing results when press **"Print"** button on the instrument for infinosis™ tests.

Limitations - interference
- The assay is unaffected by icterus (bilirubin < 513 µmol/L or < 30 mg/dL), hemolysis (Hb < 0.932 mmol/L or < 1.5 g/dL), lipemia (Intralipid < 1500 mg/dL) and biotin (< 164 nmol/L or < 40 ng/mL).
- Criterion: Recovery within ± 15 % of initial value.
- Samples should not be taken from patients receiving therapy with high biotin doses (i.e. > 5 mg/day) until at least 8 hours following the last biotin administration.
- No interference was observed from rheumatoid factors up to a concentration of approx. 1100 IU/mL.
- In rare cases, interference due to extremely high titers of antibodies to analyte-specific antibodies, streptavidin or ruthenium can occur. These effects are minimized by suitable test design.
- When determining prolactin it should be remembered that the measured concentration is dependent upon when the blood sample was taken, since the secretion of prolactin occurs in episodes and is also subject to a 24-hour cycle.
- The release of prolactin is promoted physiologically by suckling and stress. In addition, elevated serum prolactin concentrations are caused by a number of pharmaceuticals (e.g. dibenzodiazepines, phenothiazine), TRH and estrogen.
- The release of prolactin is inhibited by dopamine, L-dopa and ergotamine derivatives.
- A number of publications report the presence of macroprolactin in the serum of female patients with various endocrinological diseases or during pregnancy.Differing degrees of detection of the serum macroprolactins relative to monomeric prolactin (22-23 kD) by various immunoassays have also been described. This could make the detection of hyperprolactinemia dependent on the immunoassay used.
- In case of implausible high prolactin values a precipitation by polyethylene glycol (PEG) is recommended in order to estimate the amount of the biological active monomeric prolactin.
- For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

Limits and ranges
Measuring range
2.0-150 ng/mL (defined by the lower detection limit and the maximum of the master curve). Values below the lower detection limit are reported as < 2.0 ng/mL. Values above the measuring range are reported as > 150 ng/mL.

Lower detection limit
2.0 ng/mL
The lower detection limit represents the lowest analyte level that can be distinguished from zero. It is calculated as the value lying two standard deviations above that of the lowest standard (master calibrator, standard 1 + 2 SD, repeatability study, n = 20).

Expected values
Men: 2.3-17.5 ng/mL
Women: 2.9-25.8 ng/mL
These values correspond to the 2.5th and 97.5th percentiles of results obtained from a total of 128 healthy test subjects examined.
Each laboratory should investigate the transferability of the expected values to its own patient population and if necessary determine its own reference ranges.

Specific performance data
Representative performance data are given below. Results obtained in individual laboratories may differ.

Precision
Intra-assay
Determined by using 10 tests in the same batch to test with PRL control, CV ≤ 15%
Inter-assay
Determined by using 3 tests in 3 random and continuous batches to test with PRL control, CV ≤ 20%

Method comparison
A comparison of the Infinosis™ PRL assay (y) with the Roche Elecsys Prolactin II (x) using clinical samples gave the following correlations:

Number of samples measured: 131
Linear regression
y = 1.0421x + 0.048
r = 0.9863

Analytical specificity
The monoclonal antibodies used are highly specific against prolactin. No cross reaction with hGH, hCG, hPL, TSH, FSH and LH has been observed.

Functional sensitivity
2.5 ng/mL
The functional sensitivity is the lowest analyte concentration that can be reproducibly measured with an intermediate precision CV of ≤ 20 %.

Hook effect
There is no high-dose hook effect at prolactin concentrations up to 220000 µIU/mL (10000 ng/mL).

References

1. Smith CR, Norman MR. Prolactin and growth hormone: molecular heterogeneity and measurement in serum. Ann Clin Biochem 1990;27:542-550.
2. Runnebaum B, Rabe T. Gynäkologische Endokrinologie und Fortpflanzungsmedizin Springer Verlag 1994. Band 1:21,124-126,179-181,613, Band 2:412-417,436. ISBN 3-540-57345-3, ISBN 3-540-57347-X.

Symbols

IVD In vitro diagnostic medical device	30°C / 2°C Temperature limit	Consult instructions for use	REF Catalog number
LOT Batch code	Date of manufacture	Use-by date	Σ Contains sufficient for <n> tests
Manufacturer	Do not re-use	Do not use if package is damaged and consult instructions for use	CE European Conformity
EC REP Authorized representative in the European Community			

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