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Technical note

Hormones | Fertility and women's health

Medix Biochemica

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Introduction

Fertility is a fundamental element of human health. It can be defined as the ability to conceive and produce a child, but the processes associated with women's fertility can also have wide health impacts throughout the various stages of women's life from puberty to menopause.

Good reproductive health is based on a fine balance between various hormones, and a leading cause for infertility is hormonal imbalance. The key hormones associated with fertility are follicle-stimulating hormone (FSH), estradiol (E2), luteinizing hormone (LH), human chorionic gonadotropin (hCG), anti-Müllerian hormone (AMH), progesterone, and prolactin. Clinical manifestations of hormonal disorders, however, are often indefinite and nonspecific. Accordingly, laboratory measurements are usually required to diagnose diseases and to monitor therapeutic outcomes. Since hormone levels in bodily fluids are relatively low, reliable quantification of hormones often requires sensitive assays, which are usually immunoassays based on monoclonal antibodies that specifically recognize the target analyte. In addition to disorders and malignancies, hormone levels can also be used to monitor normal bodily processes. For example, immunoassays for hCG are used for pregnancy detection and monitoring, while different hCG forms can also be

used to detect trophoblastic tumors or pregnancy-related disorders. LH is often used for predicting ovulation, and it can also be used to investigate menstrual irregularities or to diagnose puberty-related disorders.

Medix Biochemica has over 35 years of experience in producing premium-quality monoclonal antibodies for detection of hCG, LH, and other hormones. Our company's optimized, industrial-scale *in vitro* production methods, certified batch-to-batch consistency, as well as expert customer service have made Medix Biochemica one of the most important antibody suppliers for the IVD community. Medix Biochemica also offers a large variety of antigens and biospecimens that can be used for assay validations and as control materials.

In this tech note, we present Medix Biochemica hormone products in the field of fertility and women's health. The focus is on items for which we have produced technical data to present their performance. The results shown are from prototype assays (unoptimized), indicating proof of concept with clinical samples. Further assay optimization may be required to obtain the best performance. The full item lists can be found on www.medixbiochemica.com under each analyte.

Alpha subunit

The alpha subunit is common to all glycoprotein hormones, also known as gonadotropins. The glycoprotein hormones are specific to vertebrates and include hCG, FSH, LH, and TSH. In humans, the alpha subunit consists of 92 amino acids and has an average molecular weight of 14 kDa. In all gonadotropins, the alpha subunit binds non-covalently to the beta subunit forming a heterodimer; each beta subunit is hormone-specific and mediates receptor binding and the specific functions of the glycoprotein hormones. However, the alpha subunit is also required for the biological activity of these hormones.^{1,2,3}

Medix Biochemica offers three mouse monoclonal antibodies for the detection of the human glycoprotein hormone alpha subunit. The association and dissociation characteristics of the binding reaction between the alpha subunit antibodies and the alpha subunit have been measured using multiplexed SPR technology. Anti-human alpha subunit specific antibodies are recommended only as detection antibodies with human glycoprotein hormone (hCG, LH, FSH and TSH) beta subunit specific antibodies. Anti-human alpha subunit antibodies bind to several glycoprotein hormones and therefore are not recommended to be used as capture antibodies.

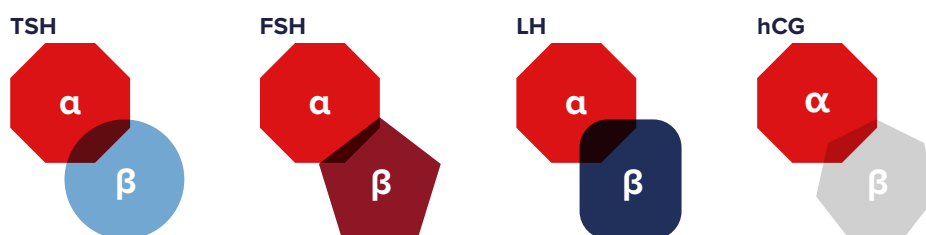
Anti-human alpha subunit monoclonal antibodies

Alpha subunit antibody	Product code	Concentration (mg/mL)	Shelf life (months at +2–8°C)	Subclass	Applications tested
5501	100035	1	36	IgG ₁	ELISA
5503	100037	1	6	IgG ₁	ELISA
6601	100066	5	36	IgG _{2a}	ELISA

Kinetic parameters

Alpha subunit antibody	Association rate constant, k_{on} (1/Ms)	Dissociation rate constant, k_{off} (1/s)	Dissociation constant, K_D (M)
5501	1.9×10^6	1.1×10^{-3}	$5.7 \times 10^{-10} = 0.57$ nM
5503	1.7×10^6	5.3×10^{-4}	$3.2 \times 10^{-10} = 0.32$ nM
6601	8.9×10^5	3.8×10^{-5}	$4.2 \times 10^{-11} = 0.04$ nM

Binding of glycoprotein hormones



Glycoprotein hormones (TSH, FSH, LH, and hCG) have an identical alpha subunit (α) and a hormone-specific beta subunit (β).

Anti-Müllerian hormone (AMH)

Anti-Müllerian hormone (AMH) is a 140-kDa glycoprotein produced by the granulosa cells of the ovary in females and by the Sertoli cells of the testis in males during sexual differentiation.⁴

In women, serum AMH levels peak at early adulthood and slowly decrease with age, becoming undetectable at menopause. AMH is used as a biomarker to monitor ovarian function, especially the ovarian reserve levels which reflect the remaining length of woman's reproductive lifespan. Serum AMH concentration reflects the size of the follicle pool, and the likelihood of pregnancy – independent of the menstrual cycle – and is utilized to

assess responsiveness to ovarian stimulation in *in vitro* fertilization (IVF) and to assess both ovarian dysfunction and the impact of gonatotoxic treatments. High serum AMH levels can help detecting polycystic ovarian syndrome (PCOS) and granulosa cell tumors. In men, serum AMH has traditionally been used as a biomarker for gonadal development.^{4,7}

Medix Biochemica offers six monoclonal antibodies for the detection of AMH with specific pair recommendations for different applications. The antibodies bind to the N-terminal region of AMH (amino acids Arg26-Arg451).

