Lab

11612

Lab Monthly Summary

Lab Name Month Constituent Group

MICROBIOLOGICAL LABORATORY

No June Year 2020

Chemistry II



Date of Result Entered: 19/06/2020 Date of Report Published: 08/08/2020

C1 N	A 1.4	Method /	L Anglyzer L No of L		DU	Participants		Your	SDI	U
Sl.No	Analyte	Principle Name	Name	Participants	DV	CV	SD	Value	SDI	U
1	GLUCOSE I	Dry Chemistry	Johnson & Johnson Dry Chemistry series	30	75.69	7.53	5.70	75.1 mg/dl	-0.10	2.08
2	UREA I	Dry Chemistry	Johnson & Johnson Dry Chemistry series	32	48.53	5.97	2.90	48.9 mg/dl	0.13	1.02
3	CREATININE I	Dry Chemistry	Johnson & Johnson Dry Chemistry series	31	3.66	7.78	0.28	4 mg/dl	1.19	0.10
4	T.BILIRUBIN I	Dry Chemistry	Johnson & Johnson Dry Chemistry series	38	5.35	8.37	0.45	5.39 mg/dl	0.09	0.15
5	T-PROTEIN I	Dry Chemistry	Johnson & Johnson Dry Chemistry series	34	4.69	6.97	0.33	4.44 g/dl	-0.76	0.11
6	ALBUMIN I	Dry Chemistry	Johnson & Johnson Dry Chemistry series	27	2.39	7.19	0.17	2.4 g/dl	0.06	0.07
7	URIC ACID I	Dry Chemistry	Johnson & Johnson Dry Chemistry series	37	3.67	7.00	0.26	3.8 mg/dl	0.51	0.08
8	CHOLESTEROL I	Dry Chemistry	Johnson & Johnson Dry Chemistry series	29	89.81	8.01	7.20	92 mg/dl	0.30	2.67
9	TRIGLYCERIDE I	Dry Chemistry	Johnson & Johnson Dry Chemistry series	30	92.70	7.82	7.25	93 mg/dl	0.04	2.65

SDI Range	Interpretation
Within -1.0 to +1.0	Excellent.
Between ± 1.0 to ± 2.0	Good.
Between ± 2.0 to ± 3.0	Accept with caution. Warning Signal.

Homogeneity and Stability of the sample is passed.

Data in CMC EQAS reports is confidential

Contact details:

Email:clinqc@cmcvellore.ac.in Contact Number: 0416-2283102



Dr. Pamela Christudoss CMC EQAS Co-Ordinator Christian Medical College, Vellore

Lab Name

Month

Constituent

Group

MICROBIOLOGICAL LABORATORY July

Lab No 11612 Year 2020

Chemistry II



Date of Result Entered : 11/07/2020 Date of Report Published : 14/08/2020

Sl.No	Analyte	Method / Principle	Analyzer	No of	DV	DV Participant		Your	SDI	U
51.140	7 that y te	Name	Name	Participants	DV	CV	SD	Value	SDI	
1	GLUCOSE I	Dry Chemistry	Johnson & Johnson Dry Chemistry series	25	375.21	4.62	17.32	392.1 mg/dl	0.98	6.93
2	UREA I	Dry Chemistry	Johnson & Johnson Dry Chemistry series	27	96.61	6.33	6.12	103.7 mg/dl	1.16	2.35
3	CREATININE I	Dry Chemistry	Johnson & Johnson Dry Chemistry series	28	0.69	12.10	0.08	0.66 mg/dl	-0.36	0.03
4	T.BILIRUBIN I	Dry Chemistry	Johnson & Johnson Dry Chemistry series	31	3.87	10.94	0.42	4.1 mg/dl	0.54	0.15
5	T-PROTEIN I	Dry Chemistry	Johnson & Johnson Dry Chemistry series	28	4.98	4.98	0.25	4.86 g/dl	-0.48	0.09
6	ALBUMIN I	Dry Chemistry	Johnson & Johnson Dry Chemistry series	25	2.89	12.34	0.36	2.8 g/dl	-0.25	0.14
7	URIC ACID I	Dry Chemistry	Johnson & Johnson Dry Chemistry series	34	7.09	6.97	0.49	7.6 mg/dl	1.03	0.17
8	CHOLESTEROL I	Dry Chemistry	Johnson & Johnson Dry Chemistry series	24	98.12	6.73	6.61	103 mg/dl	0.74	2.70
9	TRIGLYCERIDE I	Dry Chemistry	Johnson & Johnson Dry Chemistry series	21	257.97	8.95	23.10	280 mg/dl	0.95	10.08

SDI Range	Interpretation
Within -1.0 to +1.0	Excellent.
Between ± 1.0 to ± 2.0	Good.
Between ± 2.0 to ± 3.0	Accept with caution. Warning Signal.

