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CERTIFICATE OF ANALYSIS

Cat No: BXC0678A
Batch No: 161715
Expiry: 2017/09
Product: HbA1c Calibrator Set

PARAMETER	QUALITY ASSURANCE
Appearance Lyophilised	Dark Red lyophilised Plug
Appearance Liquid Stable	Dark Red solution
Appearance after 6 hours of manufacturing @ 25°C – open tube	No flocculation – maintains clarity
pH (25°C)	7.0
Bio-burden	<2 CFU/bottle

HOMOGENEITY	QUALITY ASSURANCE
HbA1c across 30 vials	1.29 % CV

Level	Analyte	Unit	Assigned Value
Calibrator Level 1	HbA1c	%	5.3
Calibrator Level 2	HbA1c	%	9.5

The product was produced according to ISO 13485 guidelines.

QC PASS/FAIL: PASS

Signed: *Catherine Caskey*

Date: 2016/07



ISO 13485:2003
 Cert. No. GB04 / 63491



ISO 9001:2000
 Cert. No. GB04 / 63490