Anti-human AMH monoclonal antibodies

AMH antibody	Product code	Concentration (mg/mL)	Shelf life (months at +2–8°C)	Subclass	Applications tested
11301	100756	5	24	IgG ₁	ELISA, CLIA, LF
11302	100757	5	36	IgG ₁	ELISA, CLIA, LF
11303	100758	5	24	IgG ₁	ELISA, CLIA, LF
11304	100759	5	36	IgG ₁	ELISA, CLIA, LF
11305	100760	5	N/D	IgG ₁	ELISA, CLIA, LF
11309	100840	5	N/D	IgG ₁	ELISA, CLIA, LF

Pair recommendations

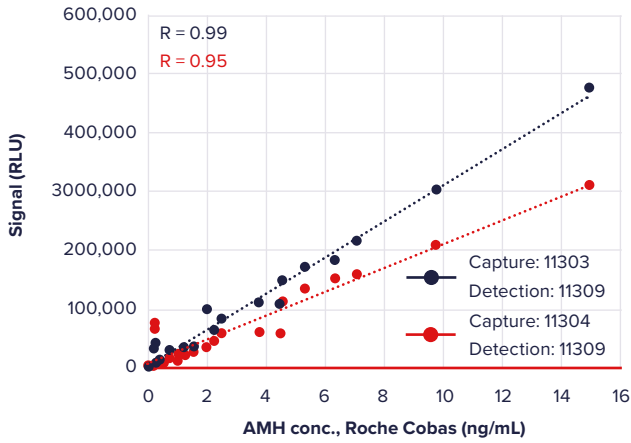
		Detection					
		11301	11302	11303	11304	11305	11309
Capture	11301	+	+	+	-	-	+
	11302	+	-	+	-	-	+
	11303	+	+	+	+	-	+
	11304	-	+	+	-	-	+
	11305	+	+	+	+	-	+
	11309	+	+	+	+	-	-

LF: 11304 (membrane) - 11303 (particles)

FIA: 11309 (capture) - 11302 (detection), 11303-11301, 11301-11303

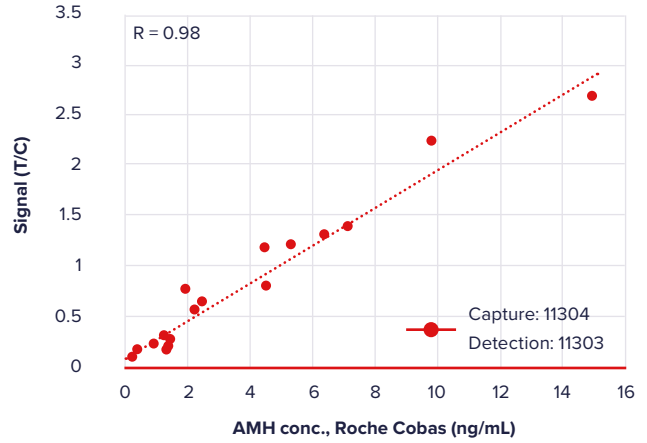
CLIA: 11303 (capture) - 11309 (detection) and 11304-11309

Correlation of AMH CLIA assay



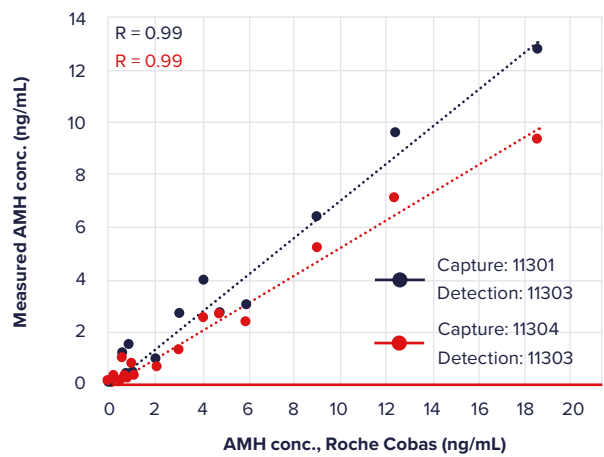
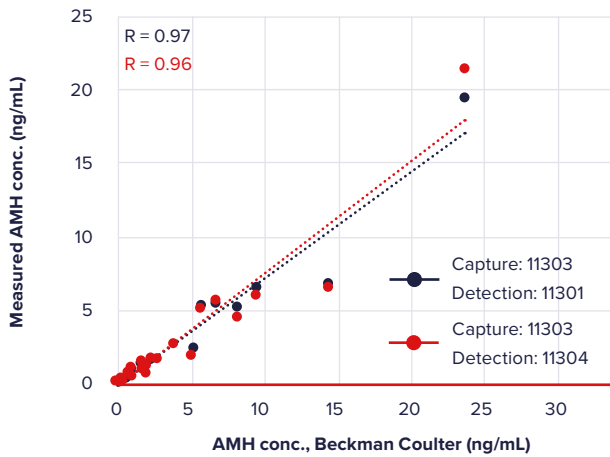
AMH detection from clinical samples with Medix Biochemica recommended pairs showed good correlation with reference chemiluminescence immunoassay (CLIA) method (Roche Cobas assay).

Correlation of AMH LF assay



AMH detection using lateral flow (LF) from clinical samples with Medix Biochemica recommended pair showed excellent correlation to results obtained with reference method (Roche Cobas assay).

Correlation of AMH FIA assay with 2 reference methods



AMH detection from clinical samples using fluoroimmunoassay (FIA) with Medix Biochemica recommended pairs showed excellent correlation to results obtained with reference methods (Beckman Coulter and Roche Cobas assays).

Estradiol (E2)

Estradiol is the primary female sex hormone and of the three major estrogens in addition to estrone (E1) and estriol (E3), and it is present both in women and men. It is produced primarily in the ovaries but also by the adrenal gland and during pregnancy by placenta in females. While women have much higher levels of estradiol than men, it still has an important role also for men e.g. in sexual function, bone maintenance and brain function.⁸⁻¹⁰

Estradiol is the most important hormone during the reproductive years of a woman. During menstrual cycle, estradiol is secreted by the follicles in ovaries leading to actions causing ovulation. After ovulation, estradiol is involved in preparing the uterus for the implantation of the

fertilized ovum and generally promotes the maintenance of the female reproductive organs.

Serum estradiol is measured in women and it reflects primarily the activity of the ovaries. High levels of E2 can cause menstrual problems and menopausal symptoms and extremely high levels also increase risk of ovarian tumors or breast cancer. Low levels of E2 can delay puberty and effect bone growth and development which can lead to osteoporosis.¹⁰

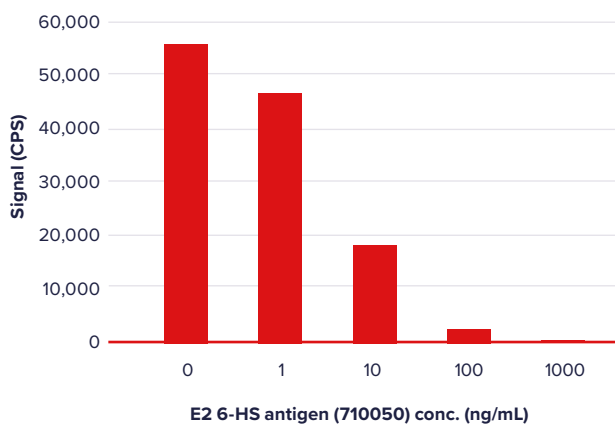
Medix Biochemica offers an antibody+antigen pair for the development of a competitive assay for detecting E2.