Homogeneity and Stability of the sample is passed.

Data in CMC EQAS reports is confidential

Contact details:

Email:clinqc@cmcvellore.ac.in Contact Number: 0416-2283102



Dr. Pamela Christudoss CMC EQAS Co-Ordinator Christian Medical College, Vellore

Lab Name

Month

Constituent

Group

MICROBIOLOGICAL LABORATORY

Lab No 11612 Year 2020

Chemistry II

August



Date of Result Entered: 15/08/2020 Date of Report Published: 10/09/2020

C1 N	A 1 /	Method /	Analyzer	2		Participants		Your	CDI	U
Sl.No	Analyte	Principle Name	Name	Participants	DV	CV	SD	Value	SDI	U
1	GLUCOSE I	Dry Chemistry	Johnson & Johnson Dry Chemistry series	27	108.76	6.44	7.01	105 mg/dl	-0.54	2.70
2	UREA I	Dry Chemistry	Johnson & Johnson Dry Chemistry series	28	73.90	4.93	3.64	72.3 mg/dl	-0.44	1.38
3	CREATININE I	Dry Chemistry	Johnson & Johnson Dry Chemistry series	29	9.96	5.91	0.59	10.41 mg/dl	0.76	0.22
4	T.BILIRUBIN I	Dry Chemistry	Johnson & Johnson Dry Chemistry series	31	5.81	6.28	0.36	5.69 mg/dl	-0.33	0.13
5	T-PROTEIN I	Dry Chemistry	Johnson & Johnson Dry Chemistry series	30	5.06	7.29	0.37	4.9 g/dl	-0.43	0.13
6	ALBUMIN I	Dry Chemistry	Johnson & Johnson Dry Chemistry series	23	2.79	6.16	0.17	2.6 g/dl	-1.10	0.07
7	URIC ACID I	Dry Chemistry	Johnson & Johnson Dry Chemistry series	37	5.43	9.04	0.49	5.8 mg/dl	0.75	0.16
8	CHOLESTEROL I	Dry Chemistry	Johnson & Johnson Dry Chemistry series	25	102.83	4.93	5.07	101 mg/dl	-0.36	2.03
9	TRIGLYCERIDE I	Dry Chemistry	Johnson & Johnson Dry Chemistry series	24	334.99	5.77	19.34	224 mg/dl	-5.74	7.89

SDI Range	Interpretation
Within -1.0 to +1.0	Excellent.
Between ± 1.0 to ± 2.0	Good.
Between ± 2.0 to ± 3.0	Accept with caution. Warning Signal.

Homogeneity and Stability of the sample is passed.

Data in CMC EQAS reports is confidential

Contact details:

