

Quality Control Certificate



Estriol high sensitive Saliva ELISA

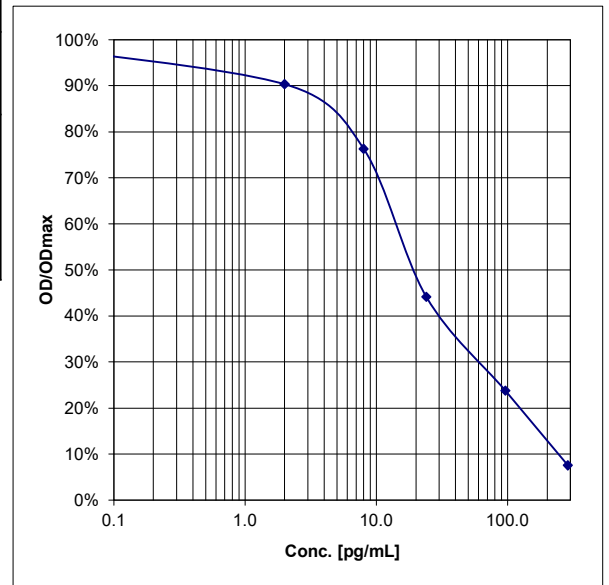
REF 30121046	LOT EOL137	2027-02-28 YYYY-MM-DD
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Final Release Results:

	Concentration pg/mL	manual			e.g.automated/ EVOlyzer
		Measured value OD	Range* OD	OD/ODmax	Measured value OD
CAL A	0	2.382	> 1.000	100%	2.250
CAL B	2	2.152	-	90%	2.016
CAL C	8	1.818	-	76%	1.608
CAL D	24	1.051	-	44%	0.968
CAL E	96	0.566	-	24%	0.550
CAL F	288	0.180	-	8%	0.169

*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 (manual/automated)				
	Concentration found pg/mL	Acceptable range		
		lower limit pg/mL	target pg/mL	upper limit pg/mL
CONTROL 1	4.8	3.1	5.6	8.1
CONTROL 2	47.3	33.6	48.0	62.3



Kit Composition:

REF		LOT	
30126288	MTP	L935	2027-02
30126290	ENZCONJ	L927	2027-02
30126291	CAL A-F	N746A-2A	2027-02
30126292	CONTROL 1	N747A-2A	2027-02
30126293	CONTROL 2	N748A-2A	2027-02
KEZZ991	TMB SUBS	L541-6	2027-10
KEZZ921	TMB STOP	L926	2028-03
KIZZ01	CONC WASHBUF	L913	2028-08

REF	LOT	

Valid edition of the instructions for use: 2024-12

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: 2025-05-15

Accepted

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



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