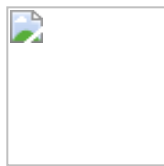
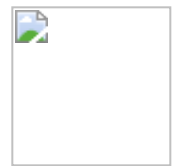


Lab Monthly Summary



Lab Name MICROBIOLOGICAL LABORATORY
 Month June
 Constituent Group Chemistry II

Lab No 11612
 Year 2020



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

Sl.No	Analyte	Method / Principle Name	Analyzer Name	No of Participants	DV	Participants		Your Value	SDI	U
						CV	SD			
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.

Beyond ± 3.0 | Unacceptable performance. Action Signal.

Homogeneity and Stability of the sample is passed.

Data in CMC EQAS reports is confidential

Contact details:

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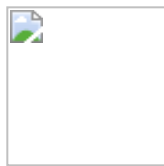
Contact Number: 0416-2283102



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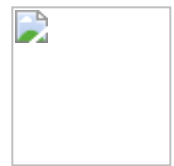
***** End of Report *****

Lab Monthly Summary



Lab Name MICROBIOLOGICAL LABORATORY
 Month July
 Constituent Group Chemistry II

Lab No 11612
 Year 2020



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

Sl.No	Analyte	Method / Principle Name	Analyzer Name	No of Participants	DV	Participants		Your Value	SDI	U
						CV	SD			
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.

Beyond ± 3.0 | Unacceptable performance. Action Signal.

Homogeneity and Stability of the sample is passed.

Data in CMC EQAS reports is confidential

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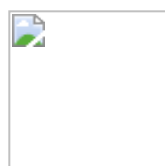
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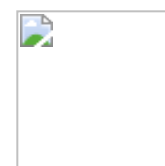
***** End of Report *****

Lab Monthly Summary



Lab Name MICROBIOLOGICAL LABORATORY
 Month August
 Constituent Group Chemistry II

Lab No 11612
 Year 2020



Date of Result Entered : 15/08/2020

Date of Report Published : 10/09/2020

Sl.No	Analyte	Method / Principle Name	Analyzer Name	No of Participants	DV	Participants		Your Value	SDI	U
						CV	SD			
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.

Beyond ± 3.0 | Unacceptable performance. Action Signal.

Homogeneity and Stability of the sample is passed.

Data in CMC EQAS reports is confidential

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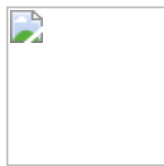
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***** End of Report *****

Lab Monthly Summary



Lab Name MICROBIOLOGICAL LABORATORY
 Month September
 Constituent Group Chemistry II

Lab No 11612
 Year 2020



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

Sl.No	Analyte	Method / Principle Name	Analyzer Name	No of Participants	DV	Participants		Your Value	SDI	U
						CV	SD			
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.

Beyond ± 3.0 | Unacceptable performance. Action Signal.

Homogeneity and Stability of the sample is passed.

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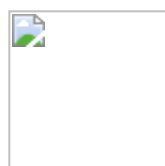
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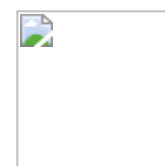
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Lab Monthly Summary



Lab Name **MICROBIOLOGICAL LABORATORY**
 Month **October**
 Constituent Group **Chemistry II**

Lab No **11612**
 Year **2020**



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

Sl.No	Analyte	Method / Principle Name	Analyzer Name	No of Participants	DV	Participants		Your Value	SDI	U
						CV	SD			
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.

Beyond ± 3.0 | Unacceptable performance. Action Signal.

Homogeneity and Stability of the sample is passed.