Email:clinqc@cmcvellore.ac.in Contact Number: 0416-2283102



Dr. Pamela Christudoss CMC EQAS Co-Ordinator Christian Medical College, Vellore

Lab

Lab Monthly Summary

Lab Name Month Constituent Group

MICROBIOLOGICAL LABORATORY

11612 No September Year 2020

Chemistry II



Date of Result Entered: 15/09/2020 Date of Report Published: 07/10/2020

		Method /				Dortio	inanta			
Sl.No	Analyte	Principle Name	Analyzer Name	No of Participants	DV	CV	ipants SD	Your Value	SDI	U
1	GLUCOSE I	Dry Chemistry	Johnson & Johnson Dry Chemistry series	31	225.73	5.88	13.26	233.9 mg/dl	0.62	4.76
2	UREA I	Dry Chemistry	Johnson & Johnson Dry Chemistry series	32	139.82	6.68	9.35	154.7 mg/dl	1.59	3.30
3	CREATININE I	Dry Chemistry	Johnson & Johnson Dry Chemistry series	32	1.34	5.52	0.07	1.38 mg/dl	0.54	0.03
4	T.BILIRUBIN I	Dry Chemistry	Johnson & Johnson Dry Chemistry series	36	5.06	10.42	0.53	5.09 mg/dl	0.06	0.18
5	T-PROTEIN I	Dry Chemistry	Johnson & Johnson Dry Chemistry series	30	5.15	5.72	0.30	5.16 g/dl	0.03	0.11
6	ALBUMIN I	Dry Chemistry	Johnson & Johnson Dry Chemistry series	27	2.89	5.54	0.16	2.8 g/dl	-0.56	0.06
7	URIC ACID I	Dry Chemistry	Johnson & Johnson Dry Chemistry series	40	6.96	8.44	0.59	7 mg/dl	0.07	0.19
8	CHOLESTEROL I	Dry Chemistry	Johnson & Johnson Dry Chemistry series	29	102.26	3.15	3.22	108 mg/dl	1.78	1.20
9	TRIGLYCERIDE I	Dry Chemistry	Johnson & Johnson Dry Chemistry series	31	104.47	10.21	10.67	102 mg/dl	-0.23	3.83

SDI Range	Interpretation
Within -1.0 to +1.0	Excellent.
Between ± 1.0 to ± 2.0	Good.
Between ± 2.0 to ± 3.0	Accept with caution. Warning Signal.

Homogeneity and Stability of the sample is passed.

Data in CMC EQAS reports is confidential

Contact details:

Email:clinqc@cmcvellore.ac.in Contact Number: 0416-2283102



Dr. Pamela Christudoss CMC EQAS Co-Ordinator Christian Medical College, Vellore

Lab Name

Month

Constituent

Group

MICROBIOLOGICAL LABORATORY October

Lab No 11612 Year 2020

Chemistry II



Date of Result Entered : 10/10/2020 Date of Report Published : 09/11/2020

C1 N	Analysta	Method /	I Analyzer I No of I	DV	Participants		Your	SDI	U	
Sl.No	Analyte	Principle Name	Name	Participants	DV	CV	SD	Value	SDI	U
1	GLUCOSE I	Dry Chemistry	Johnson & Johnson Dry Chemistry series	30	162.46	5.55	9.01	165.1 mg/dl	0.29	3.29
2	UREA I	Dry Chemistry	Johnson & Johnson Dry Chemistry series	30	116.82	5.03	5.87	125.6 mg/dl	1.49	2.14
3	CREATININE I	Dry Chemistry	Johnson & Johnson Dry Chemistry series	31	4.93	5.11	0.25	5.41 mg/dl	1.90	0.09
4	T.BILIRUBIN I	Dry Chemistry	Johnson & Johnson Dry Chemistry series	39	3.47	10.23	0.36	3.76 mg/dl	0.82	0.11
5	T-PROTEIN I	Dry Chemistry	Johnson & Johnson Dry Chemistry series	32	4.69	7.51	0.35	4.71 g/dl	0.06	0.12
6	ALBUMIN I	Dry Chemistry	Johnson & Johnson Dry Chemistry series	29	2.56	9.80	0.25	2.5 g/dl	-0.24	0.09
7	URIC ACID I	Dry Chemistry	Johnson & Johnson Dry Chemistry series	35	3.39	9.00	0.30	3.4 mg/dl	0.03	0.10
8	CHOLESTEROL I	Dry Chemistry	Johnson & Johnson Dry Chemistry series	29	88.70	5.18	4.60	96 mg/dl	1.59	1.71
9	TRIGLYCERIDE I	Dry Chemistry	Johnson & Johnson Dry Chemistry series	30	209.09	12.20	25.50	183 mg/dl	-1.02	9.31

SDI Range	Interpretation
Within -1.0 to +1.0	Excellent.
Between ± 1.0 to ± 2.0	Good.
Between ± 2.0 to ± 3.0	Accept with caution. Warning Signal.

Homogeneity and Stability of the sample is passed.

