

31-fb-9_11 Änd. Ind. 0	CoA Certificate of Analysis	DRG
Free β -HCG ELISA		

REF : EIA-4718

LOT : 31K052-4

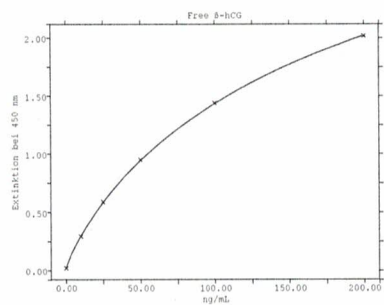
 : 2023 - 05 - 31
(yyyy - mm - dd)

Controls	Acceptance Range ng/mL	Observed concentration ng/mL	Standards (Calibrators)		OD at 450 nm (620 nm Ref)	Acceptance Range Max. OD
			Name	ng/mL		
31KL040-3	12.1 – 25.1	18.7	S0	0	0.02	≥ 1.20
31KH040-3	79.3 – 165	140	S1	10	0.27	
			S2	25	0.60	
			S3	50	1.01	
			S4	100	1.63	
			S5	200	2.28	

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	30 min at 37° C / 30 min at 37° C / 20 min at RT
------------------	--

Standard Curve



KIT COMPONENTS	VOLUME	LOT	 yyyy-mm-dd	KIT COMPONENTS	VOLUME	LOT	 yyyy-mm-dd
Microtiterwells	96 Wells	31W032	2024 - 03 - 31	Zero Buffer	1 x 14 mL	31PB052-2	2023 - 05 - 31
Enzyme Conjugate	1 x 18 mL	31D052-3	2023 - 05 - 31	Wash Solution	1 x 30 mL	TWP042	2024 - 04 - 30
Standards – lyoph.	6 x 1 mL	31S081	2023 - 08 - 31	Substrate Solution	1 x 14 mL	TMBSX10	2024 - 04 - 11
Control Low – lyoph.	1 x 1 mL	31KL040-3	2024 - 04 - 30	Stop Solution	1 x 14 mL	SD042-2	2024 - 04 - 30
Control High – lyoph.	1 x 1 mL	31KH040-3	2024 - 04 - 30	-	-	-	-

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

2022-05-24

Test Date (yyyy-mm-dd)



Quality Control Manager