

Quality Control Certificate



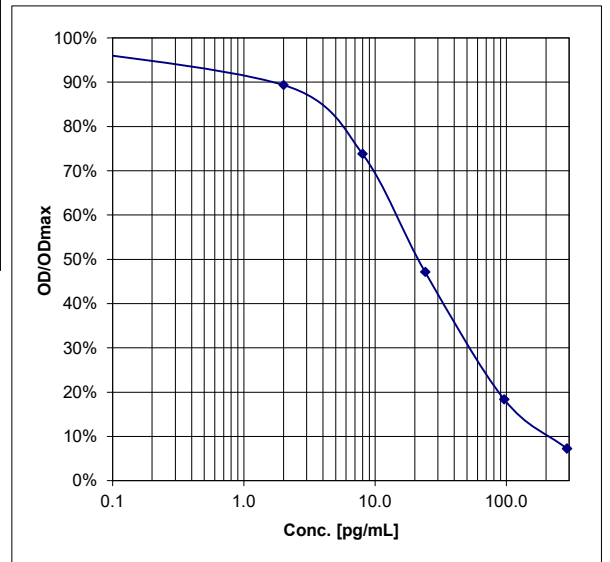
Estriol high sensitive Saliva ELISA

REF 30121046	LOT EOL138	2027-12-31 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	2.203	> 1.000	100%	2.498
CAL B	2	1.969	-	89%	2.267
CAL C	8	1.626	-	74%	1.930
CAL D	24	1.038	-	47%	1.356
CAL E	96	0.404	-	18%	0.590
CAL F	288	0.159	-	7%	0.232

*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	6.9	3.4	6.3	9.1
CONTROL 2	51.0	35.3	50.4	65.5

Kit Composition:

REF		LOT	
30126288	MTP	K559	2027-12
30126290	ENZCONJ	K569	2027-12
30126291	CAL A-F	K566	2027-12
30126292	CONTROL 1	K567	2027-12
30126293	CONTROL 2	K568	2027-12
KEZZ991	TMB SUBS	K503-2	2029-04
KEZZ921	TMB STOP	K515	2028-12
KIZZ01	CONC WASHBUF	K459	2029-04

REF	LOT	
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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: T. Borchert

Accepted

Validation date: 2026-02-27

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



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