BOWEI-BIOTECH
for better bioassays

Steroid Hormones

Shanghai Bowei Biotechnology

Steroid Hormones

Introduction

Steroid hormones are endogenous chemicals which control the main endocrinology functions of human beings. The monitoring of these hormones is necessary for examining individual and population variations in reproductive function and their relationships with demographic, health, environmental, sociocultural, and biological covariates.

Analysis of steroid hormones as biomarkers requires high sensitivity, and in some cases need to be capable of detecting down to pg/mL level. Also, steroid hormones share the same structural skeleton with three six-member rings, one five-member ring, and an oxygen at C3 on the A-ring either as double bonded oxygen (=O) or hydroxyl group (−OH). Due to this structure similarity, the analysis of steroid hormones must be specific enough to selectively detect the target analyte in biological samples with complex components. In views of these points, steroid analytics is highly challenging.

Bowei-Bio has over 10 years of experience in hapten design and antibody production for testing of steroid hormones. Our optimized conjugates and antibodies can be used for developing sensitive and accurate immunoassays of steroid hormones.

Products

Steroid Hormones	Conjugate	Antibody
Estrone-3-Sulfate (E1S)	√	√
Unconjugated Estriol (E3)	√	√
Estrone-3-Glucuronide (E3G)	√	√
Pregnanediol-3-Glucuronide (Pd3G)	√	√
17α-Hydroxyprogesterone (17αOHP)	√	√
Dehydroepiandrosterone (DHEA)	√	√
Dehydroepiandrosterone Sulfate (DHEAS)	√	√
Cortisol (Cor)	√	√
Progesterone (P)	√	√
Aldosterone (ALD)	√	√
Estradiol (E2)	√	
Testosterone (T)	√	
Estrone (E)	√	
Androstenedione	√	
Nandrolone	√	
Medroxyprogesterone	√	
Corticosterone	√	
Cortisone	√	

Steroid Hormones

Estrone-3-Sulfate (E1S)

Determination of E1S in different samples of female herbivores has long been used in livestock for pregnancy detection and litter size classification. For diagnosis of human diseases, E1S is also useful for various of clinical settings, e.g., for assessing the risk stratification of breast cancer, monitoring of the proliferation promotion of endometrial cancer, providing prognostic information in advanced prostatic carcinoma, and monitoring of the response to certain hormonal therapy for malignancy. A lot of immunoassays have been designed for E1S determination, however, the utility of these assays for human sample analysis are very limited, mainly due to their cross-reactivity with dehydroepiandrosterone sulphate (DHEAS). A very slight cross-reactivity with DHEAS in E1S immunoassay will lead to unacceptable bias in view of the 10- to 10000-fold excess of DHEAS over E1S in male serum. Besides DHEAS, other steroids may also exert interferences on E1S immunoassay. To deal with these interferences, Bowei-Bio has generated a clone of anti-E1S McAb which show < 0.0001% cross-reactivity with DHEAS, ten-times improved than the best data published in literatures. Immunoassay based on this McAb is specific enough to obviate DHEAS interference in direct E1S immunoassay, and makes it unnecessary to perform the tedious chromatographic separation for removing the cross-reacting substances prior to analysis. Also, immunoassay using this McAb is sensitive enough to detect E1S as low as 5pg per test.

