



## IDS-iSYS 17-OH Progesterone

### Fertility Hormones

An automated assay for the quantitative determination of 17-OH Progesterone in human serum or plasma. The assay is intended for use as an aid in the diagnosis and treatment of various disorders of the adrenal glands or ovaries.

The steroid 17 Hydroxyprogesterone (17-OH P) is produced by both the adrenal cortex and gonads. It is synthesised from progesterone and serves primarily as a precursor compound that is converted into cortisol in the adrenal gland, or into androgenic and estrogenic steroid hormones in the gonads. 17-OH P is routinely used for the diagnostic assessment of 21-hydroxylase deficiency, which is linked to congenital adrenal hyperplasia.

In adult non-pregnant women, 17-OH P levels in the blood depend on the phase of the menstrual cycle. Like progesterone, 17-OH P is secreted by the mature follicle and the corpus luteum. Concentrations are generally higher after ovulation. Levels of 17-OH P are influenced by daytime rhythms which correlate with the adrenal secretion of cortisol. Maximal levels are found in samples collected between midnight and 8.00 a.m.

### Features and benefits

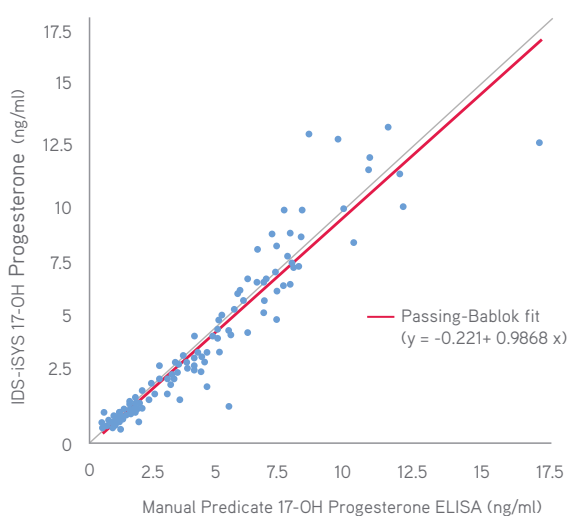
- Exceptional sensitivity and highly reproducible results
- Suitable for measurement of a variety of sample types
- Excellent correlation with existing 17-OH Progesterone ELISA assays
- Fully automated assay
- All reagents are ready to use

## Specifications

Format	Automated competitive immunoassay				
Calibrators	Ready to use – 1 each of 2 concentration levels, 1.0 mL				
Controls	Ready to use – 2 each of 3 concentration levels, 1.0 mL				
Limit of Quantitation	0.31 ng/mL				
Dynamic range	0.31 – 16.0 ng/mL				
Minimum sample volume	50 µL plus dead volume				
Sample Type	Human serum – including serum collected in serum separator tubes Human plasma – collected in lithium or sodium heparin or potassium EDTA tubes				
Reagent Stability	The IDS-iSYS 17-OH Progesterone reagent cartridge may be stored after opening on-board the IDS-iSYS Multi-Discipline Automated System or at 2 - 8°C for up to 28 days				
Calibration stability	The calibration of the IDS-iSYS 17-OH Progesterone assay is stable for up to 14 days				
Time to first result	48 minutes				
Precision	Sample ID	n	Mean (ng/mL)	Within Run	Total
	1	84	2.46	2.7%	4.8%
	2	84	5.63	1.7%	3.9%
	3	84	11.60	1.9%	3.9%
	4	80	1.04	5.3%	11.1%
	5	84	3.70	2.6%	6.8%
	6	84	8.45	1.5%	6.5%
	7	84	13.73	1.2%	6.5%

### IDS-iSYS 17-OH Progesterone vs predicate manual 17-OH Progesterone assay

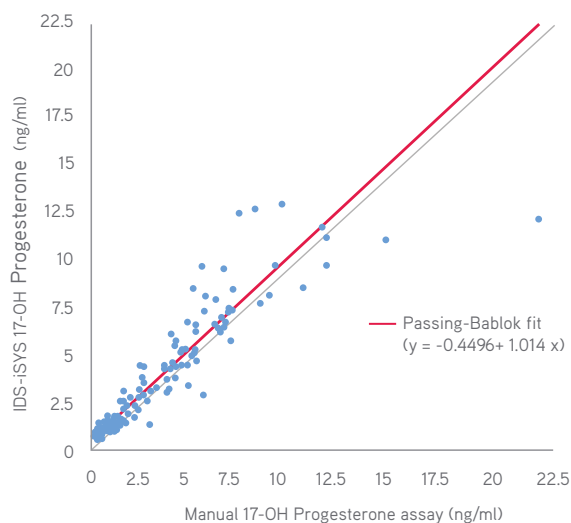
Method comparison (n=155)



155 samples (0.48 – 17.01 ng/mL) from normal 'healthy' patients were assessed with both the IDS-iSYS 17-OH Progesterone and the manual predicate 17-OH Progesterone assay

Passing-Bablok fit  $y = -0.22 + 0.99x$   $r = 0.95$

Method comparison (n=154)



154 samples (0.06 – 21.70 ng/mL) from normal 'healthy' patients were assessed with both the IDS-iSYS 17-OH Progesterone and a manual 17-OH Progesterone assay

Passing-Bablok fit  $y = 0.45 + 1.01x$   $r = 0.91$

## Ordering information

Product Name	Description	Code
IDS-iSYS 17-OH Progesterone	Reagent pack: 100 tests	IS-5100
IDS-iSYS 17-OH Progesterone Control Set	Control set: 3 levels	IS-5130

## Other assays in the Fertility portfolio – coming soon in 2016

Product Name	Code
IDS-iSYS Total Testosterone	IS-5000
IDS-iSYS 17-β Estradiol	IS-5200
IDS-iSYS Free Testosterone	IS-5300

Visit [www.idsplc.com](http://www.idsplc.com) for an extended range of IDS-iSYS assays