Data in CMC EQAS reports is confidential

Contact details:

Email:clinqc@cmcvellore.ac.in Contact Number: 0416-2283102



Dr. Pamela Christudoss CMC EQAS Co-Ordinator Christian Medical College, Vellore

Lab

Lab Monthly Summary

Lab Name Month Constituent Group

MICROBIOLOGICAL LABORATORY November

11612 No Year 2020

Chemistry II

Date of Result Entered: 05/11/2020 Date of Report Published: 05/12/2020

C1 NI-	Analyte	Method / Principle	3	No of	DV	Partic	ipants	Your	CDI	U
Sl.No	Anaiyte	Name	Name	Participants	DV	CV	SD	Value	SDI	U
1	GLUCOSE I	Dry Chemistry	Johnson & Johnson Dry Chemistry series	31	369.54	7.42	27.43	431.9 mg/dl	2.27	9.85
2	UREA I	Dry Chemistry	Johnson & Johnson Dry Chemistry series	32	55.76	7.22	4.02	63.2 mg/dl	1.85	1.42
3	CREATININE I	Dry Chemistry	Johnson & Johnson Dry Chemistry series	31	8.64	4.00	0.35	10.14 mg/dl	4.34	0.12
4	T.BILIRUBIN I	Dry Chemistry	Johnson & Johnson Dry Chemistry series	39	1.64	18.08	0.30	2.17 mg/dl	1.79	0.09
5	T-PROTEIN I	Dry Chemistry	Johnson & Johnson Dry Chemistry series	31	4.87	8.56	0.42	5.62 g/dl	1.80	0.15
6	ALBUMIN I	Dry Chemistry	Johnson & Johnson Dry Chemistry series	29	2.63	7.04	0.18	3 g/dl	2.00	0.07
7	CHOLESTEROL I	Dry Chemistry	Johnson & Johnson Dry Chemistry series	32	103.96	6.22	6.47	133 mg/dl	4.49	2.29
8	TRIGLYCERIDE I	Dry Chemistry	Johnson & Johnson Dry Chemistry series	34	176.72	12.73	22.49	89 mg/dl	-3.9	7.71

SDI Range	Interpretation
Within -1.0 to +1.0	Excellent.
Between ± 1.0 to ± 2.0	Good.
Between ± 2.0 to ± 3.0	Accept with caution. Warning Signal.
Beyond ±3.0	Unacceptable performance. Action Signal.

Homogeneity and Stability of the sample is passed.

Data in CMC EQAS reports is confidential

Contact details:

Email:clinqc@cmcvellore.ac.in

Contact Number: 0416-2283102



Dr. Pamela Christudoss CMC EQAS Co-Ordinator Christian Medical College, Vellore

Lab Name Month Constituent Group

MICROBIOLOGICAL LABORATORY December

Chemistry II

11612 No Year 2020

Lab



Date of Result Entered: 11/12/2020 Date of Report Published: 31/12/2020

Sl.No	No Analyte Method / Analyzer Principle Name		No of	DV	V Participants		Your	SDI	U	
51.1 (0	1 mary to	Name	Name	Participants	Δ,	CV SD		Value	551	
1	GLUCOSE I	Dry Chemistry	Johnson & Johnson Dry Chemistry series	31	139.86	6.45	9.02	149.1 mg/dl	1.02	3.24
2	UREA I	Dry Chemistry	Johnson & Johnson Dry Chemistry series	32	85.71	5.70	4.89	95 mg/dl	1.90	1.73
3	CREATININE I	Dry Chemistry	Johnson & Johnson Dry Chemistry series	32	4.10	4.26	0.18	4.67 mg/dl	3.26	0.06
4	T.BILIRUBIN I	Dry Chemistry	Johnson & Johnson Dry Chemistry series	40	1.99	17.72	0.35	2.42 mg/dl	1.22	0.11
5	T-PROTEIN I	Dry Chemistry	Johnson & Johnson Dry Chemistry series	31	4.46	7.45	0.33	4.94 g/dl	1.45	0.12
6	ALBUMIN I	Dry Chemistry	Johnson & Johnson Dry Chemistry series	30	2.54	5.86	0.15	2.7 g/dl	1.07	0.05
7	URIC ACID I	Dry Chemistry	Johnson & Johnson Dry Chemistry series	34	3.28	8.59	0.28	3.5 mg/dl	0.78	0.10
8	CHOLESTEROL I	Dry Chemistry	Johnson & Johnson Dry Chemistry series	30	92.56	5.58	5.17	104 mg/dl	2.21	1.89
9	TRIGLYCERIDE I	Dry Chemistry	Johnson & Johnson Dry Chemistry series	35	117.84	11.44	13.48	127 mg/dl	0.68	4.56

SDI Range	Interpretation					
Within -1.0 to +1.0	Excellent.					
Between ± 1.0 to ± 2.0	Good.					
Between ± 2.0 to ± 3.0	Accept with caution. Warning Signal.					

Homogeneity and Stability of the sample is passed.

