

# Certificate of Analysis

Product Name					
Cat. No.					
LOT No.		MFG Date			
		EXP Date			
Test Strip EXP Date		C.S. EXP Date			
Quantity		Date of Release			
Testing categories		Specification	Result		
METER	Appearance Inspection	No scratch, stain and crack etc. Printing of case and LCD window	Pass Pass		
	Mechanical Part	Uniform Gap between top and bottom case Button operation: ON/OFF, left & right button Button assembly condition Test strip can be inserted into the strip slot.	Pass Pass Pass Pass		
		Electronic Part	Performance: check strip(30uA) Criteria 30±0.1uA / environmental temperature ± 3℃ Auto-start: For inserting a test strip, no auto-starting	Pass Pass	
		STRIP 01GC110/ 01GC111	Appearance Inspection	Test strip size: W: 5.5±0.05mm / L: 30±0.05mm Quantity per one container: 10 T/vial	Pass Pass
			Repeatability	Low: CV ≤ 5% / Mid/High: CV ≤ 4%	Pass
Coding test	Testing temperature range: 10℃-45℃   50-113℉ / Testing Range: 10-600mg/dL   0.6-33.3mmol/L		Pass		
C.S. 01GC110 01GC114	Accuracy		Reference Criteria: Level-M 76~84 mg/dL   4.2-4.7mmol/L	Pass	
	Repeatability	CV ≤ 4%	Pass		
PACKING	Packaging Inspection	Packing list	[01GC110] Meter / Test strip (10T) / Check strip / Battery / 10 Lancets / Lancing device / Carrying case / User guide / Quick guide / Self test diary / Test strip package insert [01GC111] Meter / Test strip (10T) / Check strip / Battery / C.S.(Level M) / 10 Lancets / Lancing device / Carrying case / User guide / Quick guide / Self test diary / Test strip package insert/C.S. package insert [01GC112] Meter / Check strip / Battery / 10 Lancets / Lancing device / Carrying case / User guide / Quick guide / Self test diary [01GC113] Meter / Check strip / Battery / Lancing device / Carrying case / User guide / Quick guide / Self test diary [01GC114] Meter / Battery / 10 Lancets / Lancing device / Carrying case / User guide / Quick guide / Self test diary / C.S.(Level M) / C.S. package insert [01GC115] Meter / Battery / 10 Lancets / Carrying case / User guide / Quick guide / Self test diary	Pass	
		[01GC110/01GC111] Expiration date between test strip label and package		Pass	
		[01GC110/01GC111] LOT No. between test strip label and package		Pass	
		Check Strip Test	[01GC110/01GC111/01GC112/01GC113/01GC114/01GC115] To display OK message		Pass

\*C.S.: Control Solution

According to SD Biosensor quality assurance system, the above QC tests have been completed and passed the specification. We hereby approve this product release.

\* Date issued :

SunYoung Jeong  
Manager of Regulatory Affairs & QA Dept.  
SD Biosensor, Inc.