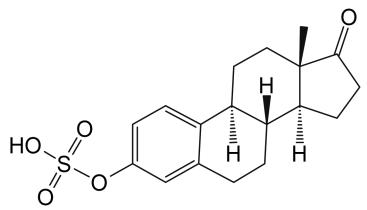

Fig. 1. The chemical structure of E1S

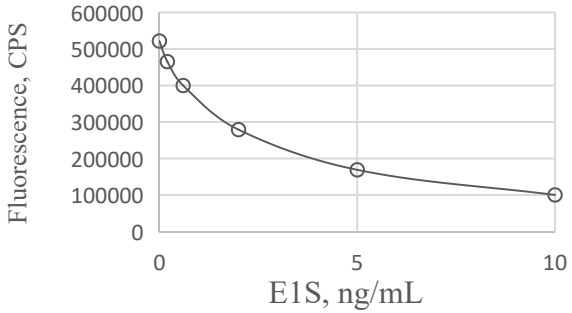

Fig. 2. Typical calibration curve for E1S-DELFIA using McAb-9

Product Type	Catalog #	Description
Mouse monoclonal antibody	• Anti-E1S McAb-9	Used for detection of E1S with LOD <100pg/mL by DELFIA. The cross-reactivity is < 0.0001% for DHEAS and < 0.1% for estrone (E1). No significant cross-reactivities were observed for other steroids with similar structure up to 10μg/mL.
Conjugate	• E1S-PEG-BSA	Paired with anti-E1S antibodies for E1S testing.

Steroid Hormones

Unconjugated Estriol (uE3)

Estriol (E3), together with 17β-estradiol (E2) and estrone (E1), plays an essential role in females for establishment of the secondary sex characteristics, maintenance of pregnancy, and regulation of bone metabolism. During pregnancy, the synthesis of E3 is greatly increased, and then secreted into maternal circulation. E3 exists in body fluids mainly in conjugated forms with sulfate or glucuronate, only a small fraction of E3 is found as unconjugated (***uE3***). It is the uE3 that has been used as a biomarker for noninvasive antenatal screening of neural tubal defect, aneuploidies, breast/ovarian cancers, and other clinical settings. Immunoassay is now the major clinical choice for uE3 determination in body fluids. The accuracy of uE3 immunoassay is of great concern with regard to its special clinical applications. This sets high requirements for the choice of anti-E3 antibodies, which must show enough affinity and selectivity for sensitive and specific E3 determination. Our anti-E3 McAb can well meet these requirements for accurate uE3 testing.

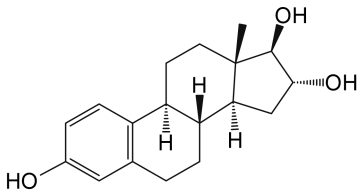

Fig. 1. The chemical structure of E3

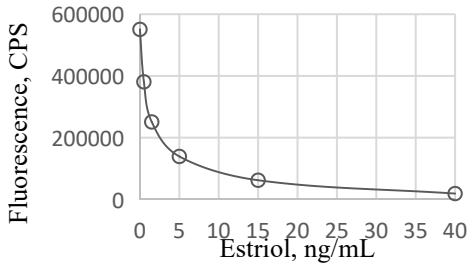

Fig. 2. Typical calibration curve for uE3-DELFIA using McAb-17

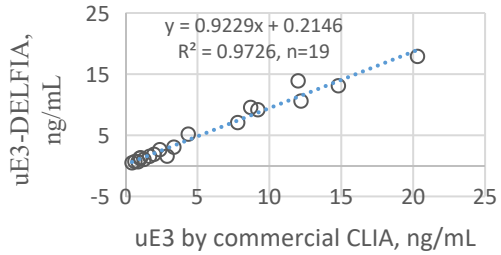

Fig. 3. Agreement between the uE3 concentration obtained by DELFIA using McAb-17 and a licensed commercial CLIA kit

Product Type	Catalog #	Description
Mouse monoclonal antibody	• Anti-E3 McAb-17	Used for testing uE3 with LOD < 0.2ng/mL by DELFIA. The cross-reactivities were < 0.35% for E2 and E1, and < 0.02% for estriol 3-sulfate, estriol 16-O-β-D-glucuronide and estriol 3-glucuronide.
Conjugate	• E3-6-BSA • E3-6-PEG-Biotin	Paired with anti-E3 antibodies for uE3 testing.

Steroid Hormones

Estrone-3-Glucuronide (E3G)

Estrone-3-glucuronide (E3G) is a metabolite of estradiol, a primary steroid that regulates the reproductive function in human females. The measurement of E3G in urine is preferred over estradiol to assess various aspects of ovarian function, since the urinary concentration of E3G is higher than the corresponding serum concentration, and urine specimens are easy to collect. E3G holds immense importance in precisely predicting the impending ovulation and the duration of the fertile period. The prediction of delineation of the fertile period is an approach to natural family planning， and is also eminent for donor insemination and in vitro fertilization. Our anti-E3G PcAb and McAb show high affinity and specificity for developing accurate E3G immunoassay.

