

Quality Control Certificate



Phenylalanine (PKU) neonatal Screening Assay

REF RE80015 & RE80019	LOT NP259	2026-10-31 YYYY-MM-DD
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Final Release Results:

	Concentration mg/dL	Measured value OD	Range OD	OD/ODmax
CAL A	1.80	0.043	-	15%
CAL B	3.30	0.066	-	23%
CAL C	6.50	0.108	-	38%
CAL D	11.50	0.181	-	64%
CAL E	17.00	0.282	-	100%

	Concentration found mg/dL	Acceptable range		
		lower limit mg/dL	target value mg/dL	upper limit mg/dL
CONTROL 1	3.3	2.4	3.1	3.7
CONTROL 2	5.2	4.2	5.2	6.2

Kit Composition:

REF		LOT	
KENP655	CONTROL 1	297	2026-10
KENP665	CONTROL 2	297	2026-10
KENP545	LYO ENZ	287	2026-12
KENP755/9	ENZDIL	295	2027-03
KENP615	CAL A-E	296	2026-10
KENP775/9	DYE	294	2027-03
KENP765/9	SUBS	290	2027-03

Valid edition of the instructions for use: 2024-11

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: 2026-04-22

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



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