

UF Calibration Report

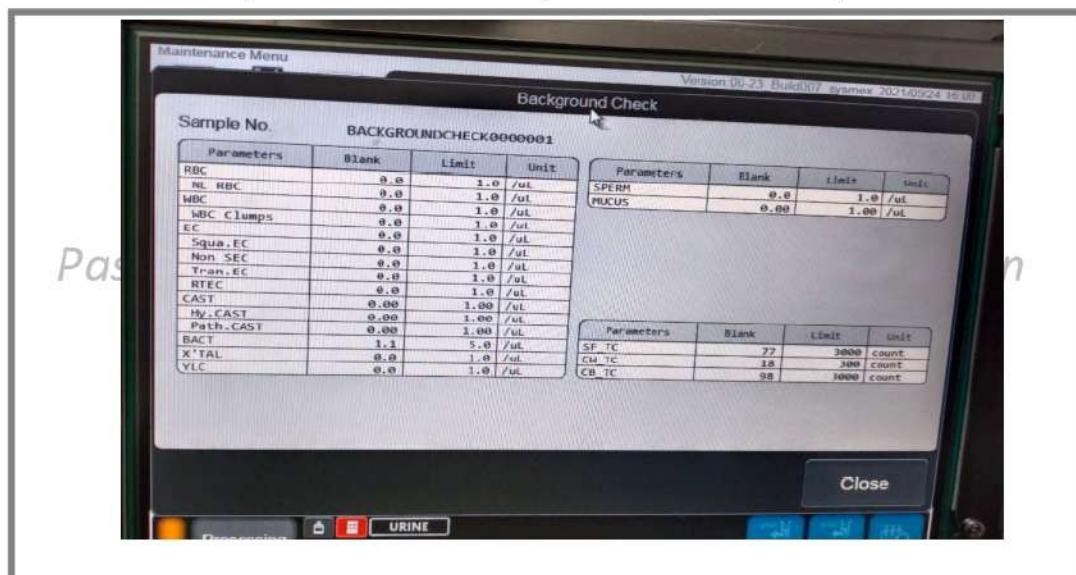
Customer:	Christian Institute of Health Sciences & Research	Date:	24.09.2021
Model:	UF-4000	Engineer:	Jakir Hussain Mondal
Serial No :	11929	A.Specialist:	
Date Install:	11.09.2021	BL Date:	

1 BACKGROUND VERIFICATION

1.1 Before performing adjustments to the Urinalysis analyzer, ensure there is no background error appeared to the analyzer.

Table 1 - result of background check

Parameters	Results	Acceptable Range	Status
RBC	0.0	≤ 1.0/uL	Pass
NL RBC	0.0	≤ 1.0/uL	Pass
WBC	0.0	≤ 1.0/uL	Pass
WBC Clumps	0.00	≤ 1.0/uL	Pass
EC	0.0	≤ 1.0/uL	Pass
Squa.EC	0	≤ 1.0/uL	Pass
Non SEC	0	≤ 1.0/uL	Pass
Tran EC	0	≤ 1.0/uL	Pass
RTEC	0	≤ 1.0/uL	Pass
CAST	0	≤ 1.0/uL	Pass
Hy. CAST	0	≤ 1.0/uL	Pass
Path.CAST	0	≤ 1.0/uL	Pass
BACT	1	≤ 5.0/uL	Pass
X'TAL	0	≤ 1.0/uL	Pass
YLC	0	≤ 1.0/uL	Pass
SPERM	0	≤ 1.0/uL	Pass
MUCUS	0	≤ 1.0/uL	Pass
SF_TC	77	≤ 3000 Count	Pass
CW_TC	18	≤ 300 Count	Pass
CB_TC	98	≤ 3000Count	Pass