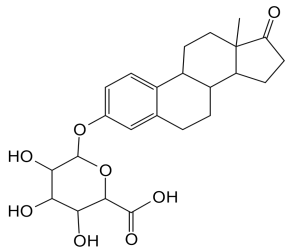

Fig. 1. The chemical structure of E3G

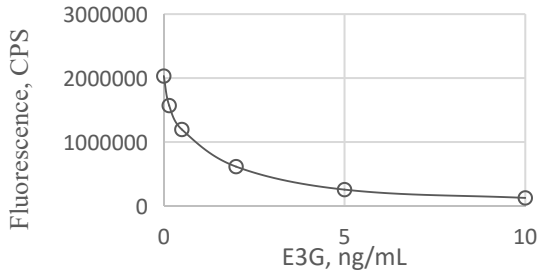

Fig. 2. Typical calibration curve of E3G-DELFIA using PcAb-5

Product Type	Catalog #	Description
Rabbit polyclonal antibody	• Anti-E3G-BSA PcAb-5	Used for testing E3G with LOD <8ng/mL by DELFIA. The cross reactivities with other steroids tested were 5.1% for estrone, 3.2% for pregnanediol, 0.15% for progesterone, 0.001% for Pd3G, and <0.05% for pregnenolone, testosterone, androstenediol, cortisol, corticosterone and 17alpha-OH-progesterone.
Mouse monoclonal antibody	• Anti-E3G McAb-66	Used for testing E3G with LOD <0.15ng/mL by DELFIA. The cross reactivities with other steroids tested were 0.12% for estrone, and <0.05% for pregnanediol, progesterone, Pd3G, pregnenolone, testosterone, androstenediol, cortisol, corticosterone and 17alpha-OH-progesterone.
Conjugate	• E3G-PEG-BCP	Paired with anti-E3G antibodies for E3G testing.

Steroid Hormones

Pregnanediol-3α-Glucuronide (Pd3G)

Pregnanediol-3α-glucuronide (Pd3G) is a major terminal metabolite of progesterone, which plays an important role in different physiological processes, such as the female menstrual cycle, pregnancy, embryogenesis and maternal immune response of humans and other species. Measurement of the level of Pd3G in urine has proved useful for monitoring ovulation and aiding in the definition of the fertile/infertile stages for natural family planning, as well as assisting in the documentation of the transition to menopause. Compared with the blood sampling, detection of urine Pd3G provides a practical alternative for rapid, accurate and simple fertility monitoring due to the non-invasive and more convenient urine sampling. Our anti-Pd3G McAbs can be used for developing accurate Pd3G immunoassays due to its high affinity and specificity. The immunoassay using McAb-51 is sensitive enough for detecting Pd3G at concentrations less than 150pg/mL; this makes it capable to measure Pd3G levels throughout the entire menstrual cycle even using spot urine as samples.