Anti-human E2 monoclonal antibodies and antigens

E2 antibody	Product code	Concentration (mg/mL)	Shelf life (months at +2–8°C)	Subclass	Applications tested
10450	700011	> 1.0	60	IgG ₁	ELISA

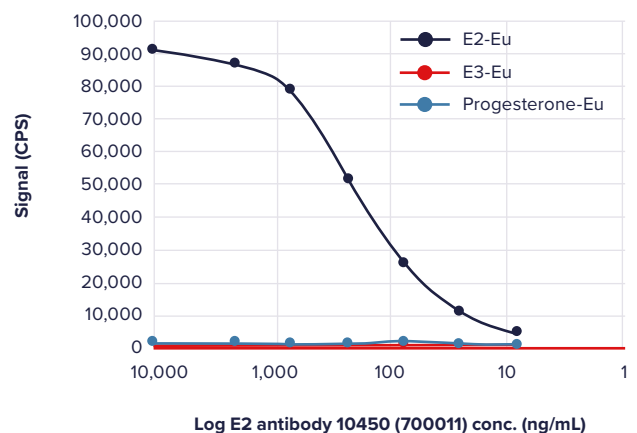
E2 antigen	Product code
Synthetic E2-6-HS antigen, lyophilized	710050

E2-6-HS antigen recognition by E2 antibody



In competitive assay, the signal decrease in higher Estradiol-6-hemisuccinate (710050) concentrations proves that it is able to displace E2-Eu label binding to 10450 mAb (700011). Thus the E2 antibody recognizes the antigen.

Specificity of Anti-human E2 antibody 10450



Medix Biochemica E2 antibody 10450 (700011) showed no reactivity with E3 or Progesterone antigens.

Estriol (E3)

Estriol (E3) is one of the three major endogenous estrogens, the others being estradiol (E2) and estrone (E1). During pregnancy, estriol is synthesized with high quantities by the placenta and by the liver of fetus. Estriol measurement from maternal blood or urine can be used to assess the health and well-being of fetus during the second trimester of pregnancy.¹¹

Decreased second trimester E3 has been shown to be a marker for Down and trisomy-18 syndromes.¹¹

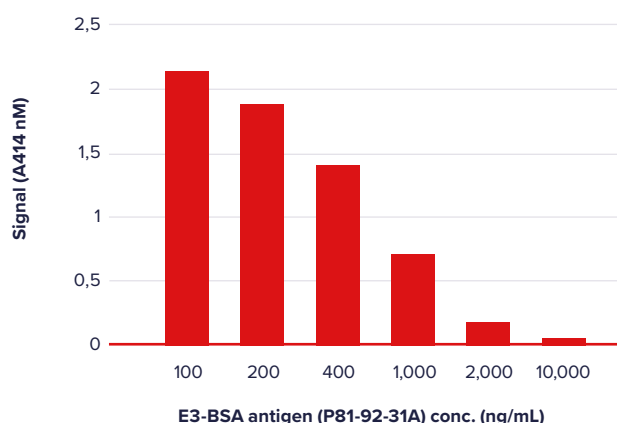
Medix Biochemica offers monoclonal antibodies and conjugated antigens that can be used for E3 detection in competitive assay.

Anti-human E3 monoclonal antibodies and antigens

E3 antibody	Product code	Concentration (mg/mL)	Shelf life (months at +2–8°C)	Subclass	Applications tested
RC10601	140022	5	N/D	IgG ₁	ELISA

E3 antigen	Product code
E3-3-HRP conjugate, liquid	P91-92-31H
E3-BSA conjugate, liquid	P81-92-31A

E3-3-HRP and E3-BSA antigen recognition by E3 antibody RC10601



In competitive assay, the signal decrease in higher E3-BSA antigen (P81-92-31A) concentrations proves that E3-BSA is able to displace E3-3-HRP (P91-92-31H) binding to E3 RC10601 antibody (140022). Thus the E3 antibody recognizes both E3-3-HRP and E3-BSA antigens used in this assay.

Follicle stimulating hormone (FSH)

Similar to luteinizing hormone (LH), follicle-stimulating hormone (FSH) is a glycoprotein hormone secreted from the anterior pituitary gland under the control of gonadotropin-releasing hormone. FSH is an α/β heterodimer consisting of the glycoprotein hormone alpha subunit and a hormone-specific FSH β chain. FSH β is a 119 amino acid peptide with two N-linked glycosylation sites. FSH mediates its biological functions by binding to the FSH receptor (FSHR), which is expressed mainly by ovarian granulosa cells and testicular Sertoli cells, but also by osteoclasts and certain tumor cells.^{12, 13-15}

FSH has several essential functions related to mammalian development and reproduction. In both sexes, FSH stimulates germ cell maturation. During male development, FSH promotes spermatogonia mitosis and ensures normal testes development by activating proliferation of Sertoli cells. In adult males, FSH maintains normal spermatogenesis and Sertoli cell activities important for testis function and maintenance of male fertility. In females, FSH drives follicle growth and granulosa cell estrogen production. FSH also prevents granulosa cell apoptosis and stimulates their proliferation. Furthermore, there is a small rise in FSH levels at the end of the menstrual cycle luteal

phase; this seems to be relevant for the initiation of the next ovulatory cycle. Besides its reproductive roles, FSH has also been associated with postmenopausal bone loss and neovascularization surrounding malignant tumors; however, these functions require further investigation.^{12, 16, 14, 17}

Clinically, FSH is commonly used for ovarian stimulation in women who are undergoing infertility treatment or oocyte retrieval. FSH can also be used for treating anovulatory infertility in women or hypogonadotropic hypogonadism in men. LH is often used as a supportive treatment with FSH therapy. FSH tests are often carried out together with an LH test. Assaying serum or urine FSH levels can be used to investigate female infertility, menstrual irregularities, or to diagnose conditions related to ovarian or testicular dysfunction.^{14, 16, 18}

Medix Biochemica offers FSH-specific mouse monoclonal antibody (6602) that can be used as a pair with an alpha subunit antibody (6601) in diagnostic tests and a native antigen. For product details on alpha subunit antibody, please see page 4.

Anti-human FSH monoclonal antibodies and antigens

FSH antibody	Product code	Concentration (mg/mL)	Shelf life (months at +2–8°C)	Subclass	Applications tested
6602	100067	5	24	IgG ₁	ELISA

FSH antigen	Grade	Product code
Native FSH, Human Pituitary Gland, lyophilized	≥ 95%	996-11

Pair recommendations

	Detection	
	6601*	
Capture	6602	+

* alpha subunit

Kinetic parameters

FSH antibody	Dissociation constant, K _d (M)
6602	$3.0 \times 10^{-11} = 0.03 \text{ nM}$

Human chorionic gonadotropin (hCG)