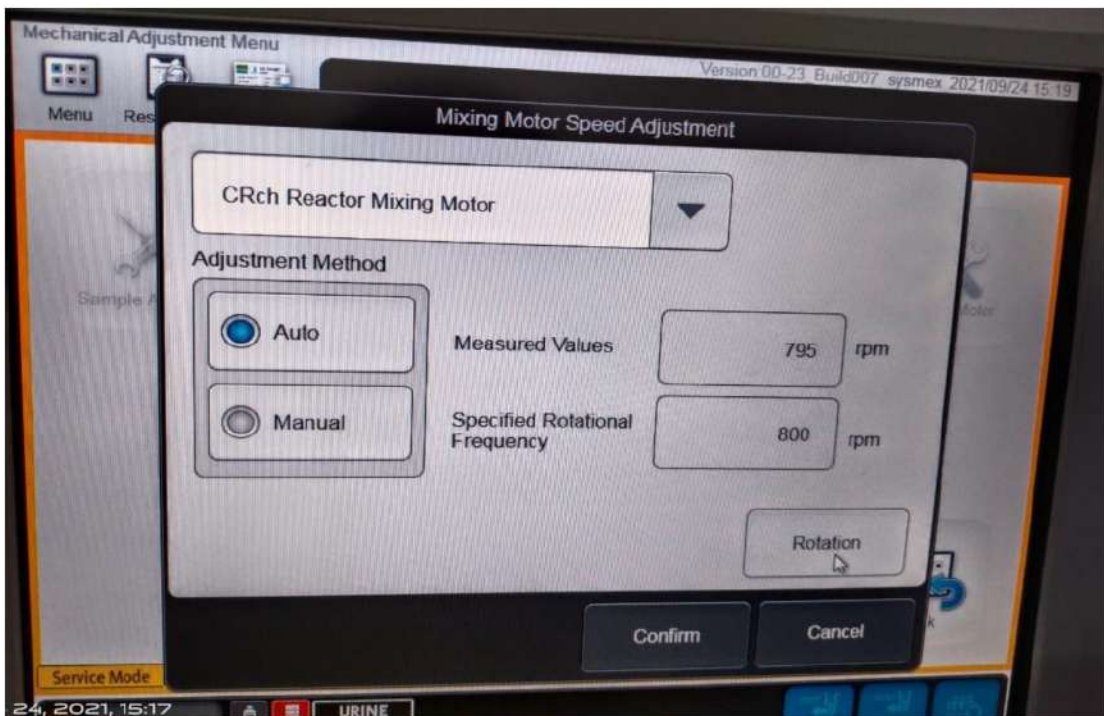
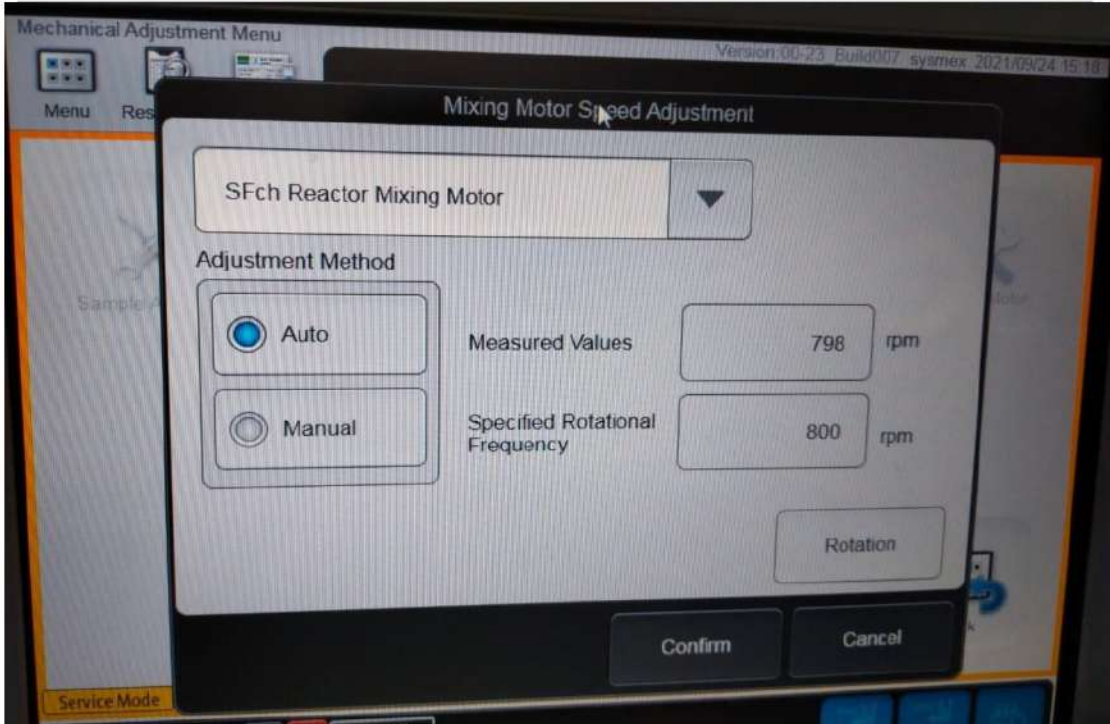


