

**Ligand Assay and Analysis Core  
Validation of New Steroid Assay Methods  
(Implementation Date – January/February, 2015)  
Revised September, 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” (Endocrinol 155:4603). 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.

<b>Test</b>	<b>Species</b>	<b>Kit Manufacturer (Cat Number)</b>	<b>% Recovery #</b>	<b>Correlation to previous method *</b>
<b>Androstenedione</b>	Human	ALPCO ELISA (11-ANRHU-E1)	93%	- 43%
	Mouse	CalBiotech ELISA (AD183E)	109%	
	Rat	CalBiotech (AD183E) ELISA	118%	
<b>Corticosterone</b>	Mouse	MP Biomedicals (07-120102)	169%	+298%
	Rat	MP Biomedicals (07-120102)	182%	+428%
<b>Estradiol</b>	Human	Calbiotech ELISA (ES180S)	86%	-5%
	Mouse	CalBiotech ELISA (ES180S-100)	172%	
	Rat	CalBiotech ELISA (ES180S-100)	82%	- 37%
<b>Progesterone</b>	Human	Siemens Immulite 2000	106%	- 28%
	Mouse	IBL ELISA (IB79105)	93%	- 55%
	Rat	IBL ELISA (IB79105)	113%	- 18%
<b>17-OH-Progest</b>	Human	ALPCO ELISA (20-17OHU-E01)	115%	- 57%
	Mouse	ALPCO ELISA (20-17OHU-E01)	97%	- 80%

	Rat	ALPCO ELISA (20-17OHU-E01)	110%	- 65%
<b>Testosterone</b>	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).