

3 MONTHLY SUMMARY

Lab Name DR APARNAS PATHOLOGY LABORATORY Lab No 11113
 Month October Year 2019
 Constituent Chemistry II
 Group

Date of Result Entered : 19/10/2019

Date of Report Published : 01/11/2019

Sl.No	Analyte	Method	No of Participants	DV	Participants		Your Value	SDI	U
					CV	SD			
1	GLUCOSE I	GOD-POD	3027	208.58	11.91	24.84	201 mg/dl	-0.30	0.90
2	UREA I	UREASE-GLDH	1422	71.96	15.70	11.30	69 mg/dl	-0.26	0.60
3	CREATININE I	JAFFES KINETIC	2692	1.65	16.53	0.27	1.73 mg/dl	0.29	0.01
4	T.BILIRUBIN I	EVELYN-MALLOY	138	2.35	22.35	0.53	4.1 mg/dl	3.33	0.09
5	T-PROTEIN I	BIURET	1702	5.33	11.62	0.62	4.3 g/dl	-1.66	0.03
6	ALBUMIN I	BCG	1681	3.21	10.12	0.32	2.9 g/dl	-0.95	0.02
7	URIC ACID I	ENZYMATIC	1722	6.46	14.62	0.94	5.6 mg/dl	-0.91	0.05
8	CHOLESTEROL I	CHOD-PAP	2964	109.07	12.61	13.75	91 mg/dl	-1.31	0.51
9	TRIGLYCERIDE I	ENZYMATIC	1800	131.48	17.34	22.80	120 mg/dl	-0.50	1.07

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.

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Homogeneity and Stability of the sample is passed.

Pamela Christudoss


Dr. Pamela Christudoss
 CMC EQAS Co-Ordinator

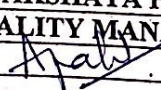
Christian Medical College, Vellore

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

ASA VLEE-DR APARNA'S PATHOLOGY LABORATORY, MALAD

NON - CONFORMITY REPORT

Origin of Non - conformity:- Clinician complaint / Quality Control indication / Instrument calibration / Inspection of consumables or supplies / Staff observations / Report checking / Audits / Other / Customer complaints Others, please specify: _____	NC No.: 1
	Date: 9/11/19
	Area of Standard (Clause No.):
NC identified by person: Nafeesa Dept :- Biochemistry	
NC raised for Department: Biochemistry - PT	
Description of NC: The Total Bilirubin in PT of CMC Vellore SDI was 3.33	
Investigation of NC / Root cause Analysis: 1) The aliquoted of PT sample was rerun on the day of result. The value observed was 2.5 mg/dl. Also a ILC was done without viral lab for the same. Report attached.	
Corrective Action Taken: 1) IQC data of 19th Oct '19 was within range.	
Preventive Action taken / proposed: Check IQC data on daily basis.	
Review of Corrective Action / Preventive Action if required: Since the rerun of PT was within reference range, it was a random error.	
Name & Sign of Person resolving the Non-conformity Nafeesa Walele 	

PREPARED & ISSUED BY :	
NAME	MS AKSHATA PATIL
DESIGNATION	QUALITY MANAGER
SIGNATURE	

ASAVLEE-DR APARNA'S PATHOLOGY LABORATORY, MALAD

Department:- Biochemistry

Date:- 9/11/19

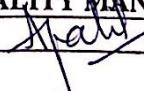
Details of Problem / Outlier (EQAS / IQC / ILC)

Survey No. / Cycle No. / Lot No. October 2019

Outlier results (In Case of EQAS / ILC) EQAS

ROOT CAUSE ANALYSIS

Sr. No.	Specifications	Check points	Observations
1	Instrument	Has the necessary maintenance (daily / weekly / monthly / AMC) performed as per the schedule.	Yes
		Was there any machine problem on the day of the outlier / problem	NO
2.	Reagent	Check the details of the kit used 1. Name of the Reagent 2. Lot no. 3. Date of expiry 4. Date of opening the kit 5. Storage conditions of the kit	Bilirubin → 051804 → 06/2020 → 25/9/2019 → 2-8°C
3	Calibration	Check the details of the calibrator used 1. Name of the Reagent 2. Lot No. 3. Date of expiry 4. Date of reconstitution 5. Stability check	NA
4	Daily Controls	If the controls are not within acceptable range on the day of the outlier / problem, check the details of the control used: 1. Name of the Reagent 2. Lot. No. 3. Date of expiry 4. Date of reconstitution 5. Stability check	
5.	Other Causes	1: Clerical Error 2. Problem with PT material recd / in case of EQAS / IQC 3. Any other technical problem	
6.	Remark		Random Error

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Summary of re-assayed outlier PT results:

Sr. No.	Analyte	Previous result	Re-assayed results	Acceptability limit	Comments
1)	Bilirubin (Total)	4.1 mg/dl	2.5 mg/dl	2.35 mg/dl	Within Range

Specific corrective action taken to prevent recurrence of the problem (If any):

Attach documentary evidence that the problem is corrected successfully:

- 1) Reassay PT sample - 2.5 mg/dl - picture xerox
- 2) IQC data xerox

Conclusion: Within Limits (Post reanalysis)

Reviewed by Apajeeva

Date:- 9/11/19

PREPARED & ISSUED BY :	
NAME	MS AKSHATA PATIL
DESIGNATION	QUALITY MANAGER
SIGNATURE	<i>[Signature]</i>