

ErbaLisa FERTILITY PANEL

Making Automation Affordable for Labs Everywhere

www.erbamannheim.com



Fertility hormone measurement

Around 10% of people of reproductive age have experienced fertility problems, with around 10% of couples not having a live-born baby after 2 years of trying naturally. Fertility declines with age, particularly in women. Women in their thirties are about half as fertile as they are in their early twenties.

There are many causes of infertility, and diagnosis depends on thorough, methodical assessment of both partners. Fertility depends on a cascade of hormone-induced processes, and so analysing these hormone levels in the blood is a hallmark of fertility assessment. Hormone testing reveals valuable information about ovarian function, ovulation, menstruation, and ovarian reserve.

ErbaLisa fertility quantitative assays

The tests in our Fertility Panel are not only essential in the evaluation of fertility, but also play a vital role in the assessment and diagnosis of a multitude of disorders in both males and females, including problems with puberty, menopause, hypothalamic and pituitary dysfunction, and some cancers.

Erba Mannheim and Calbiotech have developed a reliable and automationfriendly fertility panel, allowing for comprehensive and accurate fertility assessment. Our solid phase assays use streptavidin biotin technology, ensuring the best performance and simple interpretation of results.

Erba

All of our assays are thoroughly validated against widely used ELISA kits, assuring accurate and dependable results, every time. Intra-assay and inter-assay variation is rigorously tested meaning precision is a given.

Immuno assays

1M+ IN USE WORLDWIDE

Erba offers a wide range of clinical testing products to the growing number of smaller hospitals, reference labs, and physician clinics in the developed and emerging markets.

DEPENDABLE RESULTS EVERY TIME

ErbaLisa Fertility products provides highly reliable results in a comprehensive product range related to detecting infertility disorders.

FITS INTO EVERY LABORATORY DEMAND

Each laboratory is different. ErbaLisa Fertility product line can be successfully used in smaller, as well bigger labs. Labs with lower sample throughput can take advantage of using Erba full immunology solution, combining semi-automated instruments with wide ELISA product range. Those users, who require certain level of automation, can adapt ErbaLisa products to majority of ELISA automated platforms.







Fertility reagents

ErbaLisa FSH

Enzyme immunoassay (ELISA) kit for the accurate quantitative measurement of Follicle Stimulating Hormone (FSH) in human serum.

Follicle stimulating hormone (FSH) is a glycoprotein produced by the anterior pituitary gland, in response to gonadotropin-releasing hormone (GnRH) released by the hypothalamus. Along with luteinizing hormone (LH) it forms one of the gonadotrophic hormones. FSH is essential to pubertal development and fertility in both males and females, and testing is also done to evaluate menstrual irregularities, hypogonadism, ovulation and pituitary disorders.

In females, FSH stimulates follicular growth, prepares ovarian follicles for action by LH, and enhances the LH induced follicular release of estrogen. In general, high FSH levels are found after menopause and in premature ovarian failure. Low levels can indicate reduced oocyte production, or hypothalamus or pituitary dysfunction.

In males, FSH stimulates testicular and seminiferous tubule growth, and is involved in the early stages of spermatogenesis. Raised levels are typically found in oligospermia and primary testicular failure, whereas low levels may indicate testicular tumors.

High Reproducibility		Highly Sensitive
Intra-assay variance of 5.6-Inter-assay variance of 6.2-		 Sensitivity of 0.35 mIU/mL (mean + 2SD) No cross-reactivities
ErbaLisa kits have everythin	g you need:	
 Microwells coated with St (12x8x1) FSH Standard Set: 6 vials, use (0.5 ml x 6) FSH Enzyme Conjugate: 1 ready to use (12 ml) 	, ready to	 TMB Substrate: 1 bottle, ready to use (12 ml) Stop Solution: 1 bottle, ready to use (12 ml) 20x Wash Concentrate: 2 bottles (25 ml)
Guideline Expected Values		
Female Follicular / Luteal Pha Female Mid-Cycle Female Pregnant Female Post-menopausal Male	se	2.0 – 10 mIU/mL 2.0 – 20 mIU/mL < 2.0 mIU/mL > 15 mIU/mL 2.0 – 15 mIU/mL
Main Features		
Number of tests: 96 Solid phase: Anti-FSH / Anti-E conjugate	Biotin	Assay format: Quantitative Total incubation time: 75 minutes Sample type: Serum
Label: Biotin and HRP Method: Sandwich Streptavid	lin / Biotin	Sample volume: 50 uL
Label: Biotin and HRP	lin / Biotin	
Label: Biotin and HRP Method: Sandwich Streptavid	lin / Biotin	Sample volume: 50 uL
Label: Biotin and HRP Method: Sandwich Streptavid Built for convenience • Ready to use components • Removable strips	lin / Biotin Product name	Sample volume: 50 uL Operating Environment Interchangeable reagents Calibrators included

High Reproducibility	Highly Sensitive
Intra-assay variance of 6.2-10.6% C.V.Inter-assay variance of 8.1-11.6% C.V.	 Sensitivity of 0.12 mIU/mL (mean + 2SD) No cross-reactivities
ErbaLisa kits have everything you need:	
 Microwells coated with Streptavidin: (12x8x1) LH Standard Set: 6 vials, ready to use (0.5 ml x 6) LH Enzyme Conjugate: 1 bottle, ready to use (12 ml) 	 TMB Substrate: 1 bottle, ready to use (12 ml) Stop Solution: 1 bottle, ready to use (12 ml) 20x Wash Concentrate: 2 bottles (25 ml each)
Guideline Expected Values	
Female Follicular / Luteal Phase Female Mid-Cycle Female Pregnant Female Post-menopausal Male	1.9 - 12.5 mIU/mL 8.7 - 76.3 mIU/mL 0.5 - 16.9 mIU/mL 5.0 - 52.3 mIU/mL 1.5 - 9.3 mIU/mL
Main Features	
Number of tests: 96 Solid phase: Anti-LH / Anti-Biotin conjugate Label: Biotin and HRP Method: Sandwich Streptavidin / Biotin	Assay format: Quantitative Total incubation time: 75 minutes Sample type: Serum Sample volume: 25 uL
Built for convenience	Operating Environment
 Ready to use components Removable strips Break-apart wells 	Interchangeable reagentsCalibrators included

Catalogue Number	Product name	Format
IME00008	ErbaLisa LH	96-well ELISA

ErbaLisa LH

Enzyme immunoassay (ELISA) kit for the accurate quantitative measurement of Luteinizing Hormone (LH) in human serum.