Data in CMC EQAS reports is confidential

Contact details:

Email:clinqc@cmcvellore.ac.in Contact Number: 0416-2283102



Dr. Pamela Christudoss CMC EQAS Co-Ordinator Christian Medical College, Vellore

MICROBIOLOGICAL LABORATORY DEPARTMENT OF QUALITY MANAGEMENT							
F	/WRL/ I	VL/QIVII	o/KCA/NC	1 2/20			
<u>د</u>	1310	Che	11121 · · · · · · · · · · · · · · · · ·				
urred	(Ye	<u>a</u> hn	me				
cerc	h des	ml.o					
)\/	000	1154	· · ·				
Root Ca	uses of	Non-c					
		Cause/ Error Identified					
	Yes	No	Responsibility	Comments			
		~					
1). Error in recording test results from the instruments			Participant				
tion		/	Participant				
			Participant	2			
		/	Participant				
		\	Participant				
			EQAP				
	_						
. (2,		Issued MD	نا			
	surred Cex s Noot Ca	F/MBL/TY S 319 urred (Ye Cer S des Noven Root Causes of Yes ents ion	F/MBL/TVL/QMI S BIOChes urred (Yeshin Cerchials November Root Causes of Non-comber Yes No ents ion J J J J J J J J J J J J J	Yes No Responsibility Participant Participant			

VERSION 1.0	01-01-2020	F/M	BL/TV	L/QMD,	/RCA/NC	P 1/10
	Determination of Ro	ot Cause	es of	Non-co	nformities	
Channahana	Janat datas Producadad	-			Cause/ Error Identif	ied
Characters	s/ Activities Evaluated	aluated Yes ident an	Yes	No	Responsibility	Comments
II. PRI	S-SURVEY ISSUES					
). The EQA provider of happropriate sample	listributed by accident an			~	EQAP	
). Error in sample lab	elling			✓	EQAP	
;). Error in packing th	e sample			/	EQAP	
4). Error in distributio	on of sample			✓	EQAP	
5). Problem with sam	ple stability			✓	EQAP	
6). Problem with san	nple homogenicity			1/	EQAP	
7). Error in instructio	n letter of EQA provider			1	EQAP	
						,
						· ·
				-		
		Ĺ				
Description of t	he Cause					
5						,
Corrective action	n proposed					
						ı
	Reviewed 8	· ((2 -		Issued MD	Ai -
Preoared by QM	Approved T	D	San Carried State of the State			, ,

MICROBIOLOGI	CAL LABORATORY	DEPARTMENT OF QUALITY MANAGEMENT						
VERSION 1.0	01-01-2020	F,	/MBL/T	VL/QMI	D/RCA/NC	P 1/10		
	Determination of I	Root Ca	uses of	Non-c	onformities			
Characters/	Activities Evaluated				Cause/ Error Ide	entified		
			Yes	No	Responsibility	Comments		
III.SAMPLE	RECEIPT/ HANDLING			V				
1). Problem with the sa	mple receipt			\checkmark	Participants			
2). Inappropriate storag	ge of the sample till use			V	Participants			
3). Problem with recon	stitution of the sample			/	Participants			
 The instructions we participants 	re not followed properly by	y the			Participants			
						,		
,				_				
Description of the	Cause							
Corrective action p								
Preoared by QM My	Approved TD	Q	y#		Issued MD	Control of the Contro		

MICROBIOLOGI	CAL LABORATORY	DEPARTMENT OF QUALITY MANAGEMENT							
VERSION 1.0	01-01-2020	F/	F/MBL/TVL/QMD/RCA/NC P 1/10						
	Determination of	Root Ca	uses of	Non-co	onformities				
-	(a citizate Evaluated				Cause/ Error Iden	tified			
Characters	/ Activities Evaluated		Yes	No	Responsibility	Comments			
IV. TES	T PERFORMANCE								
1). Change in the instru	uction of manufacturer			✓	Participants/ EQAP/ Manufacturer				
2). Was there a problem	m with the equipments			\checkmark	Participants				
3). Was there a proble	m with reagents			\checkmark	Participants/ Manufacturer				
4). Was there a proble	em with the test performan	nce		1	Participants				
5). Was there a proble	em with the IQC samples			V	Participants				
Description of the	e Cause								
Corrective action	proposed								
Preoared by QM M	Reviewed Approved		Q,		Issued MI				