Data in CMC EQAS reports is confidential

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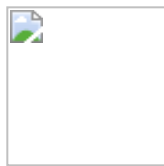
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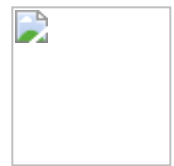
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Lab Monthly Summary



Lab Name MICROBIOLOGICAL LABORATORY
 Month November
 Constituent Group Chemistry II

Lab No 11612
 Year 2020



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

Sl.No	Analyte	Method / Principle Name	Analyzer Name	No of Participants	DV	Participants		Your Value	SDI	U
						CV	SD			
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

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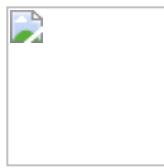
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Dr. Pamela Christudoss
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***** End of Report *****

Lab Monthly Summary



Lab Name **MICROBIOLOGICAL LABORATORY**
 Month **December**
 Constituent Group **Chemistry II**

Lab No **11612**
 Year **2020**



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

Sl.No	Analyte	Method / Principle Name	Analyzer Name	No of Participants	DV	Participants		Your Value	SDI	U
						CV	SD			
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.

Beyond ± 3.0 | Unacceptable performance. Action Signal.

Homogeneity and Stability of the sample is passed.

Data in CMC EQAS reports is confidential

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Contact Number: 0416-2283102



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Vellore

***** End of Report *****

Determination of Root Causes of Non-conformities

Characters/ Activities Evaluated	Cause/ Error Identified			
	Yes	No	Responsibility	Comments
II. PRE-SURVEY ISSUES				
1). The EQA provider distributed by accident an inappropriate sample		✓	EQAP	
2). Error in sample labelling		✓	EQAP	
3). Error in packing the sample		✓	EQAP	
4). Error in distribution of sample		✓	EQAP	
5). Problem with sample stability		✓	EQAP	
6). Problem with sample homogeneity		✓	EQAP	
7). Error in instruction letter of EQA provider		✓	EQAP	

Description of the Cause

Corrective action proposed

Prepared by QM *MJL* Reviewed & Approved TD *[Signature]* Issued MD *[Signature]*

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
IV. TEST PERFORMANCE				
1). Change in the instruction of manufacturer		✓	Participants/ EQAP/ Manufacturer	
2). Was there a problem with the equipments		✓	Participants	
3). Was there a problem with reagents		✓	Participants/ Manufacturer	
4). Was there a problem with the test performance		✓	Participants	
5). Was there a problem with the IQC samples		✓	Participants	
Description of the Cause				
Corrective action proposed				
Prepared by QM <i>M. J. ...</i>		Reviewed & Approved TD <i>[Signature]</i>		Issued MD <i>[Signature]</i>

MICROBIOLOGICAL LABORATORY		DEPARTMENT OF QUALITY MANAGEMENT	
VERSION 1.0	01-01-2020	F/MBL/TVL/QMD/RCA/NC	P 1/10
Name of the EQAS		CMC EQAS Biochemistry	
Name of the Parameter for which outlier Occurred		Creatinine	
Survey/ Programm No / Period			
Year 2020 December.			
Determination of Root Causes of Non-conformities			
Characters/ Activities Evaluated	Cause/ Error Identified		
	Yes	No	Responsibility
I. TRANSCRIPTION ERROR			
1). Error in recording test results from the instruments		✓	Participant
2). Error in reporting test results to EQA organization		✓	Participant
3). Mixing-up the test results		✓	Participant
4). Report results with wrong units		✓	Participant
5). Report wrong method and/ or instruments		✓	Participant
6). Error in data entry by EQA provider		✓	EQAP
Description of the Cause			
Corrective action proposed			
Prepared by QM	<i>[Signature]</i>	Reviewed & Approved TD	<i>[Signature]</i>
		Issued MD	<i>[Signature]</i>

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). 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 unknown	✓		Participant/ EQAP/ Manufacturer	
Description of the Cause				
<p>Since machine Daily, weekly and monthly maintenance performed perfectly, daily IQE values showed within the range, the source of deviation is unknown.</p> <p>Corrective action proposed Here the error is random error</p> <p style="text-align: right;"><i>ML</i></p>				
Prepared by QM <i>ML</i>	Reviewed & Approved TD <i>ML</i>		Issued MD <i>ML</i>	