Luteinizing hormone (LH) is a glycoprotein produced by the anterior pituitary gland, in response to gonadotropin-releasing hormone (GnRH) released by the hypothalamus. Along with follicle stimulating hormone (FSH) it forms one of the gonadotrophic hormones. LH is essential to pubertal development and fertility in both males and females, and testing is also done to evaluate menstrual irregularities, hypogonadism, ovulation and pituitary disorders.

In females, LH stimulates ovulation and the ovarian production of estradiol. In males, LH stimulates the production of testosterone from the Leydig cells in the testes, which stimulates sperm production.

In general, raised LH levels are found after menopause, and in primary hypogonadism, in the luteal phase of the menstrual cycle and in some pituitary tumors. Low levels are typically associated with ectopic steroid production and with hypothalamic or pituitary dysfunction.

ErbaLisa hCG

Enzyme immunoassay (ELISA) kit for the accurate quantitative measurement of Human Chorionic Gonadotropin (hCG) in human serum.

Human Chorionic Gonadotropin (hCG) is a glycoprotein secreted by the placenta. Consisting of alpha and beta subunits, the alpha subunit is similar to that of LH, FSH and TSH, with the beta subunit conferring its unique biological properties.

hCG is essential during early pregnancy, as it ensures the continuous production of progesterone from the corpus luteum until placental progesterone becomes established. Levels of hCG rapidly rise during early pregnancy, before declining to a lower level by around the 18th week, where it remains relatively constant throughout the rest of the pregnancy.

As well as detecting pregnancy, higher than expected levels of hCG can indicate multiple pregnancies or Down syndrome. Raised hCG found in men and non-pregnant women is suggestive of an hCG-secreting tumor. hCG measurement is therefore useful for the recognition and monitoring of chorionic tumors and as a tumor marker for other malignancies that produce hCG ectopically. These include testicular, pancreatic, and bronchogenic pulmonary cancers.

High Reproducibility		Highly Sensitive
Intra-assay variance of 2.45-6.52% C.V.Inter-assay variance of 5.2-7.1% C.V.		 Sensitivity of 0.418 mIU/mI (mean + 2SD) No cross-reactivities
ErbaLisa kits have everything	g you need:	
 Microwells coated with Streptavidin: (12x8x1) hCG Standards: 6 vials, ready to use (6 x 0.5 ml) hCG Conjugate Reagent: 1 bottle, ready to use (12 ml) 		 TMB Substrate: 1 bottle, ready to use (12 ml) Stop Solution: 1 bottle, ready to use (12 ml) 20x Wash concentrate: 2 bottles (25 ml each)
Guideline Expected Values		
hCG Normal Range = Less Th	an 5 mIU/ml.	
Main Features		
Number of tests: 96 Solid phase: Biotin labeled anti-hCG Label: Anti- hCG-HRP conjugate Method: Sandwich Streptavidin/Biotin		Assay format: Quantitative Total incubation time: 75 minutes Sample type: Serum Sample volume: 25 uL
Built for convenience		Operating Environment
Ready to use componentsRemovable stripsBreak-apart wells		Interchangeable reagentsCalibrators includedReady for automation
Catalogue Number	Product name	Format

High Reproducibility		Highly Sensitive
Intra-assay variance of 4.8Inter-assay variance of 6.7		 Sensitivity of 0.334 ng/ml (mean + 2SD) No cross-reactivities
ErbaLisa kits have everythir	ng you need:	
 Microwells coated with S (12x8x1) Prolactin Standards: 6 via ready to use (6 x 0.5 ml) Enzyme Conjugate: 1 bott ready to use (12 ml) 	i als,	 TMB Substrate: 1 bottle, ready to use (12 ml) Stop Solution: 1 bottle, ready to use (12 ml) 20x Wash concentrate: 2 bottles (25 ml each)
Guideline Expected Values		Normal Range (mIU/mL)
Male Female Pregnancy 3rd Trimester		2-17 ng/mL 3-25 ng/mL 95-480 ng/mL
Main Features		
Number of tests: 96 Solid phase: Anti-Prolactin Enzyme 7 Biotin Label: Biotin and HRP conjug Method: Sandwich Streptavio		Assay format: Quantitative Total incubation time: 75 minutes Sample type: Serum Sample volume: 25 uL
Solid phase: Anti-Prolactin Enzyme 7 Biotin Label: Biotin and HRP conjug		Total incubation time: 75 minutes Sample type: Serum
Solid phase: Anti-Prolactin Enzyme 7 Biotin Label: Biotin and HRP conjug Method: Sandwich Streptavio	din/Biotin	Total incubation time: 75 minutes Sample type: Serum Sample volume: 25 uL
Solid phase: Anti-Prolactin Enzyme 7 Biotin Label: Biotin and HRP conjug Method: Sandwich Streptavid Built for convenience • Ready to use components • Removable strips	din/Biotin	Total incubation time: 75 minutes Sample type: Serum Sample volume: 25 uL Operating Environment Interchangeable reagents Calibrators included

ErbaLisa PROLACTIN

Enzyme immunoassay (ELISA) kit for the accurate quantitative measurement of Prolactin in human serum.