Human chorionic gonadotropin (hCG) is a glycoprotein hormone essential for the maintenance of pregnancy. Physiologically, this placental hormone is produced and secreted mainly by embryonic trophoblast cells. hCG has several roles at the interface between the mother and the placenta. These roles include stimulating the ovarian corpus luteum to secrete progesterone, maintaining myometrial quiescence, and contributing to maternal immunotolerance towards the embryo. In addition, small amounts of hCG are produced in other tissues, including pituitary, testis, and colon. hCG is also expressed to some extent by several tumors, such as germ cell tumors and trophoblastic cancers, but its exact role in these cancers remains unknown.^{1, 19-21}

hCG is a 37.5 kDa heterodimer consisting of two non-covalently linked subunits: hCG α , an alpha subunit identical in all glycoprotein hormones, and hCG β , a 23.5 kDa subunit unique to hCG that confers its biological specificity. Both hCG subunits are highly glycosylated; the carbohydrate chains attached to the possible glycosylation sites of the molecule make up about 30 percent of the hCG mass. The carbohydrate content of hCG varies substantially between different cell types, with advancing pregnancy, and with tumor progression. Due to this heterogeneity, hCG occurs in biological fluids in different forms, including intact hCG, free hCG β -subunit, free hCG α -subunit, and other nicked or truncated forms of the molecule. The biological effects of hCG are mediated

through its binding to the receptor that recognizes hCG β , LHCGR, which is also activated by luteinizing hormone (LH). Both subunits are required for the biological activity of hCG.^{2, 19, 21-23}

The primary clinical use of hCG immunoassays is pregnancy detection. hCG can be detected from maternal blood already during the second week of pregnancy. Urine can also be used for hCG testing. Pregnancy tests are based on antibodies recognizing intact hCG, hCG β , or both. Additionally, measurement of hCG or its different molecular forms can be utilized for various other clinical purposes, such as pregnancy monitoring, diagnosis of pregnancy-related disorders, prenatal screening (e.g. for Down syndrome), as well as screening for trophoblastic tumors.^{19, 21, 22}

Medix Biochemica has more than three decades of experience in producing hCG mouse monoclonal antibodies for different diagnostic purposes. Currently, the company's products include several anti-hCG antibodies recognizing either the hCG complex, free hCG β , or both. The antigen epitopes of hCG recognized by Medix Biochemica antibodies have been extensively characterized.²² Medix Biochemica offers also native antigens that have been tested with the antibodies.

Scientific publications: page 22.

Anti-hCG monoclonal antibodies and antigens

hCG antibody	Product code	Concentration (mg/mL)	Shelf life (months at +2–8°C)	Subclass	Applications tested
5004	100004	1	36	IgG ₁	ELISA, CLIA
5006	100005	5	24	IgG ₁	ELISA, CLIA
5008	100006	5	36	IgG ₁	ELISA, CLIA
5009	100008	5	18	IgG ₁	ELISA, CLIA
5011	100009	1	24	IgG ₁	ELISA, CLIA
5012	100368	5	36	IgG ₁	ELISA, CLIA
5014	100011	5	36	IgG ₁	ELISA, CLIA
5016	100013	5	24	IgG ₁	ELISA, CLIA

hCG antigens	Grade	Product code
Native hCG, human pregnancy urine, lyophilized	partially purified	189-10
Native hCG, human pregnancy urine, lyophilized	≥ 96% (SDS-PAGE)	189-11
Native β-hCG, human pregnancy urine, lyophilized	≥ 98% (SDS-PAGE)	325-11

Pair recommendations

		Detection										
		hCG β							alpha subunit			
		5004	5006	5008	5009*	5011	5012**	5014	5016	5501	5503	6601
Capture	5004	-	-	-	+	+	-	+	-	+	+ ^A	+ ^A
	5006	-	-	-	-	-	-	+	-	+	+	+
	5008	-	-	-	+	-	-	+ ^D	-	+	+	+
	5009*	+	+ ^A	+	-	-	-	+ ^A	+	-	-	+
	5011	+	+	+	-	-	-	+	+	-	-	+
	5012**	+ ^C	+ ^B	+ ^C	-	-	-	+	+	-	-	-
	5014	+	+	+	+	+	-	-	+	+	+	+
	5016	-	-	-	-	-	-	+	-	+	+	+

* Recognizes an epitope at the junction of alpha and beta subunits in hCG

** Recognizes only free beta subunit of hCG

A) Recommendation for detecting intact hCG molecule (alpha/beta pair)

B) Recommendation for detecting free beta subunit of hCG

C) Recommendation for detecting free beta subunit of hCG in CLIA application

D) Recommendation for detecting total hCG (both intact and free beta subunit of hCG)

Antibodies recognizing alpha subunit are recommended only for detection antibodies, since they also recognize other gonadotropins (including hCG, FSH, LH, and TSH).

Kinetic parameters

hCG antibody	Association rate constant, k_{on} (1/Ms)	Dissociation rate constant, k_{off} (1/s)	Dissociation constant, K_D (M)
5004	hCG: 2.0×10^6	hCG: 3.7×10^{-5}	hCG: $1.9 \times 10^{-11} = 0.02$ nM
	hCG β : 5.0×10^5	hCG β : 1.2×10^{-4}	hCG β : $2.3 \times 10^{-10} = 0.23$ nM
5006	hCG: 5.7×10^6	hCG: 2.9×10^{-4}	hCG: $5.0 \times 10^{-11} = 0.05$ nM
	hCG β : 2.3×10^6	hCG β : 4.8×10^{-4}	hCG β : $2.1 \times 10^{-10} = 0.21$ nM
5008	hCG: 4.0×10^6	hCG: 1.4×10^{-4}	hCG: $3.4 \times 10^{-11} = 0.03$ nM
	hCG β : 1.6×10^5	hCG β : 3.6×10^{-4}	hCG β : $2.3 \times 10^{-10} = 0.23$ nM
5009	hCG: 1.1×10^6	hCG: 3.1×10^{-4}	hCG: $2.8 \times 10^{-10} = 0.28$ nM
	hCG β : N/A	hCG β : N/A	hCG β : N/A
5011	hCG: 2.4×10^6	hCG: 4.4×10^{-4}	hCG: $1.8 \times 10^{-10} = 0.18$ nM
	hCG β : 1.9×10^6	hCG β : 1.1×10^{-3}	hCG β : $5.7 \times 10^{-10} = 0.57$ nM
5012	hCG: N/A	hCG: N/A	hCG: N/A
	hCG β : 2.1×10^4	hCG β : 1.7×10^{-4}	hCG β : $8.1 \times 10^{-10} = 0.81$ nM
5014	hCG: 2.5×10^5	hCG: 1.5×10^{-4}	hCG: $6.1 \times 10^{-10} = 0.61$ nM
	hCG β : 2.8×10^5	hCG β : 2.8×10^{-4}	hCG β : $1.0 \times 10^{-9} = 1.0$ nM
5016	hCG: 1.5×10^6	hCG: 9.5×10^{-4}	hCG: $6.4 \times 10^{-10} = 0.64$ nM
	hCG β : 1.9×10^6	hCG β : 5.2×10^{-3}	hCG β : $2.8 \times 10^{-9} = 2.8$ nM