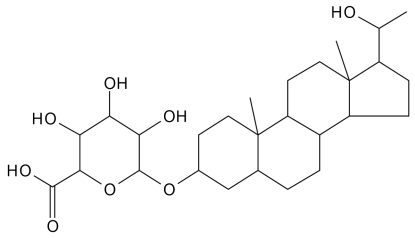

Fig. 1. The chemical structure of Pd3G

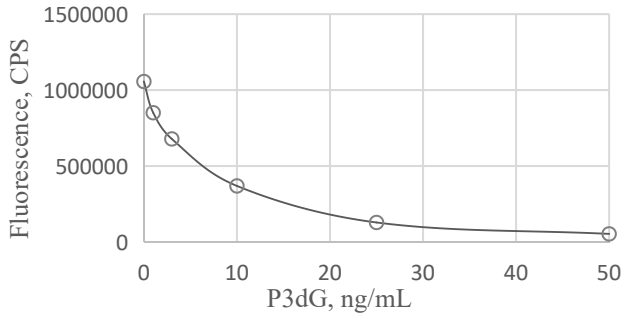

Fig. 2. Typical calibration curve of Pd3G-DELFIA using McAb-51

Product Type	Catalog #	Description
Mouse monoclonal antibody	• Anti-Pd3G McAb-51	Used for ultrasensitive detection of Pd3G with LOD < 0.15ng/mL by DELFIA. The cross-reactivity is < 0.23% with progesterone, < 0.1% for pregnenolone, estrone-3-sulfate, estradiol and estriol.
Mouse monoclonal antibody	• Anti-Pd3G McAb-3-2	Used for Pd3G testing with LOD < 2.2ng/mL by DELFIA. The cross-reactivity is < 1.7% with progesterone, < 0.1% for pregnenolone, estrone-3-sulfate, estradiol and estriol.
Conjugate	• Pd3G-BSA	Paired with anti-Pd3G antibodies for Pd3G testing.

Steroid Hormones

17α-Hydroxyprogesterone (17αOHP)

Congenital adrenal hyperplasia (CAH) is the most common inborn error of adrenal steroid metabolism, caused mainly by the deficiency of 21-hydroxylase which is necessary for cortisol synthesis. This 21-hydroxylase deficiency results in excessive ACTH secretion, leading to overproduction and accumulation of 17α-hydroxyprogesterone (17αOHP). Early diagnosis of CAH allows prompt intervention of this disease and regain of normal growth of the newborns. Accurate immunoassay of 17-αOHP provides a useful tool for this purpose, and has become a routine part of the programme for CAH screening and management. Our anti-17αOHP-BSA PcAb can be used for developing accurate 17αOHP immunoassay.

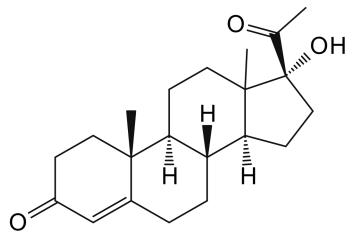

Fig. 1. The chemical structure of 17αOHP

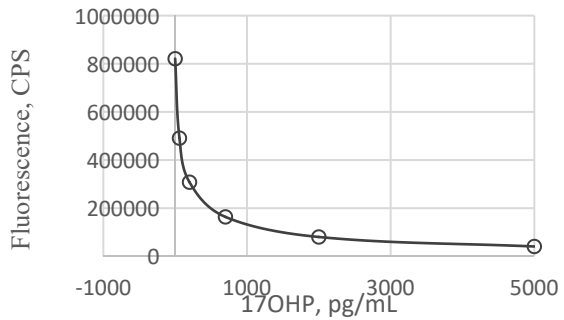

Fig. 2. Typical calibration curve for 17αOHP-DELFIA using PcAb-4

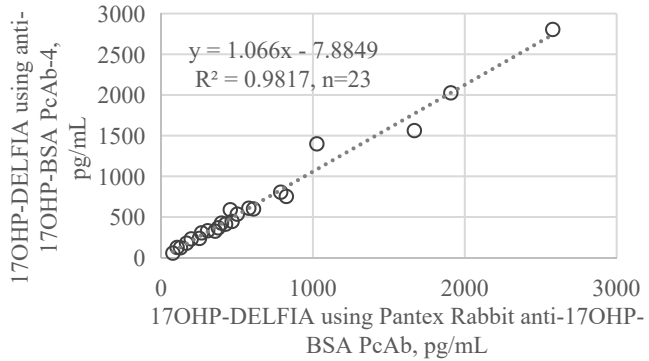

Fig. 3. Comparison of 17αOHP concentrations measured by DELFIA based on the use of two anti-17αOHP PcAbs

Product Type	Catalog #	Description
Rabbit polyclonal antibody	• Anti-17αOHP-BSA PcAb-4	Used for testing 17αOHP with LOD <20pg/mL by DELFIA. The cross-reactivities of PcAb-4 were 0.87% for progesterone, 0.62% for 11-desoxycortisol, and < 0.01% for aldosterone, corticosterone, cortisol, androstenedione, testosterone, dehydroepiandrosterone, E2, E1 and E3.
Conjugate	• 17αOHP-PEG-OVA • 17αOHP-PEG-Biotin	Paired with anti-17αOHP antibodies for 17αOHP testing.