Prolactin is a polypeptide hormone secreted by the anterior pituitary gland in both males and females. During and following pregnancy, prolactin, in association with other hormones, stimulates breast development and milk production. Although present in males, its function is unknown.

Testing of prolactin levels in the blood, along with other hormones, is an important part of the assessment of infertility. Elevated prolactin levels can be caused by pituitary tumors known as prolactinomas, hypothalamic diseases, hypothyroidism, renal failure, polycystic ovary syndrome, liver disease and as a side effect of several medications. Low levels of prolactin are rare, and may be caused by pituitary underactivity, and can result in insufficient milk production after birth.

Testing of prolactin levels may also be carried out if someone is producing breast milk when not pregnant or breast-feeding, has another pituitary disorder, has abnormal menstruation, or has a condition affecting how much dopamine they produce. In males, prolactin measurement can be helpful in the evaluation of erectile dysfunction.

ErbaLisa AMH

Enzyme immunoassay (ELISA) kit for the accurate quantitative measurement of Anti-Müllerian Hormone (AMH) in human serum.

Anti-Müllerian Hormone (AMH) is a glycoprotein produced by the follicular granulosa cells in the ovary, where it regulates and stimulates the production and development of follicles. AMH also plays a critical role in fetal sex differentiation, where it inhibits the growth of a female reproductive tract in male fetuses.

Measuring AMH levels can help to assess the ovarian egg reserve, assisting in the evaluation of fertility, as well as in the prediction of menopause. AMH levels are also used to determine treatment doses of hormones given during in vitro fertilization, allowing treatment to be individualized to the patient's needs.

AMH levels may be measured in newborn babies with ambiguous genitalia, where it's unclear whether the baby is a boy or a girl. AMH may also aid in the monitoring of the response to treatment and tumor recurrence in women with AMH-secreting ovarian tumors

High levels are typically seen in polycystic ovarian syndrome. Low levels are found after menopause, or may be related to ovarian insufficiency.

High Reproducibility		Highly Sensitive
Intra-assay variance of 2.Inter-assay variance of 6.		 Sensitivity of 0.018 ng/ml (mean + 2SD) No cross-reactivities)
ErbaLisa kits have everyth	ing you need:	
 Microwells coated with (12x8x1) AMH Standards: 6 vials 1 mL each AMH Controls: 2 levels (1 mL each AMH Conjugate Reager ready to use (12 ml) 	(lyophilized) - (lyophilized) -	 TMB Substrate: 1 bottle, ready to use (12 ml) Stop Solution: 1 bottle, ready to use (12 ml) 20x Wash concentrate: 2 bottles (25 ml each)
Guideline Expected Values	5	
Female Age < 24 months 24 months - 12 years 13 - 45 years		Female Expected Range, ng/mL < 4.7 < 8.8 0.9 - 9.5
> 45 years		<1.0
> 45 years Main Features		<1.0
		<1.0 Assay format: Quantitative Total incubation time: 120 minutes Sample type: Serum Sample volume: 50 uL
Main Features Number of tests: 96 Solid phase: Goat anti-AMH Label: Biotin and HRP		Assay format: Quantitative Total incubation time: 120 minutes Sample type: Serum
Main Features Number of tests: 96 Solid phase: Goat anti-AMH Label: Biotin and HRP Method: Sandwich Streptav	/idin/Biotin	Assay format: Quantitative Total incubation time: 120 minutes Sample type: Serum Sample volume: 50 uL
Main Features Number of tests: 96 Solid phase: Goat anti-AMH Label: Biotin and HRP Method: Sandwich Streptav Built for convenience • Standards and controls ly • Removable strips	/idin/Biotin	Assay format: Quantitative Total incubation time: 120 minutes Sample type: Serum Sample volume: 50 uL Operating Environment • Interchangeable reagents • Calibrators included

High Reproducibility	Highly Sensitive
Intra-assay variance of 2.93-3.60% C.V.Inter-assay variance of 3.67-5.45% C.V.	 Sensitivity of 0.04 ng/ml (mean + 2SD) No cross-reactivities
ErbaLisa kits have everything you need:	
 Microwells coated with Goat Anti- Rabbit IgG: (12x8x1) DHEA-S Standard Set: 7 Vials, Ready to Use (7 × 0.25 ml) DHEA-S Enzyme Reagent: 1 bottle, ready to use (12 ml) Anti-DHEA-S Antibody Reagent: 1 bottle, ready to use (12 ml) 	 TMB Substrate: 1 bottle, ready to use (12 ml) Stop solution: 1 bottle, ready to use (12ml) 20x Wash Concentrate: 2 bottles (25 ml each)
Guideline Expected Values	Normal Range (mIU/mL)
Male Female Premenopausal Term Pregnancy Postmenopausal Newborn (both sexes)	1.0 - 4.2 μg/ml 0.8 - 3.9 μg/ml 0.2 - 1.2 μg/ml 0.1 - 0.6 μg/ml 1.7 - 3.6 μg/ml
Main Features	
Number of tests: 96 Solid phase: Goat Anti-Rabbit IgG Label: DHEA-S HRP conjugate Method: Competitive Binding	Assay format: Quantitative Total incubation time: 90 minutes Sample type: Serum Sample volume: 10 uL
Built for convenience	Operating Environment
Ready to use componentsRemovable stripsBreak-apart wells	Interchangeable reagentsCalibrators includedReady for automation

Catalogue Number	Product name	Format	
IME00013	ErbaLisa DHEA-S	96-well ELISA	

ErbaLisa DHEA-S

Enzyme immunoassay (ELISA) kit for the accurate quantitative measurement of DHEA-S in human serum.

Dehydroepiandrosterone sulfate (DHEA-S) is male sex steroid hormone found in both males and females, produced by the adrenal glands and to a lesser extent in the testes and ovaries. DHEA-S plays important roles in the production of the male sex hormone testosterone and the female sex hormone estrogen, as well as being involved in the development of male sexual characteristics at puberty. DHEA-S testing can be used to diagnose problems with the testes or ovaries, to investigate early puberty in boys or the development of masculine features in females, as well as to assess adrenal gland function and to diagnose adrenal tumors.