2 MIXING MOTOR VERIFICATION

2.1 Mixing Motor speed needs to be confirmed before executing the adjustment. Execute [Mixing Motor] adjustment and result is shown here:

Table 2 - Mixing motor speed adjustment result

Mixing motor type	Reading	Acceptable range	Status
SFch Reactor Mixing Motor	798	750-850	Pass
CRch Reactor Mixing Motor	795	750-850	Pass



3 OPTICAL AXIS VERIFICATION

Material Used : Latex DUKE 4207A (7um) (P/N: CX472678)
 Latex DUKE 4010A (1um) (P/N: 52123572)
 Latex Fluorescent C47410(Marketing name: A-16500) (P/N: BP783854)

3.1 Optical Axis adjustment result must be done by executing FINE [Optical Axis Adjustment]. The results are shown here:

Table 3 - Laser Latex run results

Parameter	Latex Count Result				CV Result		
	Target	Results	Limit	Status	Results	Limit	Status
7µm SF_FSC_P	1st			#VALUE!			Pass
	2nd	NA	NA	#VALUE!	NA	NA	Fail
	3rd			#VALUE!			Pass
1µm CB_FSC_P	1st						Pass
	2nd				NA	Check for single peak	Fail
	3rd						Fail
2.5µm SF_FLH_P	1st			#VALUE!			Pass
	2nd	NA		NA	#VALUE!	NA	Pass
	3rd			#VALUE!			Pass
2.5µm SF_SSH_P	1st			#VALUE!			Pass
	2nd	NA		NA	#VALUE!	NA	Fail
	3rd			#VALUE!			Pass
2.5µm SF_DSS_P	1st			#VALUE!			Fail
	2nd	NA		NA	#VALUE!	NA	Fail
	3rd			#VALUE!		Check for single peak	Fail

4 SENSITIVITY ADJUSTMENT

4.1 Material Used : UF-Calibrator (P/N: CN383000)
 Lot No. : UA0089
 Expiry date : 16.10.2021

4.2 UF Calibrator Assay Sheet UF Calibrator Assay Sheet

Table for UF Calibrator Assay value

Parameter		Target	Lower Range	Upper Range
Calibration Particle	/uL	820.5	779.5	861.5
Conductivity	ms/cm	34.7	32.6	36.8
Parameter		Lower Range	Upper Range	Target
SF_FSC_P		152.0	155.0	153.5
SF_FSC_W		43.9	44.9	44.4
CW_FSC_P		103.5	106.5	105.0
CB_FSC_P		164.0	167.0	165.5
SF_FLL_P		113.2	123.2	118.2
SF_FLH_P		115.2	121.2	118.2
SF_DSS_P		173.2	183.2	178.3
CW_SSH_P		110.3	116.3	113.4
CW_FLH_P		60.0	64.0	62
CW_DSS_P		20.8	22.8	21.8
CB_SSH_P		206.3	212.3	209.3
CB_FLL_P		103.2	123.2	113.2
SF_SSH_P		199.0	205.0	202.0
SF_SSL_P		199.0	205.0	202.0
CW_SSL_P		21.0	23.0	22.0
CW_FLL_P		60.0	64.0	62.0
CB_FLH_P		103.2	123.2	113.2