Steroid Hormones

Dehydroepiandrosterone (DHEA)

DHEA is a useful biomarker of adrenal function for normal individuals and patients with adrenocortical disorders. DHEA affects a wide diversity of biological actions including immune, cardiovascular, endocrine, central nervous system and metabolic effects. Lower levels of DHEA have been associated with critical illness, emotional stress, and a variety of other medical conditions. On the contrary, elevated levels of DHEA can be observed in connection with obesity, diabetes, female hirsutism, and prolonged physical stress. Accurate quantification of DHEA in biological fluids is important for diagnostics and researches on pediatric, oncology, and geriatric endocrinology, as well as aging.

Compared to different kinds of mass spectrometric and chromatographic methods, immunoassay provides a convenient way for DHEA determination. However, due to the lack of anti-DHEA antibodies with enough affinity and specificity, immunoassay of DHEA usually suffers from endogenous interferences or the inability to detect very trace amount of DHEA in samples [*Journal of Immunoassay and Immunochemistry. 2010, 31:4, 266-278.*]. Our anti-DHEA McAb and its paired conjugate can be used for developing sensitive and specific DHEA immunoassay.

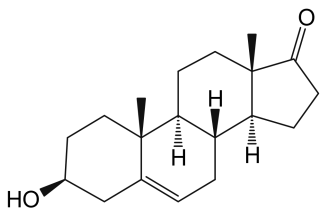

Fig. 1. The chemical structure of DHEA

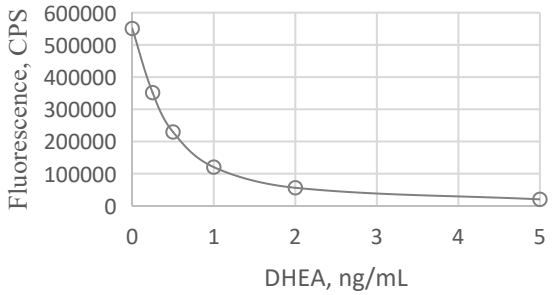

Fig. 2. The typical calibration curve of DHEA-DELFIA using McAb-1

Product Type	Catalog #	Description
Mouse monoclonal antibody	• Anti-DHEA McAb-1	Used for detection of DHEA, with LOD < 50pg/mL by DELFIA. The absolute sensitivity is calculated to be 5pg/test. The cross-reactivities is < 0.1% for androsterone, testosterone, DHEA-sulfate and androstenedione.
Conjugate	• DHEA-PEG-BCP	Paired with anti-DHEA McAb for DHEA testing.

Steroid Hormones

Dehydroepiandrosterone Sulfate (DHEAS)

DHEAS is a steroid hormone synthesized by zona reticularis of the adrenal cortex, and functions as a precursor of androgens and estrogens. Because of its long biological half-life and little diurnal variation, DHEAS serves as an effective biochemical marker for diagnosis of adrenal diseases, such as adrenal tumors, adrenal insufficiency and congenital adrenal hyperplasia. It is also useful for differential diagnosis of the etiology of Cushing's syndrome. Our mouse anti-DHEAS McAb can be used for developing sensitive and specific DHEAS immunoassay.

