

Quality Control Certificate



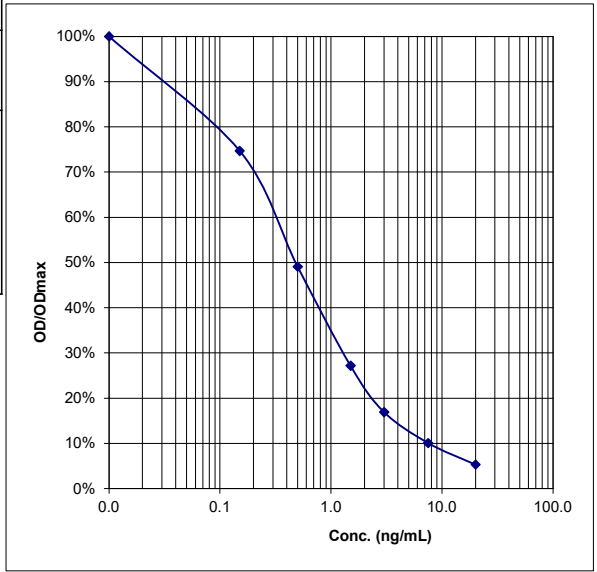
17-OH-Progesterone ELISA

REF 30223011	LOT EOH246U	2027-11-30 YYYY-MM-DD
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Final Release Results:

	Concentration ng/mL	manual			e.g. automated DSX
		Measured value OD	Range* OD	OD/ODmax	Measured value OD
CAL A	0	2.270	> 1.000	100%	2.002
CAL B	0.15	1.695	-	75%	1.504
CAL C	0.5	1.114	-	49%	0.983
CAL D	1.5	0.617	-	27%	0.539
CAL E	3.0	0.384	-	17%	0.316
CAL F	7.5	0.229	-	10%	0.160
CAL G	20	0.120	< 0.350	5%	0.078

*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	0.96	0.53	0.97	1.41
CONTROL 2	4.1	2.6	4.0	5.4

Kit Composition:

REF	LOT		REF	LOT			
KEOH651	CONTROL1	K462	2027-11	KEZZ921	TMB STOP	K356	2028-09
KEOH661	CONTROL2	K463	2027-11				
KEOH511	MTP	K422	2029-06				
KEOH541	ENZCONJ	K466	2027-11				
KEOH611	CAL A	K461	2027-11				
KEOH611	CAL B-G	K461	2027-11				
KEZZ751	CONC WASHBUF	K476	2027-12				
KEZZ991	TMB SUBS	K132-6	2028-09				

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**

Accepted

Validation date: **2025-12-23**

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