High levels of circulating DHEA-S in women are associated with fertility problems, amenorrhea (absence of menstruation), acne, excessive facial or body hair and other masculine characteristics. High levels in men may not cause noticeable symptoms. High levels in children can cause the early development of pubic or underarm hair.

Low DHEA-S levels are linked to aging and are associated with low libido, erectile dysfunction, diabetes, dementia, osteoporosis, lupus and chronic fatigue syndrome.

ErbaLisa Estradiol E2

Enzyme immunoassay (ELISA) kit for the accurate quantitative measurement of Estradiol E2 in human serum.

Estradiol E2 is a steroid hormone, and the most potent natural estrogen, making it the major female sex hormone. It is produced mainly by the ovaries and the placenta, and to a lesser extent by the adrenal glands, testes, and breasts. Estradiol E2 aids the growth and development of female sex organs, regulates menstruation, helps to control female fat distribution and is essential for bone and joint health. In males, it is involved in libido, erectile function and the production of sperm.

Testing estradiol E2 is carried out to investigate infertility, abnormal menstruation, abnormal vaginal bleeding, early or late puberty, menopause, problems with the adrenal or pituitary glands, ovarian function, and ovarian tumors. In pregnancy or for women on infertility treatments, estradiol E2 measurement is helpful in tracking progress, as well as for those on transgender hormone treatment.

High levels of estradiol E2 are found in early puberty, ovarian and testicular tumors, hyperthyroidism and cirrhosis of the liver. Low levels are associated with menopause, ovarian failure, polycystic ovarian syndrome, hypogonadism, hypopituitarism, and Turner's syndrome

High Reproducibility	Highly Sensitive
Intra-assay variance of 1.82-4.02Inter-assay variance of 5.4-7.88	
ErbaLisa kits have everything you	u need:
 Microwells coated with polyclor anti-Estradiol Antibody: (12x8x1) Estradiol Standard Set: 7 Vials, r use (0.5 ml x 7) Estradiol Enzyme conjugate Concentrate, 20X: 1 Vial (0.7 ml) Assay Diluent: 1 bottle, ready to r Estradiol Biotin Conjugate: 1 bot to use (12 ml) 	ready to use (12 ml) eady to Stop solution: 1 bottle, ready to use (12ml) 20x Wash Concentrate: 2 bottles (25 ml each) use (12 ml)
Guideline Expected Values	
Males: 10-50 pg/ml Females: Postmenopausal phase 0-30 pg/m Ovulating 30-400 pg/ml Early follicular 30-100 pg/ml	Late follicular 100-400 pg/ml, Luteal phase 50-200 pg/ml, I, Pregnant, normal up to 35,000 pg/ml, Prepubertal children, normal < 10 pg/ml
Main Features	
Number of tests: 96	Assay format: Quantitative
Solid phase: Polyclonal anti-Estrac Antibody Label: HRP-labeled E2 Method: Competitive Binding	liol Total incubation time: 90 minutes Sample type: Serum Sample volume: 25 uL
Antibody Label: HRP-labeled E2	Sample type: Serum
Antibody Label: HRP-labeled E2 Method: Competitive Binding	Sample type: Serum Sample volume: 25 uL
Antibody Label: HRP-labeled E2 Method: Competitive Binding Built for convenience • Ready to use components • Removable strips • Break-apart wells	Sample type: Serum Sample volume: 25 uL Operating Environment Interchangeable reagents Calibrators included

High Reproducibility	Highly Sensitive
Intra-assay variance of 2.84-5.97% C.V.Inter-assay variance of 4.9-6.3% C.V.	 0.06 ng/mL (mean + 2SD) No cross-reactivities
ErbaLisa kits have everything you need:	
 Microwells coated with Goat Anti-Rabbit IgG: (12x8x1) Estriol Standard Set: 6 Vials, ready to use) - 0.5 ml x 6 Estriol Control Set: 2 Vials (ready to use) 	 Rabbit Anti-Estriol Reagent: 1 bottle (ready to use) - 12 ml TMB Substrate: 1 bottle - (ready to use) - 12 ml Stop solution: 1 bottle -

- Estriol Control Set: 2 Vials (ready to use) -0.5 ml x 2
- Estriol Enzyme Reagent: 1 bottle (ready to use) 12 ml

Guideline Expected Values

Population Expected Range

Males Female (nonpregnant)

<2.0 ng/mL

(ready to use) - 12ml

(25 ml each)

• 20x Wash Concentrate: 2 bottles

Week of Gestation	Expected Range, ng/ml	Week of Gestation	Expected Range, ng/ml
12	0.3 - 1.0	34	5.1 - 25
14	0.4 - 1.6	35	5.2 - 26.4
16	1.4 - 6.5	36	8.2 - 28.1
18	1.6 - 8.5	37	8.0 - 30.1
20	2.1 - 13	38	8.6 - 38.0
22	2.7 - 16	39	7.2 - 34.3
26	3.0 - 18	40	9.6 - 28.9
30	36-22		

Main Features

Number of tests: 96 Solid phase: Goat Anti-Rabbit IgG Label: E3-HRP conjugate Method: competitive binding

Assay format: Quantitative Total incubation time: 60 minutes Sample type: Serum Sample volume: 25 uL

ErbaLisa kits have everything you need:

Ready to use components Removable strips Break-apart wells	Interchangeable reagentsCalibrators includedReady for automation

IME00015 ErbaLisa FREE ESTRIOL 96-well ELISA	Catalogue Number	Product name	Format
	IME00015	ErbaLisa FREE ESTRIOL	96-well ELISA

ErbaLisa Free Estriol E3

Enzyme immunoassay (ELISA) kit for the accurate quantitative measurement of Free Estriol E3 in human serum.

