

17OHP-SI Kit for Specific Market Need



Opportunity Translated into Success

"We now have the best kit on the market. Customers have a very positive attitude and our early work with the largest gynecological center in Moscow helped with a winning kit design against DSL and the RIA gold standard."

- Natalya Rytikova, Head of ELISA department at BioChemMack JSC, Monobind's exclusive ELISA dealer in Russia

Executive Summary

In Russia, clinicians were accustomed to patient values produced by DSL's 17OHP System. After Beckman stopped production, the market looked for other supply but was dissatisfied as other kits used different antibodies giving different values, including the 17OHP Kit produced by Monobind which clinicians believed "overestimated".

Challenges

Monobind was approached by its distributor (BCM) about making changes to its kit as to produce lower values, as well as provide mandatory, additional information in the insert (IFU) with expected values for gestational weeks. For the later, Monobind would need the cooperation of the Moscow Institute for Obstetrics and Gynecology and other users to routinely run the assay and produce a great quantity of data to establish population-specific expected value-ranges during gestation weeks, as well as normal ranges. Monobind would produce a new version of its 17OHP called 17OHP-SI for Russia and any other market facing similar challenges.

What We Did

With a big market share at stake, up to 1,000 DSL kits sold per year by Monobind's distributor, Monobind and BCM were in the unique position to influence the market.

The system was optimized and re-standardized to the DSL system, so lower values could be achieved. Kits were given to large users along with Biorad control in order to gain confidence.

Expected Values

Values were revisited and updated for the 17OHP-SI product with the help of Russian labs. The IFU was modified to include:

TABLE 1
Expected Values

Population	(ng/ml)	(nmol/L)
Prepubertal Child (1-10 yr)	0.2 - 0.8	0.64 - 2.54
Adult man	0.2 - 3.1	0.64 - 9.86
Adult woman		
Follicular phase	0.4 - 1.51	1.28 - 4.83
Luteal phase	1.00 - 4.51	3.18 - 14.34
Postmenopausal woman	0.2 - 0.9	0.64 - 2.86

TABLE 2
Expected Gestation Values

Gestation Week	1 - 6	7 - 14	15 - 24	25 - 33	34 - 40
nmol/l	4 - 10	3 - 9	5 - 14	6 - 31	8 - 36
ng/ml	1.32 - 3.30	1.1 - 2.8	1.65 - 4.62	1.98 - 10.2	2.64 - 13.20

Competitor Comparison

The entire design of the assay was reviewed and compared against DSL and other competitors to demonstrate its superiority which was achieved.

Procedure Comparison

Manufacturer	Sample Size	# of Incubations	Total Time	Shaker Requ?	Total Steps
DSL/Beckman	50µl	3	2 hrs	Yes	11
Monobind	25µl	2	1 hr 20min	No	7

The Monobind 17OHP-SI kit can produce values like DSL, but also with a simpler and quicker procedure for labs!

Procedures from Alkor Bio, a Russian manufacturer and DRG were also evaluated to determine differences and in both cases showed Monobind advantages. The Alkor product requires shaking at 37°C, larger samples size (50µl versus 25µ), and incubation in the dark, as well as offers no sensitivity claims in its IFU. The DRG product requires a 5-minute pre-incubation of samples with conjugate and its assay time is slightly longer (1 hr 35 min versus 1 hour 15 min). Field performance was not evaluated, however market feedback was and moreover the joint development with key users and influencers gave Monobind significant advantage.

Results

The 17OHP-SI product is now Monobind's best-selling ELISA kit in Russia. In 2015, sales increased 52% alone and exceed the volume of business previously held by BCM with DSL. Value assignment is provided on the Biorad Lyphocheck control for both Monobind 17OHP and 17OHP-SI systems.

"Our local expert (Institute for Obstetrics and Gynecology) has tested Monobind kits following our modifications and has said in his opinion that the Monobind 17OHP-SI kit is excellent."

- Alex Blinkovsky, BioChemMack SJC

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