Epitopes and specificity

Berger et al. 2013²²

Product	Epitope	hCG	hCGβ	hCGβcf	hCGn	hCGβn	-CTPhCG	-CTPhCGβ	ISOBM Ab codes
5004	β ₂	✓	✓	✓	✓	✓	✓	✓	402
5006	β ₂	✓	✓	✓	✓	✓	✓	✓	388
5008	β ₂	✓	✓	✓	✓	✓	✓	✓	390
5016	β ₂	✓	✓	✓	✓	✓	✓	✓	408
5012*	β ₇		✓	✓					409
5014	β ₉	✓	✓		✓	✓	✓	✓	394
5011	β	✓	✓		✓	✓	N/D	N/D	406
5009**	C ₂	✓							387
5501	α	✓			✓		✓		383
5503	α	✓			✓		✓		385
6601	α	✓			✓		✓		391

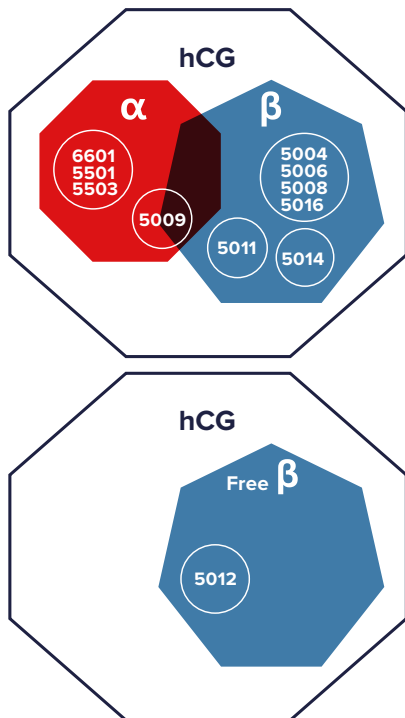
The darker blue color indicates strong reactivity.

*) Free beta subunit specific Mab
 **) αβ-heterodimer-specific Mab
 N/D not determined

Nomenclature of hCG and hCG-related variants:

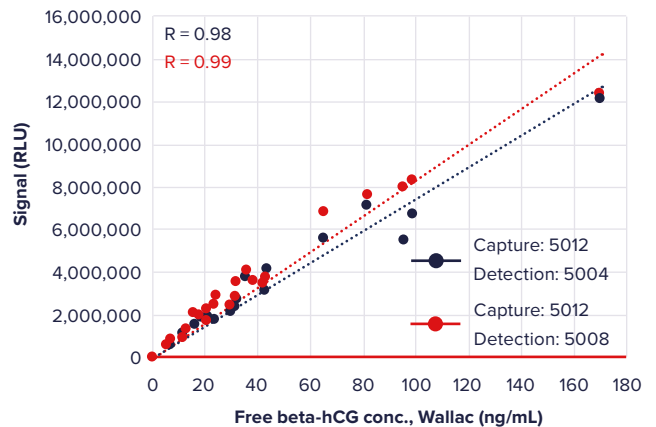
hCG Intact αβ heterodimer, bioactive
 hCGb Intact noncombined free hCGβ-subunit, aa hCGβ1-145
 hCGbcf Core fragment of hCGβ; aa hCGβ6-40 linked to hCGβ55-92
 hCGn Nicked αβ heterodimer, nicks in the region of aa hCGβ44-48
 hCGβn Nicked hCGβ, nicks in the region of aa hCGβ44-48
 -CTPhCG hCGβ truncated core hCG, missing most of the hCGβCTP (aa hCGβ121-145)
 -CTPhCGβ hCGβ truncated core hCGβ (aa hCGβ1-120), missing most of the hCGβCTP

Epitope groups of hCG antibodies



hCG antibodies can be divided into different epitope groups. Antibodies in the same group detect the same or overlapping epitopes.

Correlation of free beta-hCG CLIA assay



Free beta-hCG detection from clinical samples with Medix Biochemica recommended pairs showed good correlation with reference chemiluminescence Immunoassay (CLIA) method (Wallac).

Luteinizing hormone (LH)

Human luteinizing hormone (LH), or lutropin, is a glycoprotein hormone produced by the anterior pituitary gland. LH is produced in a pulsatile manner in response to gonadotropin-releasing hormone from the hypothalamus. LH is essential for normal reproduction in both males and females.²⁴⁻²⁵

In females, LH together with follicle-stimulating hormone (FSH) regulates normal ovarian function. During the menstrual cycle, FSH initiates follicle growth leading to a rise in estrogen levels that triggers a peak in LH production, also known as the LH surge. The LH surge results in ovulation, and also stimulates corpus luteum formation and progesterone production, thus preparing the endometrium for possible pregnancy initiation. Furthermore, LH stimulates ovarian theca cells to produce androstenedione, which is converted to the female sex hormone estradiol. In males, LH stimulates testosterone production by the Leydig cells of the testis and is thus responsible for development of puberty, male secondary sexual characteristics, and spermatogenesis.^{16, 24-27}

Like other glycoprotein hormones, LH is a heterodimer composed of a common 14 kDa alpha subunit, as well as a unique beta subunit that defines the hormone's

functional specificity. The subunits of the 28 kDa LH are non-covalently linked to each other, and both subunits are highly glycosylated. Similar to hCG, the biological functions of LH are mediated through LHCGR binding. However, although LH and hCG activate the same receptor, their molecular properties and expression patterns differ significantly due to their different physiological roles. For example, the serum half-life of LH is less than 120 minutes, while it is several hours for hCG.^{26, 28}

The clinical indications of assaying LH levels in blood or urine include predicting the timing of ovulation, investigating menstrual irregularities, and diagnosing early or delayed puberty. The LH test is often used in conjunction with other hormonal tests, such as tests for FSH or TSH levels.²⁹⁻³²

Medix Biochemica offers several different mouse monoclonal antibodies for LH detection. Antibodies 5303 and 5304 have no cross-reactivity with hCG, TSH, or FSH, antibody 5301 has negligible cross-reactivity with TSH and FSH, and antibody 5302 has cross-reactivity to hCG. In addition, the portfolio includes a native LH antigen.

Scientific publications: page 22.

Anti-human LH monoclonal antibodies and antigens

LH antibody	Product code	Concentration (mg/mL)	Shelf life (months at +2–8°C)	Subclass	Applications tested
5301	100016	5	36	IgG ₁	ELISA, CLIA, LF
5302	100018	1	36	IgG ₁	ELISA, CLIA, LF
5303	100588	5	36	IgG ₁	ELISA, CLIA, LF
5304	100022	5	36	IgG ₁	ELISA, CLIA, LF

LH antigen	Grade	Product code
Native LH, Human Pituitary Gland, lyophilized	≥ 98%	996-31

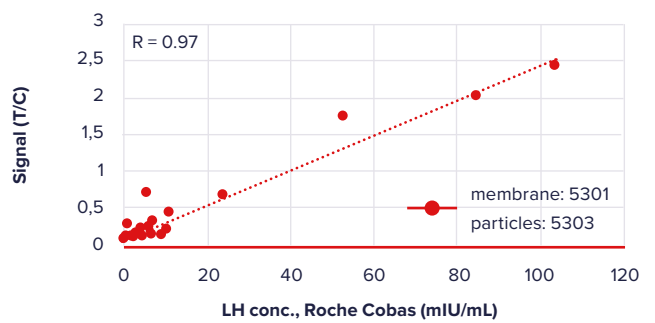
Kinetic parameters

LH antibody	Association rate constant, k_{on} (1/Ms)	Dissociation rate constant, k_{off} (1/s)	Dissociation constant, K_D (M)
5301	5.8×10^6	1.3×10^{-5}	$2.3 \times 10^{-12} = 2.3 \text{ pM}$
5302	1.3×10^6	2.6×10^{-5}	$2.1 \times 10^{-11} = 21 \text{ pM}$
5303	5.4×10^6	3.4×10^{-5}	$6.3 \times 10^{-12} = 6.3 \text{ pM}$
5304	4.7×10^6	1.6×10^{-5}	$3.4 \times 10^{-12} = 3.4 \text{ pM}$