Free estriol E3, also known as uE3, is a steroid hormone produced almost exclusively during pregnancy by the placenta. Circulating levels in non-pregnant women are almost undetectable. Measurement of maternal free (or unconjugated) estriol E3 is used to assess fetoplacental function and to help assess fetal distress in the management of patients with complications, including pre-eclampsia, diabetes, Rh immunization, choriocarcinoma and hydatidiform mole. Free estriol E3 is also a component of the triple and quadruple antenatal screening tests for fetal abnormalities.

Low circulating maternal levels of free estriol E3 may be found in fetal chromosomal or congenital abnormalities such as Down's syndrome and Turner's syndrome. High levels can be found in cases of hydrops fetalis where the fetus is dying.

In the maternal circulation, free estriol E3 undergoes rapid conjugation in the liver, with a halflife of approximately 20 minutes, followed by excretion in the urine. Therefore maternal free estriol E3 levels can provide a dynamic estimate of fetal production rates

ErbaLisa Progesterone

Enzyme immunoassay (ELISA) kit for the accurate quantitative measurement of Progesterone in human serum.

Progesterone is a steroid hormone produced mainly by the adrenal glands, the ovaries and the placenta (during pregnancy). Progesterone has many functions in the body, and is primarily involved in fertility, menstruation and maintaining early pregnancy. In females, progesterone levels increase rapidly following ovulation, remaining elevated for 4-6 days, where it triggers endometrial thickening in the preparation for potential pregnancy. If pregnancy occurs, progesterone stimulates blood vessel formation in the endometrium, and the placenta becomes the primary site of progesterone production, inhibiting ovulation. In males, progesterone is associated with sperm development, and is a necessary intermediate for the production of corticosteroids and androgens.

Measurement of progesterone is performed to determine ovulation, investigate infertility, diagnose miscarriage or ectopic pregnancy, monitor progesterone therapy in high-risk pregnancies, investigate bleeding and diagnose adrenal disorders. High levels of progesterone typically don't cause adverse effects, whereas low levels are associated with infertility, abnormal or absent menstruation, miscarriage and poor ovarian function.

High Reproducibility	Highly Sensitive
Intra-assay variance of 2.93-3Inter-assay variance of 3.67-5	
ErbaLisa kits have everything y	ou need:
 Microwells coated with Strep (12x8x1) Progesterone Standard Set: ready to use (0.25 ml x 6) Progesterone Enzyme conju Concentrate, 20X: 1Vial (0.7 Progesterone-Biotin Conjuga 1 bottle, ready to use, (12 ml) 	a Vials, • TMB Substrate: 1 bottle, ready to use (12 ml) 6 Vials, • TMB Substrate: 1 bottle, ready to use (12 ml) gate • Stop solution: 1 bottle, ready to use (12 ml)
Guideline Expected Values	
Pre-ovulation< 0.89	First trimester11–44Second trimester25–83Third trimester58–214
Main Features	
Number of tests: 96 Solid phase: Streptavidin Label: Progesterone HRP conjug Method: Competitive binding	Assay format: Quantitative Total incubation time: 75 minutes ate Sample type: Serum Sample volume: 20 uL
Built for convenience	Operating Environment
Ready to use componentsRemovable stripsBreak-apart wells	Interchangeable reagentsCalibrators includedReady for automation
Catalogue Number P	roduct name Format
IME00017 Ert	aLisa PROGESTERONE 96-well ELISA

High Reproducibility	Highly Sensitive
Intra-assay variance of 2.93-3.60% C.V.Inter-assay variance of 3.67-5.45% C.V.	 Sensitivity of 0.04 ng/ml (mean + 2SD) No cross-reactivities
ErbaLisa kits have everything you need:	
 Microwells coated with Goat Anti- Rabbit IgG: (12x8x1) 17-OHP Standard Set: 6 Vials, ready to use (0.5 ml x 6) 17-OHP Antibody Reagent: 1 bottle, ready to use (7 ml) Assay Diluent: 1 bottle, ready to use (7 ml) 	 17-OHP Enzyme conjugate Concentrate, 20X: 1 Vial (0.45 ml) TMB Substrate: 1 bottle, ready to use (12 ml each) Stop solution: 1 bottle, ready to use, (12ml) 20x Wash Concentrate: 2 bottles (25 ml each)

Guideline Expected Values

Babies more than 24 hours old - less than 400 to 600 ng/dL or 12.12 to 18.18 nmol/L Children before puberty around 100 ng/dL or 3.03 nmol/L

Main Features

Number of tests: 96 **Solid phase:** 17-OHP Enzyme conjugate Label: 17-OHP-HRP conjugate Method: Streptavidin / Biotin

Assav format: Quantitative **Total incubation time:** 75 minutes Sample type: Serum Sample volume: 25 uL

Adults - less than 200 ng/dL or 6.06

nmol/L

Built for convenience		Operating Environment	
Ready to use componentsRemovable stripsBreak-apart wells		Interchangeable reagentsCalibrators includedReady for automation	
Catalogue Number	Product name	Format	
IME00018	ErbaLisa 17(OH)	96-well ELISA	

PROGESTERONE

ErbaLisa 17(OH) Progesterone

Enzyme immunoassay (ELISA) kit for the accurate quantitative measurement of 17(OH) Progesterone in human serum.

17(OH) progesterone is a steroid hormone produced by the adrenal glands, and is metabolized to produce cortisol, a hormone involved in mediating the stress response, regulating metabolism, and immunity. When there is a deficiency in one of the enzymes involved in the metabolism of 17(OH) progesterone to cortisol (21-hydroxylase is the most common deficiency), cortisol cannot be produced, and levels of 17(OH) progesterone build up. This is known as congenital adrenal hyperplasia (CAH), and measuring circulating levels of 17(OH) progesterone is used to screen for CAH, as part of routine newborn screening, as well as in babies with signs of CAH.

