

Certificate of Analysis

Product Name	Multicare™ Lipid Profile Test kit		
Cat No.	03MS40		
Lot No.	MS4018001	MFG Date	2018.08.02.
		EXP Date	2020.02.01.
Testing categories	Specification		Result
Apperance Inspection	<ul style="list-style-type: none"> Uniform Gap between top and bottom case No scratch, stain and crack etc. Hole condition of bottom case to identify testing paramet 		Pass
	Quantity per one kit • 03MS40: 25 Test strips/kit		Pass
Repeatability	TG: (Low) STD ≤ 10mg/dL, (Mid/High) CV ≤ 7% TC, HDL: (Low/Mid/High) CV ≤ 7%		Pass
Coding test	<ul style="list-style-type: none"> Testing temperature range: 18-32℃ 64-90°F Testing Range <ul style="list-style-type: none"> - TC: 100-450mg/dL 2.59-11.64mmol/L - TG: 45-650mg/L 0.51-7.34mmol/L - HDL: 25-95mg/dL 0.65 - 2.46mmol/L 		Pass
Packaging Inspection	Quantity of Test strip / Code chip /Test strip package insert		Pass
	Expiration date between the pouch and package of test strip		Pass
	LOT No. between the pouch and package of test strip		Pass
	Code chip number between the pouch and package of test strip		Pass

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

SD Biosensor, Inc

Geunkuk Song
 Quality Management Representative
 QA Division

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 Quality Management Representative
 QA/RA Division

Certificate of Analysis

Product Name		MultiCare™ Analyzer	
Cat No.	03MA10	REF No.	03MA10
Lot No.	MA0118003	MFG Date	2018.09.17.
Testing categories		Specification	Result
ANALYZER	Apperance Inspection	No scratch, stain and crack etc.	Pass
		Printing of case and LCD window	Pass
	Mechanical Part	Uniform Gap between top and bottom case	Pass
		Button operation: Enter, left & right, SET/PRT, Start/Eject button	Pass
		Button assembly condition	Pass
		Test strip can be inserted into the strip slot.	Pass
	Function	Power Inspection	Pass
		LCD Display Inspection	Pass
		Motor Function	Pass
		Barcode Scanner Function	Pass
		Printer Function	Pass
		Temperature Detection Function: environmental $\pm 2^{\circ}\text{C}$	Pass
PACKING	Packaging Inspection	Analyzer / Check strip / User guide / Package	Pass
	Check Strip Test	To display OK message	Pass

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Certificate of Analysis

Product Name	MultiCare™ HbA1c Test Kit		
Cat No.	03MS10	REF No.	M-A1C
Lot No.	MS1019006	MFG Date	2019.03.07.
		EXP Date	2020.09.06.
Testing categories	Specification		Result
Apperance Inspection	<ul style="list-style-type: none"> • Uniform Gap between Upper and Lower device • No scratch, stain and crack etc. • No contamination 		Pass
Repeatability	Low/Mid/High: CV ≤ 3%		Pass
Coding test	<ul style="list-style-type: none"> • Testing temperature range: 15-32 °C 59-90°F • Testing Range: 4.0% (20.2 mmol/mol) ~ 15.0% (140.5 mmol/mol) 		Pass
Packaging Inspection	Quantity per one kit • 03MS10 : 20 Test Set, 20 Buffer Solution Tube, 1 Code Chip, 1 Insert		Pass
	• No leakage in sealing part of pouch		Pass
	• No leakage in sealing part of buffer solution tube		Pass
	Expiration date between the pouch and package of test kit		Pass
	LOT No. between the pouch and package of test kit		Pass
	Code chip number between the pouch and package of test kit		Pass

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Product Name	MultiCare™ U-Albumin Test Kit		
Cat No.	03MS20	REF No.	M-UALB
Lot No.	MS2018006	MFG Date	2018.10.16.
		EXP Date	2020.04.15.
Testing categories	Specification		Result
Apperance Inspection	<ul style="list-style-type: none"> • Uniform Gap between Upper and Lower device • No scratch, stain and crack etc. • No contamination 		Pass
Repeatability	Low/Mid/High: CV ≤ 7%		Pass
Coding test	<ul style="list-style-type: none"> • Testing temperature range: 15-32 °C 59-90°F • Testing Range - 5.0-300mg/L 		Pass
Packaging Inspection	Quantity per one kit • 03MS20 : 20 Test Set, 20 Buffer Solution Tube, 1 Code Chip, 1 Insert		Pass
	• No leakage in sealing part of pouch		Pass
	• No leakage in sealing part of buffer solution tube		Pass
	Expiration date between the pouch and package of test kit		Pass
	LOT No. between the pouch and package of test kit		Pass
	Code chip number between the pouch and package of test kit		Pass

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Product Name	MultiCare™ CRP Test Kit		
Cat No.	03MS30	REF No.	M-CRP
Lot No.	MS3019001	MFG Date	2019.01.16.
		EXP Date	2020.07.15.
Testing categories	Specification		Result
Apperance Inspection	<ul style="list-style-type: none"> • Uniform Gap between Upper and Lower device • No scratch, stain and crack etc. • No contamination 		Pass
Repeatability	Low/Mid/High: CV ≤ 10%		Pass
Coding test	<ul style="list-style-type: none"> • Testing temperature range: 15-32 °C 59-90°F • Testing Range: <ul style="list-style-type: none"> - whole blood : 3.0-150mg/L - Serum/Plasma : 3.0-120mg/L 		Pass
Packaging Inspection	Quantity per one kit • 03MS30 : 20 Test Set, 20 Buffer Solution Tube, 1 Code Chip, 1 Insert		Pass
	• No leakage in sealing part of pouch		Pass
	• No leakage in sealing part of buffer solution tube		Pass
	Expiration date between the pouch and package of test kit		Pass
	LOT No. between the pouch and package of test kit		Pass
	Code chip number between the pouch and package of test kit		Pass

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