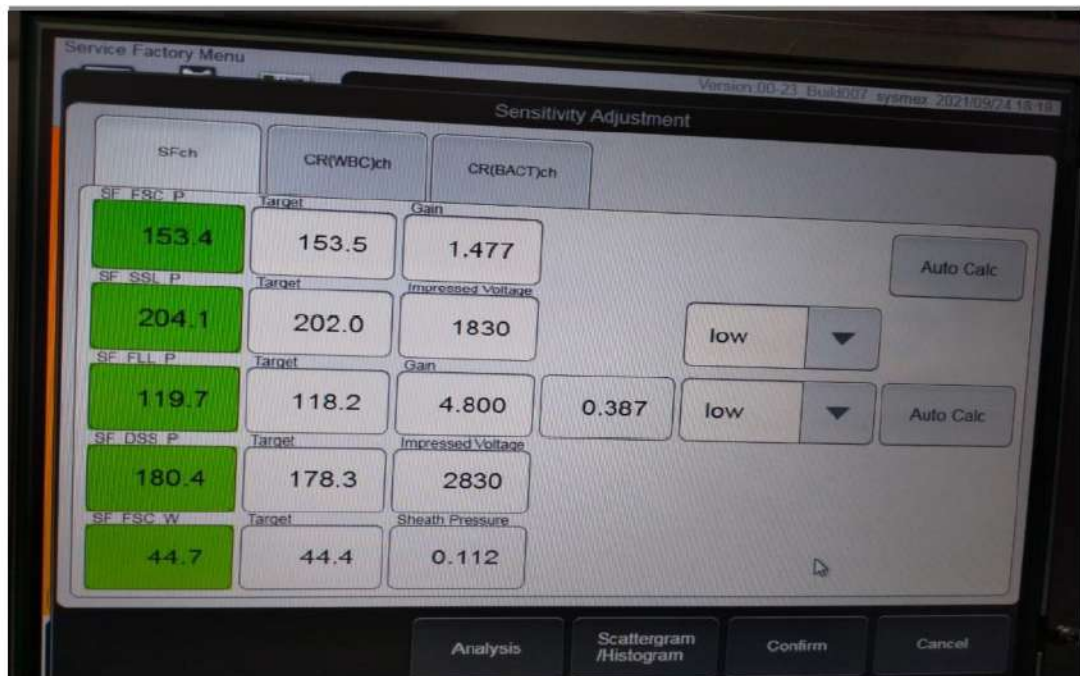
4.3 Sensitivity adjustment is done by executing [Sensitivity adjustment]. The results are shown here:

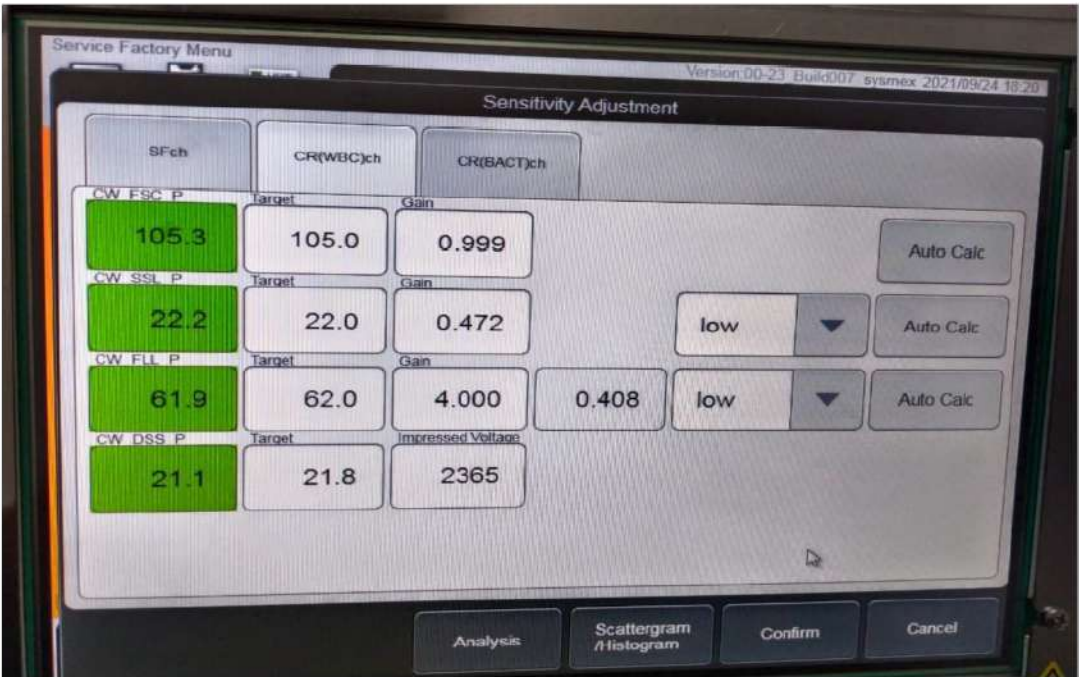
4.4 Go to sensitivity adjustment

Table 6 - result of sensitivity

Parameter SED (Ch)	LL	Target	UL	Results	Acceptable Range(±)	Status
SF_FSC_P		153.5		153.4	1.5	Pass
SF_FSC_W		44.4		44.7	0.5	Pass
CW_FSC_P		105.0		105.3	1.5	Pass
CB_FSC_P		165.5		164.6	1.5	Pass
SF_FLL_P		118.2		119.7	5.0	Pass
SF_FLH_P		118.2		119.5	3.0	Pass
SF_DSS_P		178.3		180.4	5.0	Pass
CW_SSH_P		113.4		114.2	3.0	Pass
CW_FLH_P		62.0		61.6	2.0	Pass
CW_DSS_P		21.8		21.1	1.0	Pass
CB_SSH_P		209.3		207.5	3.0	Pass
CB_FLL_P		113.2		116.4	10.0	Pass
SF_SSH_P		202.0		202.8	5.0	Pass
SF_SSL_P		202.0		204.1	3.0	Pass
CW_SSL_P		22.0		22.2	1.0	Pass
CW_FLL_P		62.0		61.9	2.0	Pass
CB_FLH_P		113.2		116.1	10.0	Pass

* Due to average of the UF Calibrator target value was been round-up to one decimal point, adjustment final result will be base on the status result.







5 CONDUCTIVITY SENSOR ADJUSTMENT

5.1 Material Used : UF-Calibrator (P/N: CN383000)
 RO Water - flash for the DI water distiller
 Sample Cup
 Lot No: UA0089
 Expiry date: 16.10.2021