Older children and adults can develop forms of CAH, and high levels of 17(OH) progesterone is diagnostic in the investigation of symptoms such as infertility, early or abnormal puberty, and a deep voice. Periodic measurement of 17(OH) progesterone in people with CAH is essential to monitor treatment, where normal or low levels suggest good treatment response, and high levels indicate a change in treatment may be needed.

ErbaLisa Total Testosterone

Enzyme immunoassay (ELISA) kit for the accurate quantitative measurement of Total Testosterone in human serum.

Testosterone is a steroid hormone primarily secreted by the testes in males and the ovaries in females, with smaller amounts secreted by the adrenal glands. It is the main male sex hormone and the most important androgen. Testosterone is responsible for the development of secondary male sex characteristics in puberty, and in adult men it controls libido and aids the production of sperm. Present in smaller quantities in females, it plays a role in fertility, as well as in menstrual and vaginal health. Measuring circulating testosterone levels is helpful in the evaluation of hypogonadism and infertility.

In males, high levels of testosterone are found in testicular tumors, hypothalamic-pituitary disorders, congenital adrenal hyperplasia and prostate cancer. High levels in females are associated with hirsutism, virilization, adrenal or ovarian tumors, polycystic ovarian syndrome, and adrenal hyperplasia. Low levels of testosterone can be found in hypopituitarism, Klinefelter syndrome, testicular feminization, some autoimmune diseases, enzymatic defects, orchidectomy and cryptorchidism.

 Intra-assay variance of 2.9-3.8% C.V. Inter-assay variance of 5.4-8.65% C.V. Sensitivity of 1.16 ng/ml (mean + 2SD) No cross-reactivities 	 Intra-assay variance of 2.9-3.8% C.V. Inter-assay variance of 5.4-8.65% C.V. Sensitivity of 1.16 ng/ml (mean + 2SD) No cross-reactivities ErbaLisa kits have everything you need: Microwells coated with Mouse Anti Testosterone: (12x8x) Anti-Testosterone Biotin Reagent: 1 bottle, Ready to use, 7 ml Testosterone Standard Set: 6 Vials, ready to use (0.5 ml x 6) Testosterone Enzyme Conjugate 20X: 1 vial (0.7 ml) Assay Diluent: 1 bottle, ready to use (12 ml) Males: prepubertal (late): 0.1 – 0.2 ng/ml, Adult: 3.0 – 10.0 ng/ml, Females: Prepubertal(late): 0.1 – 0.2 ng/ml, Follicular phase: 0.2 – 0.8 ng/ml, Luteal phase: 0.2 – 0.8 ng/ml, Post menopausal: 0.08 – 0.35 ng/ml Main Features Mumber of tests: 96 Solid phase: Streptavidin Label: Testosterone-HRP conjugate Method: Competitive binding Built for convenience Noperating Environment Interchangeable reagents Calibrators included Ready to use components Ready to use components Ready for automation 			
Inter-assay variance of 5.4-8.65% C.V. (mean + 2SD) No cross-reactivities ErbaLisa kits have everything you need: • Anti-Testosterone Biotin Reagent: 1 bottle, Ready to use, 7 ml • Testosterone Standard Set: 6 Vials, ready to use (0.5 ml x 6) • Anti-Testosterone Biotin Reagent: 1 bottle, Ready to use, 7 ml • Testosterone Enzyme Conjugate 20X: 1 vial (0.7 ml) • Stop solution: 1 bottle, ready to use (12 ml) • Assay Diluent: 1 bottle, ready to use (12 ml) • Stop solution: 1 bottle, ready to use (12 ml) Suideline Expected Values Normal Range (mlU/mL) Males: prepubertal (late): 0.1 – 0.2 ng/ml, Adult: 3.0 – 10.0 ng/ml, Females: Prepubertal(late): 0.1–0.2 ng/ml Follicular phase: 0.2 – 0.8 ng/ml, Luteal phase: 0.2 – 0.8 ng/ml, Post menopausal: 0.08 – 0.35 ng/ml Main Features Assay format: Quantitative Total incubation time: 90 minutes Sample type: Serum Sample volume: 50 uL Number of tests: 96 Solid phase: Streptavidin .abel: Testosterone-HRP conjugate Wethod: Competitive binding Assay format: Quantitative Total incubation time: 90 minutes Sample type: Serum Sample volume: 50 uL Built for convenience Operating Environment • Interchangeable reagents • Calibrators included • Ready to use components • Ready to use components • Ready for automation	 Inter-assaý variance of 5.4-8.65% C.V. (mean + 2SD) No cross-reactivities ErbaLisa kits have everything you need: Microwells coated with Mouse Anti Testosterone: (12x8xl) Testosterone Standard Set: 6 Vials, ready to use (0.5 ml × 6) Testosterone Enzyme Conjugate 20X: 1 vial (0.7 ml) Assay Diluent: 1 bottle, ready to use (12 ml) Stop solution: 1 bottle, ready to use (12 ml) Stop solution: 1 bottle, ready to use (12 ml) Quideline Expected Values Males: prepubertal (late): 0.1 – 0.2 ng/ml, Adult: 3.0 – 10.0 ng/ml, Females: Prepubertal(late): 0.1 – 0.2 ng/ml, Post menopausal: 0.08 – 0.35 ng/ml Follicular phase: 0.2 – 0.8 ng/ml, Post menopausal: 0.08 – 0.35 ng/ml Main Features Number of tests: 96 Solid phase: Streptavidin Label: Testosterone-HRP conjugate Method: Competitive binding Built for convenience Ready to use components Removable strips Break-apart wells Interchangeable reagents Calibrators included Ready for automation 	High Reproducibility	Highly Se	ensitive
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Number of tests: 96 Assay format: Quantitative Solid phase: Streptavidin Total incubation time: 90 minutes Label: Testosterone-HRP conjugate Sample type: Serum Method: Competitive binding Sample volume: 50 uL Built for convenience Operating Environment • Ready to use components • Interchangeable reagents • Removable strips • Calibrators included • Break-apart wells • Ready for automation	Number of tests: 96Assay format: QuantitativeSolid phase: StreptavidinTotal incubation time: 90 minutesLabel: Testosterone-HRP conjugateSample type: SerumMethod: Competitive bindingSample volume: 50 uLBuilt for convenienceOperating Environment• Ready to use components• Interchangeable reagents• Removable strips• Calibrators included• Break-apart wells• Ready for automation		Prepuber Follicular Luteal ph	phase: 0.2 – 0.8 ng/ml, ase: 0.2 – 0.8 ng/ml,
Solid phase: Streptavidin Total incubation time: 90 minutes Label: Testosterone-HRP conjugate Sample type: Serum Method: Competitive binding Sample volume: 50 uL Built for convenience Operating Environment Ready to use components Interchangeable reagents Removable strips Calibrators included Break-apart wells Ready for automation	Solid phase: Streptavidin Label: Testosterone-HRP conjugate Method: Competitive bindingTotal incubation time: 90 minutes Sample type: Serum Sample volume: 50 uLBuilt for convenienceOperating Environment• Ready to use components • Removable strips • Break-apart wells• Interchangeable reagents • Calibrators included • Ready for automationCatalogue NumberProduct nameFormat	Main Features		
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ME00019 ErbaLisa TESTOSTERONE 96-well ELISA		Method: Competitive binding Built for convenience Ready to use components Removable strips Break-apart wells	Sample v Operating • Interch • Calibra • Ready	olume: 50 uL g Environment angeable reagents tors included for automation