Pair recommendations

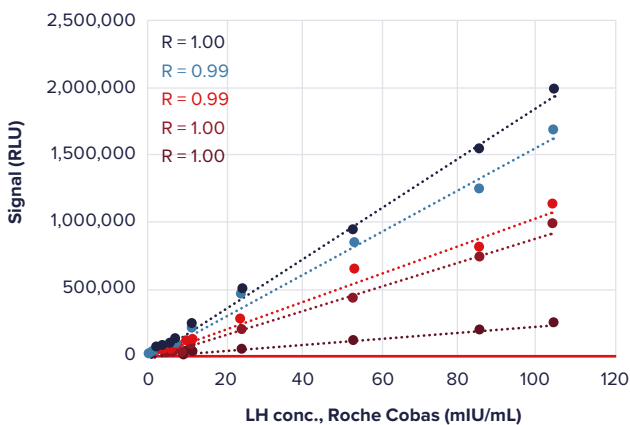
		Detection				
		LH				alpha subunit
		5301	5302	5303	5304	5501
Capture	5301	-	+	+	+	+
	5302	+	-	-	-	+
	5303	+	-	-	-	-
	5304	+	-	-	-	-

Correlation of LH LF assay



LH detection from clinical samples with Medix Biochemica recommended LF pair showed good correlation to reference method (Roche Cobas).

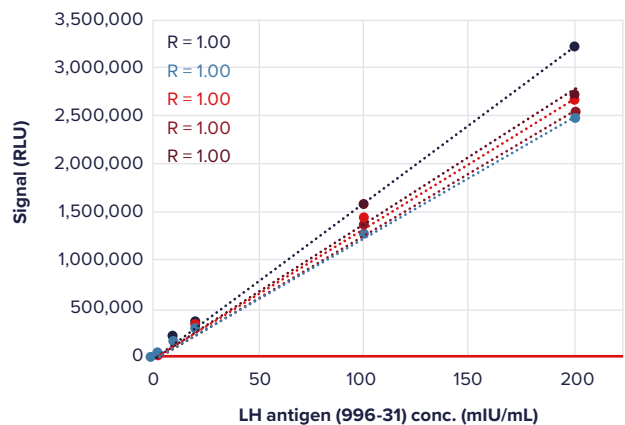
Correlation of LH CLIA assay



- Capture: 5301
● Detection: 5304
- Capture: 5301
● Detection: 5303
- Capture: 5304
● Detection: 5301
- Capture: 5302
● Detection: 5301
- Capture: 5301
● Detection: 5302

LH detection from clinical samples with Medix Biochemica antibody pairs showed excellent correlation to results obtained with CLIA reference method (Roche Cobas assay).

Standard curves in LH CLIA assay



Wide linear measuring range for LH CLIA assay can be achieved with Medix Biochemica recommended antibody pairs and antigen (996-31).

Pregnanediol (PDG)

Pregnanediol-3-glucuronide (PDG) is the predominant urinary metabolite of progesterone. Increased levels of PDG in urine accurately confirm ovulation and have high agreement with serum progesterone. Understanding an individual's ovarian activity is important for a complete fertility assessment.³³⁻³⁴

Due to complex and variable cycle patterns, frequent sample collection is necessary. Immunoassays for the detection of PDG in urine enable a non-invasive collection method and point of care or at home monitoring for the confirmation of ovulation.³⁵

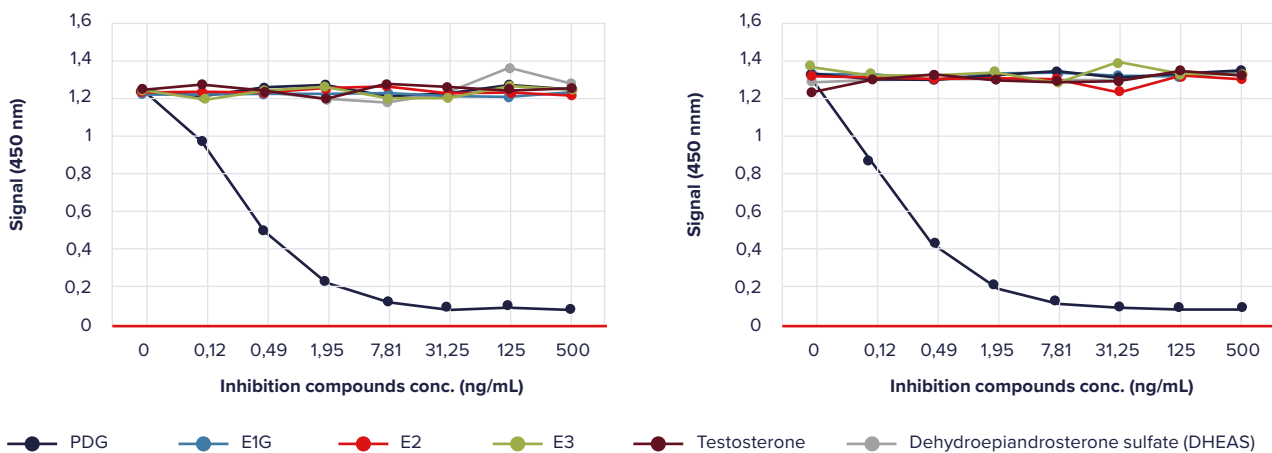
Medix Biochemica offers two PDG monoclonal antibodies (HM386, HM387) which pair with PDG-BSA antigen (LA286) in competitive lateral flow and ELISA applications.

Anti-human PDG monoclonal antibodies and antigens

PDG antibody	Shelf life (months at +2–8°C)	Subclass	Applications tested
HM386	60	IgG ₁	ELISA, LF
HM387	60	IgG ₁	ELISA, LF

PDG antigen	Product code
PDG-BSA conjugate, liquid	LA286

Specificity of anti-PDG antibodies



In this competitive assay the signal level decreases only when PDG antigen concentration is increased proving that only PDG is able to bind to the PDG antibody (HM386 and HM387) and replace the labelled PDG-BSA antigen. Thus the PDG antibodies (HM386 and HM387) are specific to PDG and do not cross-react with other compounds tested.

