

Quality Control Certificate



Phenylalanine (PKU) neonatal Screening Assay

REF RE80015 & RE80019	LOT NP230	2022-02-28 YYYY-MM-DD
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Final Release Results:

	Concentration mg/dL	Measured value OD	Range OD	OD/ODmax
CAL A	1.60	0.052	-	19%
CAL B	3.50	0.069	-	25%
CAL C	6.50	0.120	-	44%
CAL D	12.00	0.203	-	75%
CAL E	17.00	0.271	-	100%

	Concentration found mg/dL	Acceptable range		
		lower limit mg/dL	target value mg/dL	upper limit mg/dL
CONTROL 1	3.3	2.5	3.2	3.8
CONTROL 2	5.4	4.5	5.7	6.8

Kit Composition:

REF		LOT	
KENP655	CONTROL 1	114	2022-02
KENP665	CONTROL 2	114	2022-02
KENP545	LYO ENZ	993	2022-05
KENP755/9	ENZDIL	991	2022-05
KENP615	CAL A-E	113	2022-02
KENP775/9	DYE	992	2022-05
KENP765/9	SUBS	990	2022-05

Valid edition of the instructions for use: 2019-02

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

Verified by: S. Geweke

Accepted

Validation date: 2021-08-26

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



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