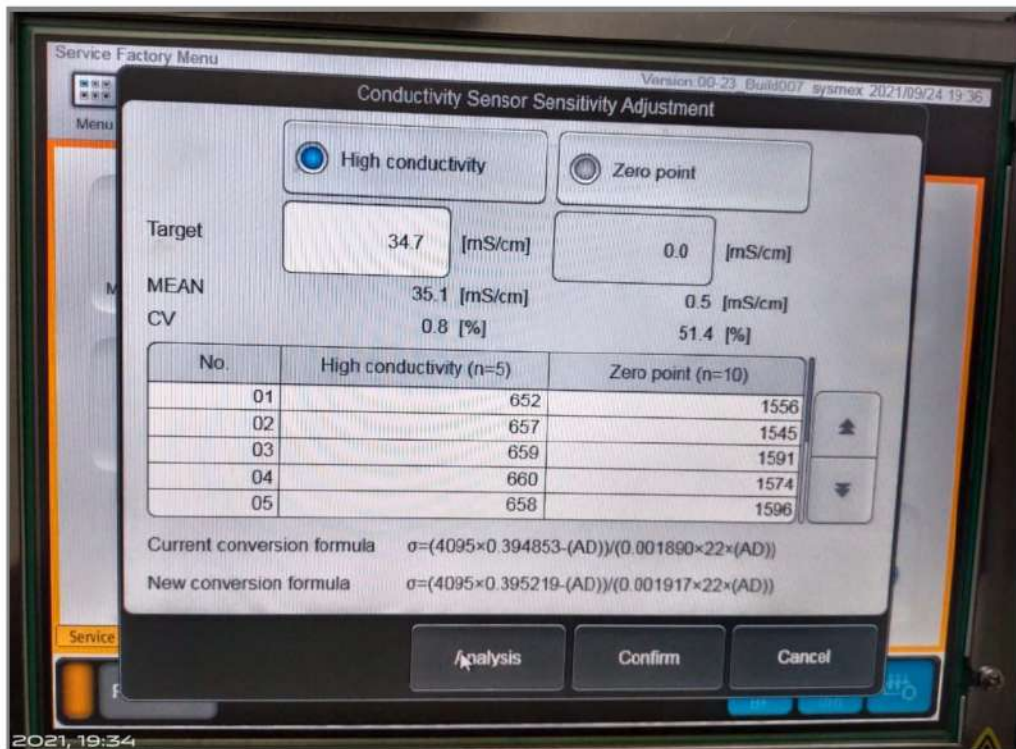
Table 7 - Result for conductivity "0" point adjustment

Target	Result Ms	Acceptable Range	Status
0.0	0.5	± 0.5 Ms	Pass

B. Result of the Conductivity adjustment

Table 8 - Result for conductivity "Target" adjustment

Mean			Results		Status	
Target	Limit	CV %	Mean	CV %	Mean	CV %
34.7	± 1.0 mS	< 5 %	35.1	0.8	Pass	Pass

