



Certificate of Conformity and Calibration

TO WHOMSOEVER IT MAY CONCERN

Instrument model: EC5PlusV2

Serial No : S211213

ISO 15189:2012 REQUIREMENTS REGARDING,"CALIBRATION AND VERIFICATION PROCEDURE"

All Transasia Bio-Medicals Ltd diagnostics products which are distributed and for which a certificate is issued are CE Marked. Transasia Bio-Medicals Ltd, Mumbai, manufacturers of diagnostic devices with company quality management system in compliance with standard ISO13485:2016 ;ISO9001:2015. This means that all the processes in development and manufacturing of TBM products are guided by quality management system.

TBM declares and assures following

- The mentioned regulations require that production system and measuring devices are qualified and manufacturing and test procedures are validated as per ISO 13485:2016 and ISO 9001:2015 standard and it is assured through schedule maintenance and by regular qualification.
- TBM declares to have established procedure and to maintain it in order to assure the post marketing surveillance according to directive of 98/79/EC.
- All physical quantities, calibrators and controls used in TBM system are fully traceable to certified standards or reference materials.
- All TBM products are factory calibrated and final qc passed at the time of release.
- The performance of TBM system at customer site is assured if regular QC measurements, cleaning and maintenance procedure as described in the instruction for use or service documentation are performed
- Additional calibration or verification procedure is not required in order to assure the specified performances of every TBM system. Only if user deviates from the manufacturer's recommendation does he have to establish site specific calibration and verification procedure as part of his accreditation process.

Date: 26/04/2021

Manish Airan

Head Of Quality Department & Regulatory

CREATININE

C1 CRE 1.55 mg/dl +1SD
LINEAR REACTION

DATE OF REPORT: 11/08/22
TEST CRE (C1)



C-MEAN: 1.550
C-SD:
C-CV:

GLUCOSE

DATE OF REPORT: 11/08/22
TEST GLU (C1)



C-MEAN: 109.9
C-SD:
C-CV:

C1 GLU 109.9 mg/dl

UREA

DATE OF REPORT: 11/08/22
TEST URE (C1)



C-MEAN: 0.335
C-SD: 43.2
C-CV: 12896%

URIC ACID

1 URIC: 4.45 mg/dl -1SD

DATE OF REPORT: 11/08/22
TEST URIC (C1)

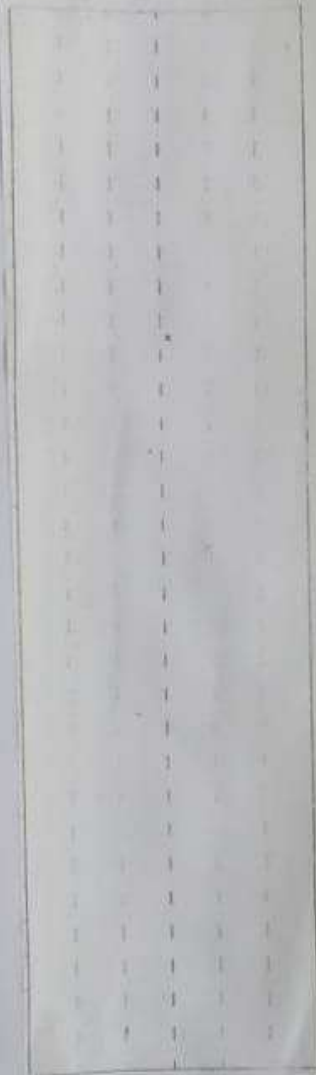


2
LC-MEAN: 3.120
LC-SD: 1.88
LC-CV: 60.26%

TOTAL PROTEIN

11/08/22
MONTHLY QUALITY CONTROL
TEST TPRO (C1)

+3SD
+2SD
+1SD
MEAN
-1SD
-2SD
-3SD



5.950
5.600
5.250
4.900
4.550
4.200
2.800

MEAN: 4.950
SD:
CV:

10/08/22 20:43:02

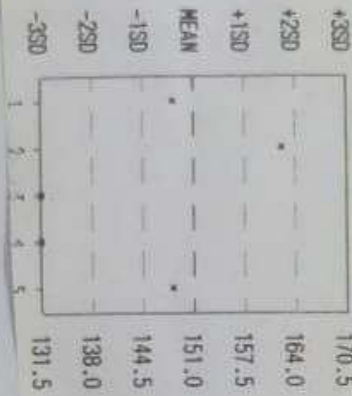
C1 TPRO 4.95 g/dl

TRIGLYCERIDES

~~CONFIDENTIAL~~

C1 TRIG 162.2 mg/dl +1SD

DATE OF REPORT: 11/08/22
TEST TRIG (C1)



ALC-MEAN: 131.5
ALC-SD: 29.8
ALC-CV: 22.66%

ALBUMIN

DATE OF REPORT: 11/08/22
TEST ALB (C1)



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C1 ALB 2.92 g/dl

C-MEAN: 2.920
C-SD:
C-CV:

BILIRUBIN TOTAL

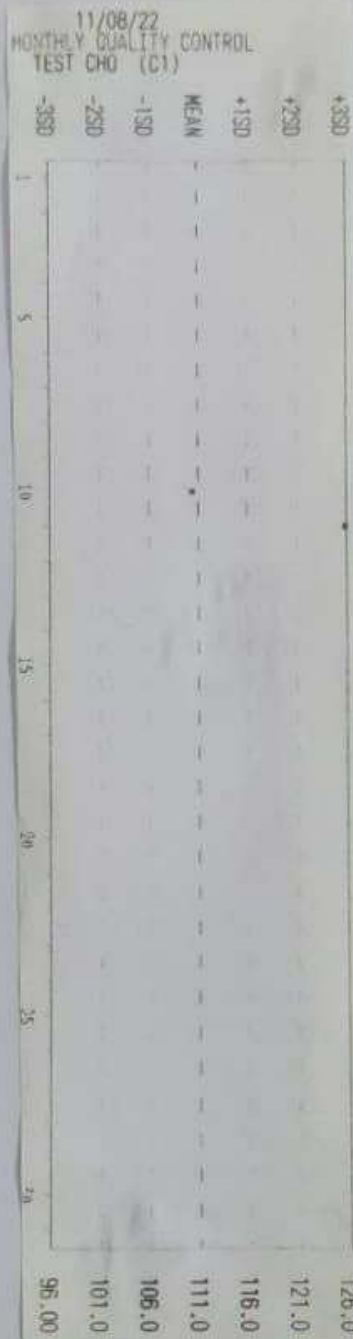
C1 BIT 1.43 mg/dl -1SD
4:1S

DATE OF REPORT: 11/08/22
TEST BIT (C1)



4:5
CALC-MEAN: 1.446
CALC-SD: 0.47
CALC-CV: 32.50%

TOTAL CHOLESTEROL



C1 CHO 110.3 mg/dl