MICROBIOLOGICAL LABORATORY		DEPARTMENT OF QUALITY MANAGEMENT					
VERSION 1.0 01-01-2020	F/	/MBL/TVL/QMD/RCA/NC P 1/10					
Determination of I	Root Ca	uses of	Non-co	onformities			
Characters/ Activities Evaluated				Cause/ Error Ider	ntified		
and deterny metrices available		Yes	No	Responsibility	Comments		
V. DATA HANDLING EQA PROVIDE	R						
t). The ststistical procedure used is probably not appropriate for the distribution of test			~	EQAP			
2). Error establishment of assigned value (AV)			1/	EQAP			
3). Error in presentation of results			/	EQAP			
Description of the Cause							
· · · · · · · · · · · · · · · · · · ·	*			· ***	,		
•					+		
Corrective action proposed							
Reviewed 8	 .	, —		Issued MD			
Preoared by QM My Mill Reviewed & Approved T		7		issued MD	A STATE OF THE PARTY OF THE PAR		

DEPARTMENT OF QUALITY MANAGEMENT MICROBIOLOGICAL LABORATORY P 1/10 F/MBL/TVL/QMD/RCA/NC 01-01-2020 **VERSION 1.0 Determination of Root Causes of Non-conformities** Cause/ Error Identified **Characters/ Activities Evaluated** Comments Responsibility Yes VI. REPORT AND INTERPREATION Participant/ EQAP/ 1). Deviation in accordance with previous EQA results Manufacturer EQAP/ 2). Large variation in EQA results for the method used Manufacturer Participant/ EQAP/ 3). Deviation in systematic for all EQA samples Manufacturer Participant/ EQAP/ Repeated analysis showed similar deviation Manufacturer Participant/ EQAP/ 5). Source of deviation is unknown Manufacturer Description of the Cause since ige volues are within the stonge end matthe maintenace performed pertectly, its source of dewichen is unknow, here Corrective action proposed we considered as andomerror. Preoared by QM Million 1771 Reviewed & Approved TD Issued MD

TO STATE OF CHALTY MANAGEMENT									
MICROBIOLOGICAL			DEPARTMENT OF QUALITY MANAGEMENT						
VERSION 1.0	01-01-			/MBL/T	VL/QMI	D/RCA/NC	P 1/10		
Name of the EQAS	CM		QA:	5 1	310CF	ne mistry in ine			
Name of the Parameter f	or which out	lier Occ	urred	Cr	reat	inine			
									
Survey/ Programm No /		LJ.	eev	202	0	Decemb	ov.		
1	Determinati	ion of I	Root Ca	uses of	Non-c	onformities			
Characters/ Ac	tivities Eval	uated		Cause/ Error Identified					
Characters/ AC	tivities Evai	uateu		Yes	No	Responsibility	Comments		
I. TRANSCR	IPTION ERR	OR							
1). Error in recording test re	sults from the	instrum	ents		<u> </u>	Participant			
2). Error in reporting test re	sults to EQA o	organizat	tion		V	Participant			
3). Mixing-up the test resul	ts				\checkmark	Participant			
4). Report results with wro	ng units	•			\checkmark	Participant			
5). Report wrong method a	ınd/ or instrum	ents			✓ _/	Participant			
6). Error in data entry by EC	QA provider				<u> </u>	EQAP			
					11				
				•		-			
		*				9	-34		
Description of the Caus	se						7		
							1		
Corrective action propo	osed								
reoared by QM Mymin		wed & oved TD	. (<u></u>		Issued MD	منا		

SION 1.0 01-01-2020				OF QUALITY MANA RCA/NC	P 1/10
Determination					•
	·			Cause/ Error Identif	ied
Characters/ Activities Evaluat	ed	Yes	No	Responsibility	Comment
II. PRE-SURVEY ISSUES					
e EQA provider distributed by accident ropriate sample	an		V	EQAP	
ror in sample labelling				EQAP	
ror in packing the sample			~	EQAP	ook ee ee
rror in distribution of sample			✓	EQAP	1
roblem with sample stability			✓	EQAP	g1 _m .
Problem with sample homogenicity			1	EQAP	
Error in instruction letter of EQA provid	ler ·			EQAP	
	1				
50-00 p			-		
ef the Cause		L			
Description of the Cause					
				¥	
				¥	
Corrective action proposed					
Preoared by QM My minh	eviewed & approved TD	- Q		Issued I	MD