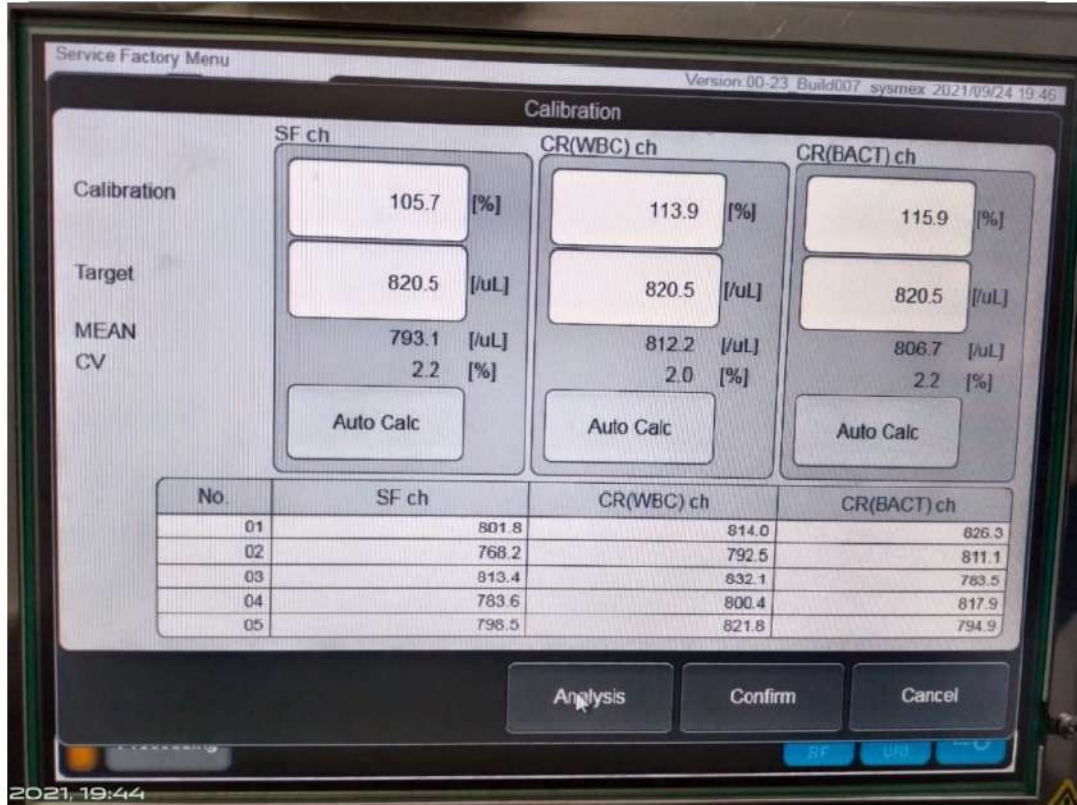


6 SFch and CR Calibration

6.1 Particle count calibration results are shown here:

Table 9 - Result for SED/BAC Total particle adjustment

	Range			Mean		CV% <5%	
	Target	Lower	Upper	Result	Status	Result	Status
SFch	820.5	779.5	861.5	793.1	Pass	2.2	Pass
CR(WBC)	820.5	779.5	861.5	812.2	Pass	2.0	Pass
CR(Bact)	820.5	779.5	861.5	806.7	Pass	2.2	Pass



7 Performance verification with using SYSMEX UF Control QC

7.1 Material Used : UF Control
 Lot No:
 Expiry date:

Table 10 - Result for Control QC - L

UF CONTROL		Result	Target	UF Control -L Assay Value			Status
Parameter				Limit	Min	Max	
RBC	<i>uL</i>						
WBC	<i>uL</i>						
EC	<i>uL</i>						
CAST	<i>uL</i>						
BACT	<i>uL</i>						
COND	<i>mS/cm</i>						

Table 11 - Result for Control QC - H

UF CONTROL		UF Control -H Assay Value				Status
Parameter	Result	Target	Limit	Min	Max	
RBC	uL					
WBC	uL					
EC	uL					
CAST	uL					
BACT	uL					
COND	mS/cm					
SF_FSC_P	CH					
SF_FSC_W	CH					
SF_FLH_P	CH					
SF_SSL_P	CH					
SF_DSS_P	CH					
CW_FSC_P	CH					
CW_FLH_P	CH					
CW_SSH_P	CH					
CW_SSL_P	CH					
CW_DSS_P	CH					
CB_FSC_P	CH					
CB_FLL_P	CH					
CB_SSH_P	CH					

Patient Sample comparison

Sample No-553064

In UF instrument:

Parameters	Result	Unit	Parameters	Result	Unit
RBC	5.5	/uL	CAST	0.27	/uL
NL RBC	5.0	/uL	Hy.CAST	0.27	/uL
WBC	5.1	/uL	Path.CAST	0.00	/uL
WBC Clumps	0-3	/uL	BACT	301.3	/uL
EC	68.4	/uL	X'TAL	0.0	/uL
Squa.EC	65.8	/uL	YLC	2.1	/uL
Non SEC	2.6	/uL	SPERM	0.0	/uL
Tran.EC	0.1	/uL	MUCUS	0.0-1.0	/uL
RTEC	2.4	/uL			

Manual:

Sample No-553064

NAME	xxxxx	HIN	553064
AGE	xxxxx	SEX	xx
WARD	xxxx	DATE	25.09.2021

DEPARTMENTS	TESTS	RESULTS	NORMAL
URINALYSIS: URISCAN	Microscopy Examination	pus cells : 0-1/hpf RBC : Nill Epithelial cells: +++ Bacteria: Nill Cast: Nill	