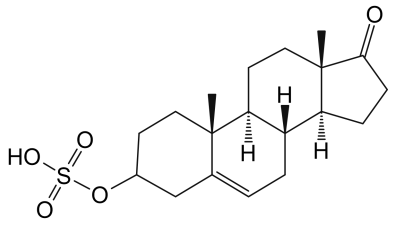

Fig. 1. The chemical structure of DHEAS

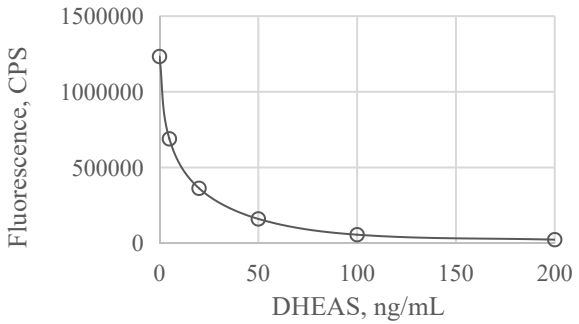

Fig. 2. Typical calibration curve for DHEAS-DELFIA using McAb-4

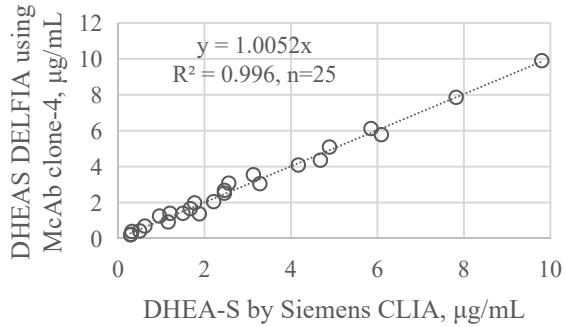

Fig. 3. Comparison of DHEAS measurements obtained by commercial Siemens CLIA and DELFIA using McAb clone-4

Product Type	Catalog #	Description
Mouse monoclonal antibody	• Anti-DHEAS McAb-4	Used for testing DHEAS with LOD <0.8ng/mL by DELFIA. The cross-reactivities are < 3% for dehydroepiandrosterone, and < 2% for estrone. Other steroids with similar structure at their highest physiological concentration don't cause significant bias for the immunoassay using McAb-4.
Conjugate	• DHEAS-PEG-OVA • DHEAS-BSA	Paired with anti-DHEAS McAb for DHEAS testing.

Steroid Hormones

Cortisol (Cor)

- Cortisol (Cor) is the most abundant glucocorticoid secreted by the adrenal cortex. Cor plays a critical role in regulating several key physiological processes of the body. The determination of cortisol level in human samples is primarily used to diagnose disorders associated with abnormal cortisol secretion, including excessive cortisol production in Cushing's syndrome (CS) and adrenal steroid deficiency in Addison's disease. It is also applied for the monitoring of therapeutic efficacy (e.g., the dexamethasone suppression test in CS and hormone replacement therapy monitoring in Addison's disease). Elevated serum cortisol levels are also observed in stress responses, psychiatric disorders, obesity, diabetes mellitus, alcoholism, and pregnancy. These physiological elevations may interfere with the clinical diagnosis of CS patients. Decreased cortisol levels are mostly seen in patients with rare adrenal enzyme defects and individuals after prolonged stress exposure. Our anti-Cor McAbs can be used to establish sensitive and specific cortisol immunoassay. The immunoassay using McAb-19 is capable of detecting cortisol at concentration as low as 30pg/mL, sensitive enough for accurate quantification of free cortisol or cortisol in hair.

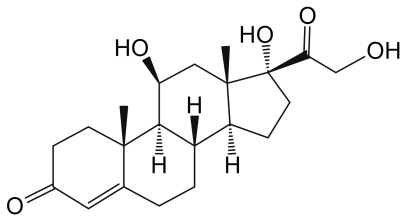

Fig. 1. The chemical structure of Cortisol

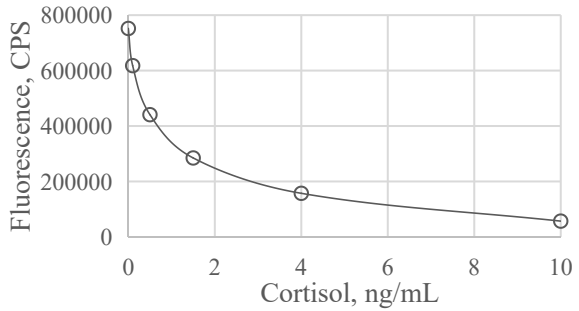

Fig. 2. Typical calibration curve for Cor-DELFIA using McAb-56

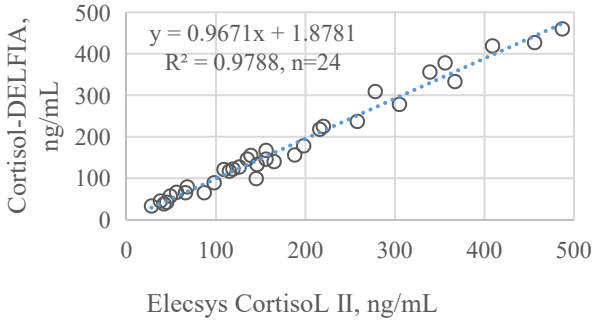

Fig. 3. Comparison of Cor measurements obtained by Elecsys CortisoL-II and DELFIA using McAb clone-56

