

Quality Control Certificate



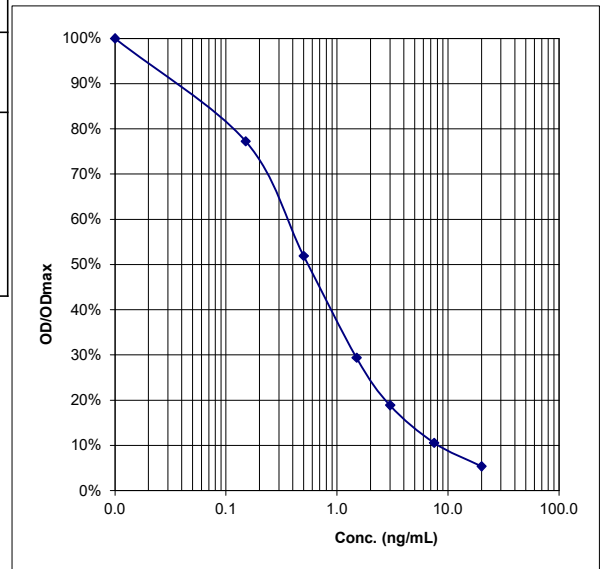
17-OH-Progesterone ELISA

REF RE52071	LOT EOH247	2028-02-29 YYYY-MM-DD
--------------------	-------------------	---------------------------------

Final Release Results:

	Concentration ng/mL	manual			e.g. automated DSX
		Measured value OD	Range* OD	OD/ODmax	Measured value OD
CAL A	0	2.252	> 1.000	100%	2.207
CAL B	0.15	1.739	-	77%	1.677
CAL C	0.5	1.169	-	52%	1.064
CAL D	1.5	0.662	-	29%	0.590
CAL E	3.0	0.425	-	19%	0.377
CAL F	7.5	0.238	-	11%	0.191
CAL G	20	0.121	< 0.350	5%	0.095

*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	0.95	0.51	0.93	1.34
CONTROL 2	3.7	2.4	3.7	5.0

Kit Composition:

REF	LOT		REF	LOT			
KEOH651	CONTROL1	K591	2028-02	KEZZ921	TMB STOP	K595	2029-03
KEOH661	CONTROL2	K592	2028-02				
KEOH511	MTP	K588	2029-10				
KEOH541	ENZCONJ	K589	2028-03				
KEOH611	CAL A	K590	2028-02				
KEOH611	CAL B-G	K590	2028-02				
KEZZ751	CONC WASHBUF	K593	2028-03				
KEZZ991	TMB SUBS	K503-3	2029-04				

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: S. Geweke

Accepted

Validation date: 2026-04-14

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