High Reproducibility

Highly Sensitive

- Intra-assay variance of 4.93-5.88% C.V.
 Inter-assay variance of 3.75-6.87% C.V.
- Sensitivity of 0.057 pg/mL (mean + 2SD) No cross-reactivities

• 20x Wash Concentrate: 2 bottles

TMB Substrate: 1 bottle.

ready to use (12 ml)

• Stop solution: 1 bottle,

ready to use (12 ml)

(25 ml each)

ErbaLisa kits have everything you need:

- Microwells coated with Goat Anti-Rabbit IgG: (12x8x1)
- Free Testosterone Standard Set: 6 Vials, ready to use, (0.5 ml x 6)
- Free Testosterone Enzyme Conjugate: 1 bottle, ready to use (7 ml)
- Rabbit Anti-Testosterone Reagent:
 1 bottle, ready to use (7 ml)

Guideline Expected Values

Male Adult: 5 – 30 pg/mL Female Adult: 0 – 3 pg/mL Children 1 – 10: 0.1 – 1.25 pg/mL

Main Features

Number of tests: 96 Solid phase: Free Testosterone Enzyme Conjugate Label: Testosterone-HRP conjugate Method: Competitive binding Assay format: Quantitative Total incubation time: 75 minutes Sample type: Serum Sample volume: 25 uL

Built for convenience Operating Environment • Ready to use components • Interchangeable reagents • Removable strips • Calibrators included • Break-apart wells • Ready for automation Catalogue Number Product name Format IME00020 ErbaLisa 96-well ELISA

FREE TESTOSTERONE

ErbaLisa Free Testosterone

Enzyme immunoassay (ELISA) kit for the accurate quantitative measurement of Free Testosterone in human serum.

Testosterone is a steroid hormone is primarily secreted by the testes in males and the ovaries in females, with smaller amounts secreted by the adrenal glands. It is the main male sex hormone and the most important androgen. Testosterone is responsible for the development of secondary male sex characteristics in puberty, and in adult men it controls libido and aids the production of sperm. Present in smaller quantities in females, it plays a role in fertility, as well as in menstrual and vaginal health.

Circulating testosterone is principally bound to proteins, the most important of which is sex hormone binding globulin (SHBG). Free, or unbound, testosterone represents the physiologically bioactive fraction. Measuring free testosterone rather than total testosterone is helpful when SHBG is increased or decreased, such as in hypothyroidism, obesity, treatment with corticosteroids and sex steroids, inherited abnormalities of SHBG binding, liver disease and polycystic ovarian syndrome.

ErbaLisa Free beta-hCG

Enzyme immunoassay (ELISA) kit for the accurate quantitative measurement of Free beta-hCG in human serum.

Human chorionic gonadotropin (hCG) is a glycoprotein secreted by the placenta during pregnancy. Structurally intact hCG consists of an alpha and a beta subunit. Several other isoforms of hCG circulate in the blood during pregnancy, including free alpha subunits, free beta subunits and beta core fragments. hCG can be measured as total hCG, useful in detecting pregnancy and certain tumors, whereas measuring free beta-hCG detects only the free beta subunits, and is used as part of antenatal screening for Down's syndrome and other fetal abnormalities.

The free beta-hCG test is combined with other tests and factors (usually PAPP-A, nuchal translucency ultrasound and maternal age) to determine a numerical risk of chromosomal defects in the fetus during the first trimester of pregnancy. Around 85% of fetuses with Down's syndrome are detected this way, and up to 75% with Edward's syndrome. This screening allows pregnancies with a high risk of chromosomal abnormalities to undergo more definitive investigations.

