

**Ligand Assay and Analysis Core
Validation of New Steroid Assay Methods
(Implementation Date – January/February, 2015)
Revised July, 2016**

In 2014, the manufacturer of most steroid radioimmunoassays used in the Core (Siemens) discontinued these product lines. Evaluations of replacement methods were conducted based on the recommendations of the Endocrine Society “Sex Steroid Assays Reporting Task Force” (J Clin Endocrinol Metab 99:4375, 2014). Evaluations were performed for each species and included accuracy (i.e. recovery from steroid-spiked serum pools), matrix specificity, assay performance (i.e. precision, functional sensitivity) and correlation to the previous methods. The results of this evaluation are summarized in the Table, below.

Test	Species	Kit Manufacturer (Cat Number)	% Recovery #	Correlation to previous method *
Androstenedione	Human	ALPCO ELISA (11-ANRHU-E1)	93%	- 43%
	Mouse	CalBiotech ELISA (AD183E)	109%	
	Rat	CalBiotech (AD183E) ELISA	118%	
Corticosterone	Mouse	IBL ELISA (IB79175)	105%	- 74%
	Rat	IBL ELISA (IB79175)	89%	- 88%
Estradiol	Human	Calbiotech ELISA (ES180S)	86%	-5%
	Mouse	CalBiotech ELISA (ES180S-100)	172%	
	Rat	CalBiotech ELISA (ES180S-100)	82%	- 37%
Progesterone	Human	Siemens Immulite 2000	106%	- 28%
	Mouse	IBL ELISA (IB79105)	93%	- 55%
	Rat	IBL ELISA (IB79105)	113%	- 18%
17-OH-Progest	Human	ALPCO ELISA (20-17OHU-E01)	115%	- 57%
	Mouse	ALPCO ELISA (20-17OHU-E01)	97%	- 80%

	Rat	ALPCO ELISA (20-17OHU-E01)	110%	- 65%
Testosterone	Human	Siemens Immulite (L2KTW2/10381190)	90%	- 19%
	Mouse	IBL ELISA (IB79106)	111%	- 37%
	Rat	IBL ELISA (IB79106)	171%	+ 62%

Serum pools were spiked with various concentrations of steroid reference preps (Cerilliant-Sigma) to determine recovery across the assay range and parallelism to the standard curve. Each assay presented showed acceptable parallelism to the standard curve. Mean recovery shown.

* Serum pools (n = 50 for human; n = 20 each for mouse and rat) were run in the previous and new methods to determine shifts in assay values (positive or negative).