Progesterone

Progesterone (PR) is a steroid hormone produced in the corpus luteum after ovulation and in the placenta during pregnancy. Progesterone is also produced in the adrenal glands. The main functions of progesterone include induction of endometrial transition from a proliferative to a secretory stage during the menstrual cycle, facilitating blastocyst nesting, as well as maintenance of pregnancy. Progesterone also promotes insulin release and may have some neuroprotective effects, including slowing down Alzheimer's disease progression.³⁶⁻³⁸

In women, progesterone levels are generally low (approximately <1 ng/mL) before ovulation and rise thereafter up to 10 to 35 ng/mL. During pregnancy,

progesterone levels may reach 100 to 300 ng/mL. In early pregnancy, progesterone measurements are used in addition to hCG measurements for more precise diagnosis of an ectopic or otherwise dysfunctional pregnancy. As low progesterone levels can lead to pregnancy termination, progesterone levels are often monitored during high-risk pregnancies to evaluate and ensure fetal health.³⁶⁻³⁷

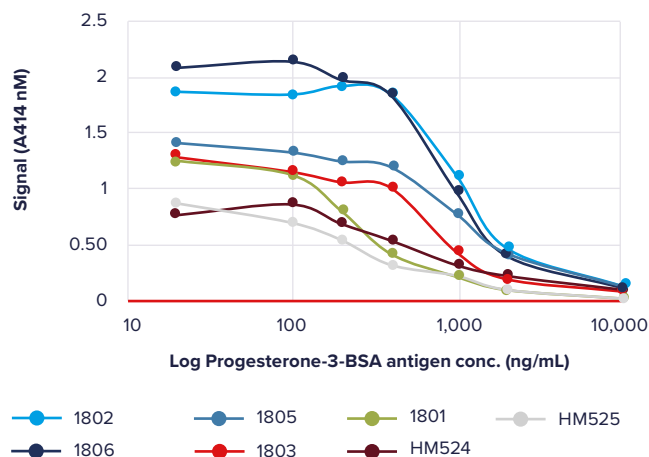
Medix Biochemica offers several anti-progesterone mouse monoclonal antibodies and tested antigen conjugates for the detection of progesterone. Due to the small size of the analyte, competitive immunoassay is recommended for progesterone level determination.

Anti-human progesterone monoclonal antibodies and antigens

PR antibody	Product code	Concentration (mg/mL)	Shelf life (months at +2–8°C)	Subclass	Applications tested
1801	100248	5	24	IgG ₁	ELISA
1802	100249	5	36	IgG _{2a}	ELISA
1803	100250	5	24	IgG _{2a}	ELISA
1805	100252	5	36	IgG _{2a}	ELISA
1806	100907	5	N/D	IgG ₁	ELISA
PR antibody	HM524	lot dependent	60	IgG ₁	ELISA
PR antibody	HM525	lot dependent	60	IgG ₁	ELISA

Upcoming

Progesterone-3-HRP antigen recognition by Progesterone antibodies



PR antigen	Product code
Progesterone-3-HRP conjugate, liquid	170063

All Medix Biochemica antibodies recognize the PR-3-HRP antigen (170063) used in this competitive assay.

Prolactin

Prolactin (PRL) is a peptide hormone secreted primarily by the lactotroph cells of the pituitary gland. PRL is also produced by various extrapituitary cells and sites, including immune cells, neurons, prostate, mammary epithelium, and skin. During pregnancy, PRL acts in concert with other hormones, including progesterone and insulin, to promote mammary gland growth and development. In the postpartum period, PRL stimulates lactation by initiating milk synthesis and maintaining its secretion. PRL production reduces the secretion of gonadotropin-releasing hormone, thereby suppressing LH and FSH secretion and inhibiting ovulation. Besides its effects on pituitary-gonadal processes, PRL is involved in various other processes. These include regulating osmotic balance, increasing bile and insulin secretion, and regulating the immune system, for example via stimulation of T and NK cell cytokine expression.³⁹⁻⁴⁰

PRL is a 23 kDa hormone that consists of 199 amino acids. Structurally, PRL resembles members of cytokine family molecules and consists of a single polypeptide chain with three intramolecular disulfide bonds. The various effects of PRL are mediated by its binding to a specific PRL receptor (PRLR), a type I cytokine receptor family member

expressed in various tissues and as several different isoforms. PRL secretion is controlled mainly by dopamine, which inhibits the release of PRL. There are also several other molecules that influence PRL secretion either by stimulation (e.g. thyrotropin-releasing hormone, serotonin, oxytocin) or by inhibition (e.g. serotonin, histamine, noradrenaline).⁴⁰⁻⁴¹

PRL blood levels are generally relatively low, but high PRL levels are expected during pregnancy and nursing. High PRL levels in other situations may indicate a potential disorder. For example, high PRL levels may be related to pituitary or other PRL-releasing tumors, certain kidney or liver diseases, or hypothalamus diseases. PRL levels are often measured in cases of infertility or irregular menstrual periods, testicular dysfunction, or symptoms suggesting prolactinoma, including visual impairment. PRL levels vary significantly during the day, which should be taken into account when using them as a diagnostic tool.^{40, 42-44}

Medix Biochemica offer several anti-PRL mouse monoclonal antibodies and a native antigen for detection of prolactin.

Anti-human prolactin monoclonal antibodies and antigens

PRL antibody	Product code	Concentration (mg/mL)	Shelf life (months at +2–8°C)	Subclass	Applications tested
5601	100967	5	36	IgG ₁	ELISA
5602	100360	5	24	IgG ₁	ELISA

PRL antigen	Grade	Product code
Native PRL, Human Pituitary Gland, lyophilized	≥ 98%	996-41

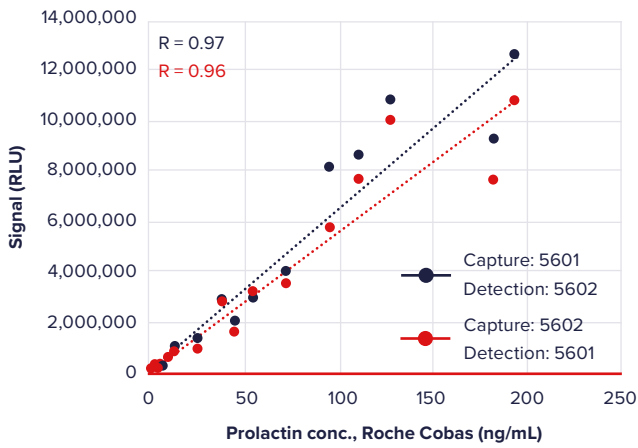
Pair recommendations

		Detection	
		5601	5602
Capture	5601	-	+
	5602	+	-

Kinetic parameters

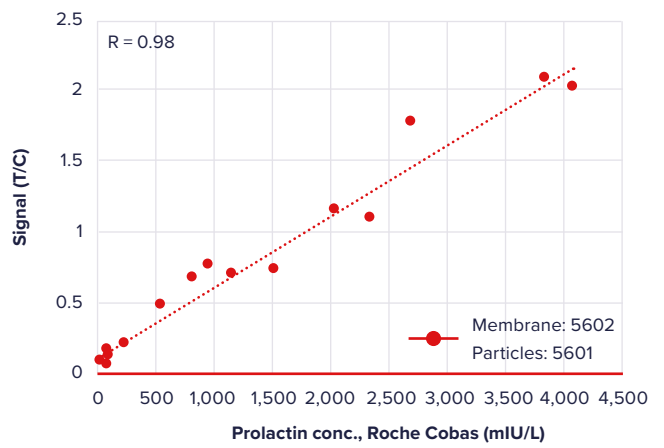
PRL antibody	Dissociation constant, K_D (M)
5601	$3.8 \times 10^{-11} = 0.04 \text{ nM}$
5602	$1.05 \times 10^{-10} = 0.1 \text{ nM}$

Correlation of PRL CLIA assay



PRL detection from clinical samples with Medix Biochemica recommended pairs showed good correlation with reference chemiluminescence Immunoassay (CLIA) method (Roche Cobas assay).

