**SimulTRAC® Dual Label Assay**

- **Simultaneous Radioimmunoassay**
- **Unique Assay System**
- **Serum or Plasma Samples**

**PROCEDURE:**

1. Add 200 µl of standards, controls or sample to the tubes.
2. Add 100 µl of antiserum to each tube and mix well. Incubate 30 minutes at room temperature.
3. Add 100 µl of 57Co LH / 125I FSH to each tube and vortex. Incubate 60 minutes at room temperature.
4. Add 200 µl of standards, controls or sample to the tubes. Add 1.0 ml of precipitating antiserum to each tube and mix well. Centrifuge for 15 minutes at 1500 x g.
5. Decant the supernatant.
6. Count tubes in a gamma counter calibrated for 125I / 57Co and calculate results.

**For In Vitro Diagnostic Use**

- **Standard Range:** 2.5 - 160 mIU/ml LH
  1.0 - 100 mIU/ml FSH
- **Sensitivity:** 1.1 mIU/ml LH
  0.4 mIU/ml FSH
- **Calibrated Against**
  WHO 1st IRP hLH (68/40) AND
  WHO 2nd IRP hFSH (78/549)
**CLINICAL SIGNIFICANCE**

- LH is a pituitary hormone that regulates ovulatory function in women and testicular function in men.
- FSH is a pituitary hormone that regulates ovulatory function in women and testicular function in men.

Human Luteinizing Hormone (LH) and Follicle Stimulating Hormone (FSH) are glycoprotein hormones with molecular weights of approximately 30,000 with each composed of two polypeptide chains, alpha and beta subunits. The same alpha subunit is shared by LH and FSH as well as by human Chorionic Gonadotropin (hCG) and Thyroid Stimulating Hormone (TSH). The beta subunit differs among these hormones and determines their biologic (target organ) and immunologic specificity.

LH and FSH are secreted by the basophilic cells of the anterior pituitary in response to the gonadotropin-releasing hormone (GnRH) produced by the hypothalamus. In both males and females, LH and FSH control the development and maintenance of the gonadal tissues, which synthesize and secrete steroid hormones. In females, FSH controls the developing ovarian follicles and LH triggers ovulation. In males, FSH maintains spermatogenesis in the testes with the aid of LH and testosterone. LH promotes secretion of estrogen and progesterone by the ovary and of testosterone by the testis. These steroidal hormones control the circulating levels of LH and FSH by a negative feedback effect on the hypothalamus. The cyclic pattern of LH/FSH secretion in females is determined primarily by ovarian estrogen production.

LH and FSH increase markedly as a result of failure of ovarian response at the menopause and in younger women of child-bearing age with ovarian failure or immature ovaries. Elevated LH levels may accompany Stein-Leventhal syndrome (polycystic ovaries and hirsutism).

In both males and females, measurement of LH and FSH concentrations is indicated in diagnosis of infertility caused by hypogonadism or hypopituitarism, during clinical administration of gonadotropins, for ovulation timing and monitoring of ovulation induction and in the diagnosis of primary and secondary amenorrhea.

**MEASUREMENTS ARE USEFUL FOR**

- Diagnosis of ovarian failure in women
- Ovulation prediction
- Predicting response to superovulatory drugs used for *in vitro* fertilization
- Investigating amenorrhea
- Determining cause of hypogonadism in men
SimulTRAC® LH / FSH RIA

Catalog Number: 06B-262790 (100 Tube Kit)

ASSAY: Simultaneous dual radioimmunoassay

SAMPLE: 200 µl

INCUBATION: 30 minutes / 60 minutes

STANDARDS: LH: 0, 2.5, 7.5, 20, 60, 160 mIU/ml
FSH: 0, 1.0, 3.0, 10, 30, 100 mIU/ml

MINIMUM DOSE: LH: 1.1 mIU/ml / FSH: 0.4 mIU/ml

EXPECTED VALUES: LH: 1.7 - 11.9 mIU/ml (males)
FSH: 1.3 - 16.7 mIU/ml (males)
LH: 1.4 - 50.2 mIU/ml (females)
FSH: 1.1 - 125 mIU/ml (females)
(See package insert for further detail)

TEST PRINCIPLE

In radioimmunoassay, the antibody used should have an equal affinity for the standard and the analyte which is present in the patient’s serum. The unlabeled analyte competes with labeled analyte for the limited number of available antibody binding sites thereby reducing the amount of labeled analyte bound to antibody. The level of radioactivity bound is, therefore, inversely related to the concentration of analyte in the patient sample or standard.

With the ICN SimulTRAC® LH/FSH Radioimmunoassay kit, LH and FSH levels are determined simultaneously in a single tube. The LH and FSH standards, tracers and antibodies are supplied in a combined form minimizing the number of pipettings required to determine both hormone levels. These two analytes can be assayed in a single tube because the two tracers [57Co] for LH and [125I] for FSH, produce energies at levels which can be easily separated by many commercial gamma counters. Both isotopes can be counted in a single cycle on a two-channel gamma counter, reducing counter time by one half.

PRECISION - LH

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<th>LEVEL II</th>
<th>LEVEL III</th>
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<tbody>
<tr>
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<tr>
<td>mean =  5.7</td>
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<td>SD = 0.5</td>
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<tr>
<td>%CV = 8.8</td>
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PRECISION - FSH

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<tr>
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INTER-ASSAY PRECISION (mIU/ml)

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<th>LEVEL C</th>
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<tbody>
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<td>SD = 0.7</td>
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<td>%CV = 13.5</td>
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INTER-ASSAY PRECISION (mIU/ml)

<table>
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<th>LEVEL C</th>
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</thead>
<tbody>
<tr>
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<td>44</td>
</tr>
<tr>
<td>mean =  4.8</td>
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<tr>
<td>SD = 0.8</td>
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<td>%CV = 16.7</td>
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ASSAY CORRELATION - LH

\[ y = 0.95x + 1.6 \]
\[ r = 0.976 \]

n = 126

Comparison LH (mIU/mL)

ICN LH (mIU/mL)

Comparison FSH (mIU/mL)

ICN FSH (mIU/mL)

n = 93

\[ y = 0.76x - 0.6 \]
\[ r = 0.996 \]

SAMPLE STANDARD CURVE

Percent of Trace Binding, B/Bo

\[ \text{FSH (mIU/mL)} / \text{LH (mIU/mL)} \]

TO ORDER CALL (800) 854-0530