



Certificate of Release


Form

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CERTIFICATE OF RELEASE

Product	Strip Vial Max	
Finished Product Lot Number	4417075	
Finished Product Part Number	02234603	B
Packaging and Labelling country configuration	OTSelect Strip 10 APC	
Expiry Date	11/2019	
Number of test strips released	159720	
Packaging Status	Fully Packaged	
Calibration Code	25	
Control Solution Information	127 - 172 mg/dL 322 - 436 mg/dL	7 - 9.5 mmol/L 17.9 - 24.2 mmol/L

Glucose Level	Within Blood Precision	Mean Bias
Level 1	1.47 SDB < 3.5 mg/dL	2.94 -4.5 to 7.5 mg/dL
	N/A SDB 3.5 to 3.75 mg/dL	N/A -4 to 7 mg/dL
	N/A SDB 3.75 to 4.5 mg/dL	N/A -2 to 5 mg/dL
Level 2	1.51 SD%B < 5.5%	2.23 -5.2 to 6.8 %
Level 3	1.78 SD%B < 5.5%	2.59 -3.2 to 6.8 %
Level 4	1.23 SD%B < 5.5%	3.66 -1.9 to 8.1 %
Level 5	1.51 SD%B < 5.5%	5.2 -0.7 to 11.3 %
Level 6	1.35 SD%B < 5.05%	4.67 -3.8 to 10.2 %
	N/A SD%B 5.05 to 5.5%	N/A -2.8 to 9.2 %
Within Lot Precision (excluding level 1)	1.51 SD%B < 5.05 %	N/A

Authorised by:  Quality Assurance 30 APR 18 Date

The designated Lot No./Packaging configuration has been manufactured according to cGMP requirements and has met all release criteria.