MICROBIOLOGICAL LABORATORY		DEPARTMENT OF QUALITY MANAGEMENT					
VERSION 1.0 01-01-2020	F,	F/MBL/TVL/QMD/RCA/NC P 1/10					
Determination of	Root Ca	uses of	Non-co	onformities			
Characters/ Activities Evaluated	1			Cause/ Error Iden	tified		
		Yes	No	Responsibility	Comments		
III.SAMPLE RECEIPT/ HANDLING	i						
1). Problem with the sample receipt .			/	Participants			
2). Inappropriate storage of the sample till use			1	Participants			
3). Problem with reconstitution of the sample			V	Participants			
4). The instructions were not followed properly participants	by the	-		Participants			
1° - 1							
				1			
	r	140					
	idea -aa						
		4					
				-			
		-	_				
Description of the Cause							
Corrective action proposed					FIFTH No. THE PLAN.		
Ì							
Reviewed	& 1/	?		j	\		
Preoared by QM My Preoared Approved	TD		24	Issued MD			

MICROBIOLOGICA	AL LABORATORY	DEPARTMENT OF QUALITY MANAGEMENT					
VERSION 1.0	01-01-2020	F/	F/MBL/TVL/QMD/RCA/NC P 1/10				
<u> </u>	Determination of I	Root Ca	uses of	Non-co	onformities		
Characters/	Activities Evaluated				Cause/ Error Iden	tified	
			Yes	No	Responsibility	Comments	
IV. TEST	PERFORMANCE						
1). Change in the instruct	tion of manufacturer			J	Participants/ EQAP/ Manufacturer		
2). Was there a problem	with the equipments			1	Participants		
3). Was there a problem	with reagents			1	Participants/ Manufacturer		
4). Was there a problem	with the test performan	ce		1	Participants		
5). Was there a problem	with the IQC samples			1	Participants	- comment	
			= 1			,	
						-	
,				-			
		_			_	, k	
			,				
Description of the C	Cause			1-	I slower	_	
Corrective action p			œ.				
Preoared by QM MY	Approved T		Me.		Issued MD	-40	

MICROBIOLOGICAL LABORAT	ORY	Markety and process as a person	DEPARTMENT OF QUALITY MANAGEMENT						
VERSION 1.0 01-	01-2020	F/	NAME OF TAXABLE PARTY.	MBL/TVL/QMD/RCA/NC P 1/10					
Determin	ation of I	Root Ca	uses of	Non-co	onformities				
Characters/ Activities E	valuated	The second of the second of	Cause/ Error Identified						
			Yes	No	Responsibility	Comm	ents		
V. DATA HANDLING EQA	PROVIDE	R		`					
1). The ststistical procedure used is pro appropriate for the distribution of tes	obably not t			✓	EQAP				
2). Error establishment of assigned va	lue (AV)			V	EQAP				
3). Error in presentation of results				7	EQAP				
	_								
,									
Description of the Cause		1				,			
					-1 r				
							×		
Corrective action proposed							3 2 1		
						/			
1 1 1							-		
				·					
Preoared by QM My mirin	eviewed & pproved TI		lssued MD				Pi -		

MICROBIOLOGICAL LABORATORY	DEPARTMENT OF QUALITY MANAGEMENT				
VERSION 1.0 01-01-2020	F/MBL/TVL/QMD/RCA/NC P 1/10				
Determination of Root Causes of Non-conformities					
Characters/ Activities Evaluated		Cause/ Error Identified			
		Yes	No	Responsibility	Comments
VI. REPORT AND INTERPREATION				1	
1). Deviation in accordance with previous EQA results			/	Participant/ EQAP/ Manufacturer	
2). Large variation in EQA results for the method used			>	EQAP/ Manufacturer	
3). Deviation in systematic for all EQA samples			>	Participant/ EQAP/ Manufacturer	
4). Repeated analysis showed similar deviation			>	Participant/ EQAP/ Manufacturer	
5). Source of deviation is unkown		/		Participant/ EQAP/ Manufacturer	
·					
					,
					, s ²⁵
Description of the Cause					
since machine Daily, weekly and monthly maintene performed perteetly, daily 10e values showed within the manch,					
The source of decision is unknown.					
Corrective action proposed Hene me armis vondom					
enm					
Preoared by QM M/Cmmmin Reviewed & Approved TD Issued MD					