Sample No-553063

In UF instrument:

Menu Results list Details Previous Next Last 10 FIND Validate Out Delete Service

553063
Validated URI 2021/09/25 12:05:49 0005-02

Analysis Research1 Research2

Parameters	Result	Unit	Parameters	Result	Unit
RBC	1.4	/uL	CAST	0.00	/uL
NL RBC	1.2	/uL	Hy.CAST	0.00	/uL
WBC	0.7	/uL	Path.CAST	0.00	/uL
WBC Clumps	0-3	/uL	BACT	10.4	/uL
EC	1.5	/uL	X'TAL	0.0	/uL
Squa.EC	1.1	/uL	YLC	0.2	/uL
Non SEC	0.4	/uL	SPERM	0.0	/uL
Tran.EC	0.0	/uL	MUCUS	0.0-1.0	/uL
RTEC	0.4	/uL			

Review Comment

Research Information

Manual Method:

Sample No-553063

Christian Institute of Health Sciences and Research
4th Mile Dimapur, Nagaland Phone 03862-242555, 242531. E-mail: cihsrlab@gmail.com
(A NABH Pre-Accreditation Entry Level Hospital)

LABORATORY REPORT

NAME	xxxxx	HIN	553063
AGE	xxxxx	SEX	xx
WARD	xxxx	DATE	25.09.2021

DEPARTMENTS	TESTS	RESULTS	NORMAL
URINALYSIS: URISCAN	Microscopy Examination	pus cells : Nil RBC : Nil Epithelial cells: Nil Bacteria: Nil Cast: Nil	



UF-CALIBRATOR™ ASSAY SHEET

Lot No. UA0089
 Exp. Date 2021-10-16

		TARGET
Calibration Particle (WBC)	(/ μ L)	820.5
Cond.	(mS/cm)	34.7

		TARGET
SF_FSC_P	(ch)	153.5
SF_FSC_W	(ch)	44.4
SF_FLH_P	(ch)	118.2
SF_FLL_P	(ch)	118.2
SF_SSH_P	(ch)	202.0
SF_SSL_P	(ch)	202.0
SF_DSS_P	(ch)	178.3
CW_FSC_P	(ch)	105.0
CW_FLH_P	(ch)	62.0
CW_FLL_P	(ch)	62.0
CW_SSH_P	(ch)	113.4
CW_SSL_P	(ch)	22.0
CW_DSS_P	(ch)	21.8
CB_FSC_P	(ch)	165.3
CB_FLH_P	(ch)	113.2
CB_FLL_P	(ch)	113.2
CB_SSH_P	(ch)	209.3

1.5
 0.5
~~3~~
 3
 5
 5
 5
 1.5
 2
 10
 3
 1
 1
 1.5
 10
 10
 8

TARGET values may vary depending on the different production lots.
 Les valeurs CIBLES(TARGET) peuvent varier en fonction des différents lots de production.
 Los valores OBJETIVO(TARGET) pueden variar según el lote de producción.
 Os valores ALVO(TARGET) podem variar consoante os diferentes lotes de fabrico.
 대상 (TARGET) 값은 생산 로트에 따라 다를 수 있습니다.
 目標 (TARGET) 值的差異性取決於不同的生產批量。
 靶值 (TARGET) 随生产批次不同会有变化。
 TARGETは、製品ロットにより値が異なることがあります。

9 CERTIFICATION

9.1 We certify that the UF Automated Urine Particle Analyzer S/N : **11929** has been successfully calibrated in accordance with the manufacturer's recommendations.

Report and Calibration Performed By :

Report Reviewed and Accepted By :



Signature (Engineer 1)

Signature (Customer)

Name: Jakir Hussain Mondal

Name: _____

Date: 25.09.2021

Date: _____
