



## CERTIFICATE OF ANALYSIS

**Cat No: BXC0675A**

**Lot no. 676-01-026 & 677-02-027**

**Expiry: 2018/11**

**Product: HbA1c Control Set**

PARAMETER	QUALITY ASSURANCE
Appearance Lyophilised	Red lyophilised plug
Appearance after reconstitution	Red solution without clumps
Appearance after 6 hours of manufacturing @ 25°C – open tube	Maintains conformity
Moisture Content	<1.4%
Bio-burden	<6 CFU/ml

HOMOGENEITY	QUALITY ASSURANCE
HbA1c Level 1	1.0 % CV
HbA1c Level 2	0.95 % CV

COMPONENTS	PROJECTED VALUE	RANGE	PASS/FAIL
HbA1c Level 1	5.89	4.54 – 6.82	PASS
HbA1c Level 2	8.91	8.57 – 12.85	PASS

**QC PASS/FAIL: PASS**

**Signed: *Cherith Morris* (QC Manager)**

**Date: 2017-06**