High Reproducibility		Highly Sensitive
Intra-assay variance of 3.3-Inter-assay variance of 3.0-		 Sensitivity of 0.04 ng/mL (mean + 2SD) FSH, LH, TSH: 0% cross reaction
ErbaLisa kits have everythin	g you need:	
 Microwells coated with St (12x8x1) Free β-hCG Standard Set: ready to use (0.5 ml x 6) Anti-Free β-hCG Biotin Re 1 bottle, ready to use (12 ml) Anti-Free β-hCG Enzyme C 1 bottle, ready to use (12 ml) 	: 6 Vials, eagent: I) Conjugate:	 TMB Substrate: 1 bottle, ready to use (12 ml) Stop solution: 1 bottle, ready to use (12ml) 20x Wash Concentrate: 2 bottles (25 ml each)
Guideline Expected Values		
Analytical Range = 5 - 250 ng	/ml	Each laboratory to establish its own normal ranges, for the population it serves
Main Features		
Number of tests: 96 Solid phase: Anti -Free β-hCG Conjugate Label: Biotin and HRP Method: Streptavidin / Biotin	6 Enzyme	Assay format: Quantitative Total incubation time: 60 minutes Sample type: Serum Sample volume: 25 uL
Built for convenience		Operating Environment
Ready to use componentsRemovable stripsBreak-apart wells		Interchangeable reagentsCalibrators includedReady for automation
Catalogue Number	Product name	e Format
IME00045	ErbaLisa FREE BETA hC	96-well ELISA CG

High Reproducibility

Highly Sensitive

- Intra-assay variance of 3.3-4.8% C.V.Inter-assay variance of 3.0-4.6% C.V.
- Sensitivity of 0.165 ng/ml (mean + 2SD) No cross-reactivities

20x Wash Concentrate: 2 bottles

• TMB Substrate: 1 bottle,

ready to use (12 ml)

• Stop solution: 1 bottle,

ready to use, (12ml)

(25 ml each)

ErbaLisa kits have everything you need:

- Microwells coated with Streptavidin: (12×8×1)
- AFP Standard Set: 6 Vials, ready to use (0.5 ml x 6)
- Anti-AFP-Biotin Reagent: 1 bottle, ready to use (12 ml)
- Anti-AFP Enzyme Conjugate: 1 bottle, ready to use (12 ml)

Guideline Expected Values

AFP level between 10 ng/mL to 20 ng/ mL is normal for adults. An extremely high level of AFP in your blood—greater than 400 ng/mL—could be a sign of liver tumors.

Main Features

Number of tests: 96				
Solid phase: Anti-AFP Enzyme				
Conjugate				
Label: Biotin and HRP				
Method: Streptavidin / Biotin				

Built for convenience

- · Ready to use components
- Removable strips
- Break-apart wells

Calibrators includedReady for automation

Interchangeable reagents

Assay format: Quantitative Total incubation time: 75 minutes

Sample type: Serum

Sample volume: 25 uL

Operating Environment

Catalogue Number	Product name	Format
IME00037	ErbaLisa AFP	96-well ELISA

ErbaLisa AFP

Enzyme immunoassay (ELISA) kit for the accurate quantitative measurement of AFP in human serum.

Alpha fetoprotein (AFP) is a glycoprotein hormone produced during fetal development by the fetal liver, yolk sac and to a lesser degree, the gastrointestinal tract. After birth, serum AFP levels in the neonate decrease rapidly, and are present only in trace amounts by the second year of life.

During pregnancy, AFP is detectable in the maternal circulation, and is used to screen for birth defects and genetic disorders in the fetus. High levels are found in fetal neural tube defects, such as spina bifida and anencephaly. Low levels are found in individuals with Down's syndrome. Abnormal AFP results during pregnancy provide an indication of which women will need more definitive investigations.

Outside of pregnancy, AFP has an important role as a tumor marker for several tumors including nonseminomatous testicular cancer, ovarian cancer and primary hepatocellular carcinoma. Additionally, raised AFP levels can be found in viral hepatitis, cirrhosis and ataxia telangiectasia.

Clinical areas



Semi-automated ELISA Microplate Reader and Washer

The Erba LisaScan EM can perform various ELISA tests with elaborate reports and printing of graphs. The Erba LisaWash can easily accomodate different well shaped microplates, providing efficient versatility to semi-automated labs.

Erba LisaScan® EM Reader



100 TEST PROGRAMS

100 user-programmable ELISA test slots

UVU VARIOUS PLATE GEOMETRICS

Compatible to various plate geometrics of 96 well microplates (Flat, U and V bottom) and in 8 or 12 well formats

MULTI-WAVELENGTH READING

Single, Dual and Multi-wavelength reading options with advanced 8-channel optical system



8 seconds for 96 wells plate



4 Filter and 6 Filter

Erba LisaWash® Reader

50 WASH PROTOCOLS

Large memory, up to 50 protocols can be programmed and stored by the user

AEROSOL PROTECTION COVER

Standard aerosol protection cover and easy to decontaminate plate carrier

8/12-CHANNEL MANIFOLD

Easy, removable 8-channel manifold and 12-channel optional, with separate needles for aspiration and dispensing eliminating risk of contamination

ACCUARCY & PRECISION

 \leq 3 µl residual volume, ensuring accuracy and precision

UVU FULL FOCUS ON YOUR ELISA

Washes 96-well format microplate with Flat, U or V bottom





We are an emerging player in in-vitro diagnostics, with a global footprint. Our mission is to make automation affordable for labs everywhere.

Providing hospitals and labs with a full range of diagnostic instruments, reagents and support services in more than 100 countries, our focus is on improving health outcomes in developing nations.

We believe every lab should benefit from automation, no matter how big or small. And we know that different labs have different needs, so we offer three distinct ranges of products, helping you to find the ideal solution.

Nexus Total Lab Automation Made Accessible

Vertex Powerful Automation for Mid-Sized Labs

Apex Basic Automation for Small Labs

Automa	tion		wantaj kajar
or A			
		Workload	
	VSEX	VERTEX	NEXUS
	BASIC AUTOMATION FOR SMALL LABS	POWERFUL AUTOMATION FOR MID-SIZED LABS	TOTAL LAB AUTOMATION MADE ACCESSIBLE
Lab size	Small	Mid-size	Large
Throughput	Low	Mid-range	Large
Automation	Semi-automation	Full automation	Full automation
Туре	Bench-top	Bench-top or floor standing	Bench-top or floor standing
Footprint	Super compact	Compact	Compact/Medium
Look out for this symbol	ΛΞ	VE	NE

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