Correlation of PRL LF assay



PRL detection using lateral flow (LF) from clinical samples with Medix Biochemica recommended pair (membrane 5602 - particle 5601) showed excellent correlation to results obtained with reference method (Roche Cobas assay).

Sex hormone binding globulin (SHBG)

Sex hormone binding globulin (SHBG) is a steroid-binding serum glycoprotein synthesized in the liver. Synthesized SHBG is secreted into the circulation, where it binds the sex hormones testosterone and estradiol with high affinity and specificity. Thus, SHBG regulates sex hormone bioavailability and affects steroid responses by inhibiting their function. Some SHBG is also expressed by testicular germ cells, suggesting that the protein may have influence on sperm function. SHBG serum levels are regulated primarily by sex hormone blood levels, but also e.g. by nutritional factors.⁴⁵⁻⁴⁶

SHBG is an approximately 90 kDa homodimeric glycoprotein that is present in blood only as dimer. Dimerization occurs automatically upon synthesis and secretion of the molecule, and is promoted by high-affinity steroid ligands of the hormone. Upon dimerization, eight hydrogen bonds form between β -sheets of the monomers. This leads to an elongated, cylinder-shaped mature dimer.⁴⁵⁻⁴⁶

SHBG immunoassays are often used to assess patient testosterone status, such as in male infertility treatment or female hirsutism. In addition, several conditions affect SHBG plasma levels either by increasing or decreasing it. For example, low SHBG levels can indicate diabetes, hypothyroidism, or polycystic ovary syndrome. High SHBG levels may be associated with pregnancy, hyperthyroidism, or anorexia nervosa. Furthermore, recent research has also linked high SHBG levels with breast and testicular cancer. Epidemiological studies indicate that low serum SHBG levels predict a higher risk for metabolic syndrome.⁴⁵⁻⁴⁷

Medix Biochemica's selection of mouse monoclonal anti-SHBG antibodies includes three products (6001, 6002, and 6007).

Anti-human SHBG monoclonal antibodies

SHBG antibody	Product code	Concentration (mg/mL)	Shelf life (months at +2–8°C)	Subclass	Applications tested
6001	100539	5	24	IgG ₁	ELISA
6002	100540	5	24	IgG ₁	ELISA
6007	100569	5	24	IgG ₁	ELISA

Pair recommendations

		Detection		
		6001	6002	6007
Capture	6001	–	+	+
	6002	–	–	–
	6007	+	–	–

Kinetic parameters

SHBG antibody	Association rate constant, k_{on} (1/Ms)	Dissociation rate constant, k_{off} (1/s)	Dissociation constant, K_D (M)
6001	4.1×10^5	4.7×10^{-5}	$1.2 \times 10^{-10} = 0.12$ nM
6002	1.5×10^5	1.0×10^{-4}	$6.8 \times 10^{-10} = 0.68$ nM
6007	1.2×10^5	2.3×10^{-4}	$1.9 \times 10^{-10} = 1.9$ nM

Biospecimens

Medix Biochemica offers a range of biospecimens related to women's health and pregnancy which can be used as control and test materials for immunoassay development as well as confirmatory/exploratory research purposes.

Product	Product code
Urine - Pregnancy Samples - 1st Trimester	991-03-PT1
Urine - Pregnancy Samples - 2nd Trimester	991-03-PT2
Urine - Pregnancy Samples - 3rd Trimester	991-03-PT3
Urine - Postmenopausal	991-03-POSTM
Whole Blood - Pregnancy Samples - 1st Trimester	991-50-PT1
Whole Blood - Pregnancy Samples - 2nd Trimester	991-50-PT2
Whole Blood - Pregnancy Samples - 3rd Trimester	991-50-PT3
Sweat - Pregnancy Samples	991-20-S-01
Serum - Pregnancy Samples - 1st Trimester	991-24-PT1
Serum - Pregnancy Samples - 2nd Trimester	991-24-PT2
Serum - Pregnancy Samples - 3rd Trimester	991-24-PT3
Saliva - Pregnancy Samples - 1st Trimester	991-05-PT1
Saliva - Pregnancy Samples - 2nd Trimester	991-05-PT2
Saliva - Pregnancy Samples - 3rd Trimester	991-05-PT3
Vaginal Swab - Normal	991-25-S
Vaginal Swab - Pre-Coitus	991-25-PREC
Vaginal Swab - Post-Coitus	991-25-POSTC
Menstrual Blood - Normal - Bulk Volumes	991-15-P
Vaginal Fluid - Normal	991-10-P



Analyte list

Full range of antibodies and antigens primarily used in area of fertility and women's health offered by Medix Biochemica.

	antibody	antigen
Alpha fetoprotein (AFP)	✓	✓
Alpha subunit	✓	✓
Anti-Müllerian hormone (AMH)	✓	✓
Estradiol (E2)	✓	✓
Estriol (E3)	✓	✓
Ferritin	✓	✓
Follicle stimulating hormone (FSH)	✓	✓
Growth hormone	✓	✓
Human chorionic gonadotropin (hCG)	✓	✓
Inhibin A	✓	✓
Inhibin B	✓	✓
Luteinizing hormone (LH)	✓	✓
Parathyroid hormone (PTH)	✓	✓
Procollagen I N-terminal peptide (PINP)	✓	
Pregnanediol (PDG)	✓	✓
Progesterone	✓	✓
Prolactin	✓	✓
Sex hormone binding globulin (SHBG)	✓	✓
Testosterone	✓	✓
Thyroid-stimulating hormone (TSH)	✓	✓
Vitamin D	✓	✓
Vitamin D-binding protein (DBP)		✓

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Scientific publications describing the use of Medix Biochemica's monoclonal anti-hCG antibodies include:

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Medix Biochemica

More information on our products

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CPS = Counts per second

CLIA = Chemiluminescence immunoassay

ELISA = Enzyme-linked immunosorbent assay

FIA = Fluoroimmunoassay

IT = Immunoturbidimetry

LF = Lateral flow

N/A = Not Applicable

N/D = Not Determined

RLU = Relative light units

T/C = Test line signal/ control line signal

The results shown in this technical note are from prototype assays (unoptimized), indicating proof of concept with clinical samples. Further assay optimization may be required to obtain the best performance.

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