

6.2.2. ต้องทดสอบและตรวจสอบการทำงานของเครื่องมือทางการแพทย์ก่อนการตรวจรับ



E for L Aim
Public Company

System Performance Check

FUS-1000 Urinalysis Hybrid

Hospital Name : San Kamphaeng Hospital

Serial No. : 2201000FUS0348

Software version : V1.001.173.en

Date Performed : 02/04/2024

Review and Accepted by

Customer Signature.....

Customer Name.....

Position.....

Person in charge of Performed

.....


Thanapong Chatboonward

**Application specialist
Center of Excellence (COE)**

FUS-1000 Urinalysis Hybrid Analyzer Check Sheet

Model...FUS-1000 ...Serial No...2201000FUS0348... Software Version...V1.001.173.en...

Organization Name.....San Kamphaeng Hospital..... Address.....Chiang mai.....

Performed Date : 02/04/2024

Conditions Confirming List

Item	Specific Requirement	Qualified		Remark
		YES	NO	
Power supply	100-240V~, 50/60Hz	✓		
Grounding condition	Reliable grounding	✓		
Temperature	Instrument temperature 10 °C ~ 30 °C	✓		Temp. : <u>27.6</u> °C
	Strip selecting temperature 10 °C ~ 40 °C	✓		Temp. : <u>28.3</u> °C
Humidity	Strip selecting humidity ≤ 75 %	✓		Hum. : <u>40.1</u> %
Air conditioner	Available	✓		
Sunlight	Away from direct sunlight	✓		

Process Confirming List

Installation Procedure	Specific Requirement	Finished		Remark
		YES	NO	
Preparation before power on	Check packing list	✓		
	Analytical system horizontal adjusting and fixing	✓		
	Peripheral equipment connection	✓		
	Host computer software installation	✓		
	Check before power on (pipeline & circuit check)	✓		
Performance test	System settings	✓		
	Sediment focus	✓		
	Blank testing	✓		
	Sediment calibration	✓		
	Standard strip test	✓		
	Sediment QC	✓		
	Chemistry QC	✓		
	Sample test	✓		
Optional parts confirming	Optional handheld barcode reader	✓		
	Optional printer : (model: HP)	✓		

Performance Acceptance Hydrometer module

Test Item	Pass		Remark
	YES	NO	
Calibrate Refractometer : High SG : 1.040 Low SG : 1.000	✓		
Calibrate Turbidimeter : High Turbid : 400 Low Turbid : 0	✓		
Calibrate Conductivity : High Con : 80.0 Mid Con : 50.0 Low Con : 1.50		✓	N/A N/A N/A

Hydrometer module Control

Test Item	Pass		Result
	YES	NO	
Specific gravity Control : Level 1 Lot No. <u>20230413</u> Level 2 Lot No. <u>20230413</u> Level 3 Lot No. <u>20230310</u>	✓ ✓ ✓		<u>1.003</u> <u>1.030</u> <u>1.050</u>
Turbidimeter Control : Level 1 Lot No. <u>20230207</u> Level 2 Lot No. <u>20230207</u>	✓ ✓		<u>Clear</u> <u>Turbid</u>
Color Control : Red Lot No. <u>20230201</u> Blue Lot No. <u>20230201</u> Green Lot No. <u>20230201</u>	✓ ✓ ✓		<u>Red</u> <u>Blue</u> <u>Green</u>
Conductivity Control : Level 1 Lot No. _____ Level 2 Lot No. _____		✓ ✓	N/A N/A