

Quality Control Certificate



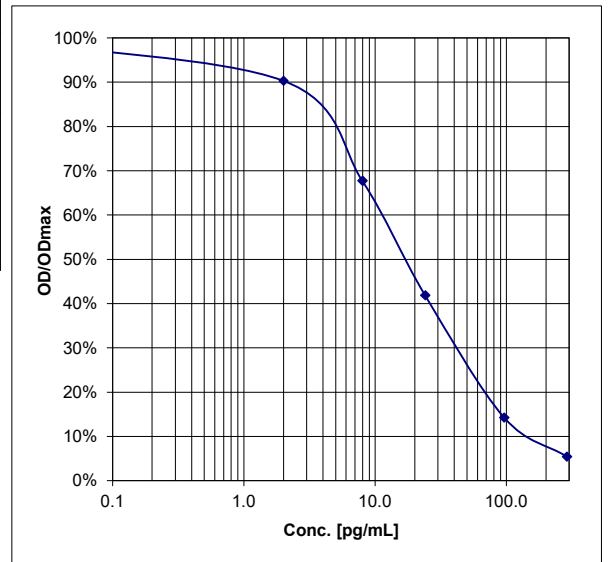
Estriol high sensitive Saliva ELISA

REF 30121046	LOT EOL136	2026-05-31 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	1.939	> 1.000	100%	2.169
CAL B	2	1.751	-	90%	2.002
CAL C	8	1.313	-	68%	1.646
CAL D	24	0.812	-	42%	1.103
CAL E	96	0.276	-	14%	0.448
CAL F	288	0.105	-	5%	0.180

*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	5.7	3.1	5.7	8.2
CONTROL 2	46.3	34.1	48.8	63.4

Kit Composition:

REF		LOT	
30126288	MTP	L398	2026-05
30126290	ENZCONJ	L399	2026-05
30126291	CAL A-F	M560A-2A	2026-05
30126292	CONTROL 1	M561A-2A	2026-05
30126293	CONTROL 2	M562A-2A	2026-05
KEZZ991	TMB SUBS	M840-4	2027-02
KEZZ921	TMB STOP	L132	2027-02
KIZZ01	CONC WASHBUF	L345	2027-11

REF	LOT	
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Valid edition of the instructions for use: 2023-04

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

Verified by: M.Dries

Accepted

Validation date: 2024-07-10

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



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