

Quality Control Certificate



17-OH-Progesterone ELISA

REF 30223011

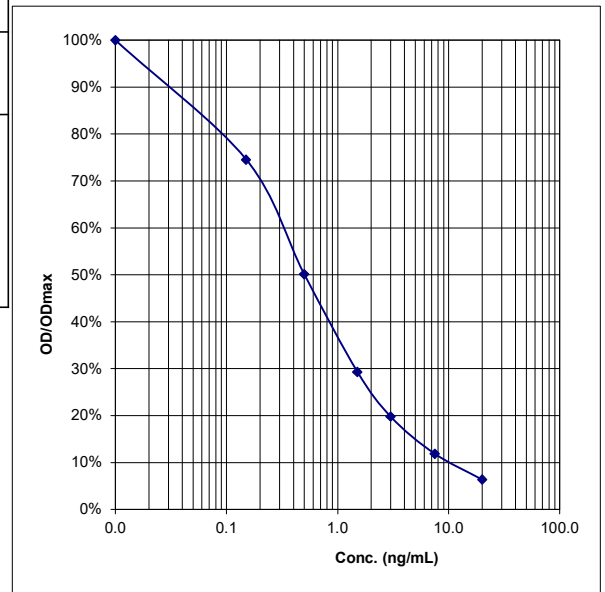
LOT EOH245U

2027-04-30
YYYY-MM-DD

Final Release Results:

	Concentration ng/mL	Measured value OD	manual		e.g. automated DSX
			Range* OD	OD/ODmax	Measured value OD
CAL A	0	2.375	> 1.000	100%	2.133
CAL B	0.15	1.770	-	75%	1.668
CAL C	0.5	1.190	-	50%	1.078
CAL D	1.5	0.696	-	29%	0.608
CAL E	3.0	0.470	-	20%	0.370
CAL F	7.5	0.281	-	12%	0.220
CAL G	20	0.151	< 0.350	6%	0.108

*During automated procedure the optical densities of calibrators and controls may rise due to temperature and specific device conditions. In case of none conformance with the OD ranges stated on the QC Certificate please contact IBL-International or use the validation criteria only!



Validation criteria

	Concentration found ng/mL	Acceptable range		
		lower limit ng/mL	target ng/mL	upper limit ng/mL
CONTROL 1	0.86	0.49	0.90	1.30
CONTROL 2	3.6	2.6	4.0	5.4

Kit Composition:

REF		LOT	
KEOH651	CONTROL1	L994	2027-04
KEOH661	CONTROL2	L995	2027-04
KEOH511	MTP	L882	2028-09
KEOH541	ENZCONJ	L996	2027-04
KEOH611	CAL A	L993	2027-04
KEOH611	CAL B-G	L993	2027-04
KEZZ751	CONC WASHBUF	K131	2027-06
KEZZ991	TMB SUBS	L541-6	2027-10

REF		LOT	
KEZZ921	TMB STOP	L861	2028-01

Valid edition of the instructions for use: 2024-02

This product has been tested successfully by the Quality Control Department and was released for sale according to the existing specifications.

Verified by: Dr. Spangenberg

Validation date: 2025-06-20

Accepted

This document has been produced electronically and is valid without a signature.



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