Product Type	Catalog #	Description
Mouse monoclonal antibody	• Anti-Cor McAb-56	Used for Cor testing with LOD <30pg/mL by DELFIA. The cross-reactivities are < 1% for corticosterone, < 2.5% for cortisone, <79% for prednisolone. Other steroids with similar structure at their highest physiological concentration don't cause significant measurement bias.
Mouse monoclonal antibody	• Anti-Cor McAb-45	Used for Cor testing with LOD <100pg/mL by DELFIA. The cross-reactivities are < 0.3% for corticosterone, < 6% for cortisone, <10% for prednisolone. Other steroids with similar structure at their highest physiological concentration don't cause significant measurement bias.
Conjugate	• Cor-BSA	Paired with anti-Cor antibodies for Cor testing.

Steroid Hormones

Aldosterone (ALD)

Accurate quantification of serum aldosterone (ALD) is valuable for correct diagnosis of a panel of diseases that affect the renin-angiotensin-aldosterone axis, such as primary aldosteronism, renal artery stenosis, bartter syndrome, gitelman syndrome, congenital adrenal hyperplasia, renin-secreting tumors, liddle syndrome, and gordon syndrome. LC-MS and GC-MS are regarded as the reference methods for aldosterone determination because of their potentially excellent specificity and accuracy. However, up to now the use of these methods is often limited to reference laboratories and academic centers, due to the lack of automation, complex manipulation of the expensive equipment. The growing demand for aldosterone determination, especially for the diagnosis of high prevalent primary aldosteronism, necessitates most of the laboratories switching to the faster, more convenient and automated immunoassays. Our anti-ALD McAb and its paired conjugate can be used for developing accurate ALD immunoassay.

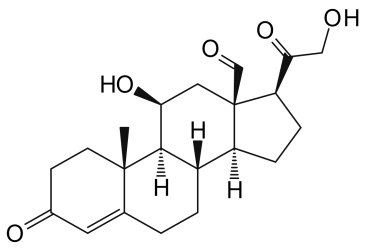

Fig. 1. The chemical structure of ALD

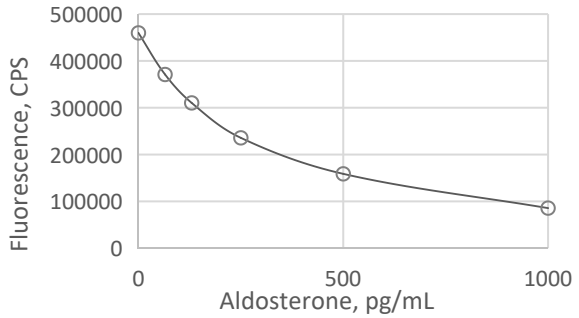

Fig.2. Typical calibration curve of ALD-DELFIA using McAb-5511

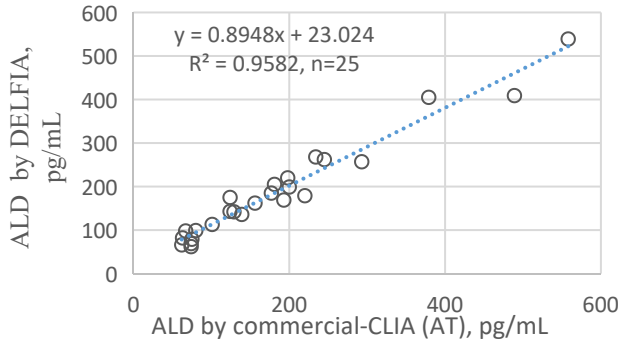

Fig. 3. The agreement between the ALD concentration obtained by DELFIA using McAb-5511and a licensed commercial CLIA

Product Type	Catalog #	Description
Mouse monoclonal antibody	• Anti-ALD McAb-5511	Used for testing ALD with LOD <30pg/mL by DELFIA.
Conjugate	• ALD-BSA	Paired with anti-ALD antibodies for ALD testing.