

33-fb-9_11 Änd. Ind. 1	CoA Certificate of Analysis	
β-HCG ELISA		

REF : EIA-1911

LOT : 33K092

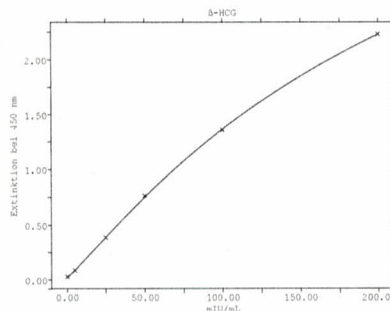
⌚ : 2023 - 09 - 30
 (yyyy - mm - dd)

Controls	Acceptance Range mIU/mL	Observed concentration mIU/mL	Standards (Calibrators)		OD at 450 nm (620 nm Ref)	Acceptance Range Max. OD
			Name	mIU/mL		
40411	1.82 – 4.06	3.49	S0	0	0.02	≥ 1.20
40412	7.25 – 16.1	11.8	S1	5	0.07	
40413	67.2 – 150	98.5	S2	25	0.38	
			S3	50	0.76	
			S4	100	1.38	
			S5	200	2.35	

All materials of human origin have been tested for the presence of HBs antigen and antibodies to HIV 1, HIV 2 and HCV, and were found to be nonreactive by licensed tests in accordance with standard EN 13641.

Incubation times	60 min at RT / 15 min at RT
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Standard Curve



KIT COMPONENTS	VOLUME	LOT	⌚ yyyy-mm-dd	KIT COMPONENTS	VOLUME	LOT	⌚ yyyy-mm-dd
Microtiterwells	96 Wells	33W072	2024 - 07 - 31	Sample Diluent	1 x 10 mL	33N092	2024 - 09 - 30
Enzyme Conjugate	1 x 11 mL	33D092	2023 - 09 - 30	Substrate Solution	1 x 14 mL	TMBSX13	2024 - 06 - 13
Standards – lyoph.	6 x 1 mL	33S080-3	2023 - 12 - 31	Stop Solution	1 x 14 mL	SD082-2	2024 - 08 - 31

A sample of this product lot has been tested and found to meet all product specifications. This lot is released.

2022-09-06

Test Date (yyyy-mm-dd)

Quality Control Manager

Freigegebenes Originaldokument siehe Ablage QMB/QA:
„QMH Kapitel 9“

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