Calibration Certificate

Sr. No. AQ100360 Installed at Nerfblut Diagnostic Services-Hyderabad has calibrated by our engineer on 10-Jan-2024 with appropriate and sophisticated tools. This is to Certify that Biochemistry Analyzer Meril AutoQuant-200Excelus Instrument Below parameter has been calibrated:

TEST ITEMS AND RESULT

25.0 degree C	Room temp.
37.0 ° C	Incubation temp.
OK >33000	Cuvette Blank Value
OK NO	Cuvette Absorbance
OK NO	Light Quality Check
0K5415152524141112	Hardware Check-Functional Test
Mean- 97.55/14.34/24.79	Mean-Kinetic/End point/two Point
SD- 1.15/0.39/0.69	SD-Kinetic/End point/two Point
CV- 1.77% /2.42% /2.80%	CV-Kinetic/End point/two Point
230 Volts and Grounding less then 5 V	Power Supply and Earthing
In range (0 to 150 ul)	Reagent Dispensing Volume
Working Properly	Valve & Motor
±34000 (≥25,000)	Threshold value
Working Properly	Waster & Water Sensor
0.65	Optical Path length
2.8 ° C (0 to 15 Degree)	Reagent cooling Temperature
In range (0 to 30 ul)	Sample Dispersing Volume
0k	Lamp Check
24.0 degree C	Ambient temp (15-32) Degree
No water leakage	Leakage in Water tubing or CRU
No Imbalance Probe Movement	Appearance

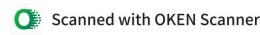
This Calibration Certificate is Valid Up to 09-Jan-2025.

(As per Meril terms.) Conclusion: All parameter are within range. The Machine is working properly.

Engineer Name: Mr. Manoj Chintala Designation: Service Engineer

Engineer Sign:







BioCAL Kit

Assayed Clinical Chemistry Calibrator

Read this pack insert thoroughly before use

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REF	Pack Size	R1 BioCal	R2 BioCal
CALCNC-01	4 × 3ml	4 x 3ml	1 x 12ml

INTENDED USE

BioCal is intended for use in the calibration of quantitative methods on Meril automated clinical chemistry analyzers.

SUMMARY

BioCal is a lyophilized calibrator based on human serum with added concentrations and activities.

RECONSTITUTION

Carefully open one vial, avoiding the loss of lyophilizate. Using a volumetric pipette, reconstitute each vial with 3.0 ml of R2 BioCAL (Reconstitution Buffer) at +15 °C to +25 °C. Replace the stopper and allow the control to stand for 20 minutes, swirling occasionally. Before sampling, gently swirl the vial several times to ensure homogeneity. Avoid formation of foam. Do not shake.

CALIBRATOR VALUES

The calibrator values were determined under strictly standardized conditions on Meril automated clinical chemistry analyzers using Meril AutoQuant/ AriQuant reagents and master calibrator. The target value is the mean of the values obtained.

STORAGE & STABILITY

Stability: up to expiration date on label when stored unopened at 2-8 °C.

Stability once reconstituted: 5 days when stored tightly at 2-8 °C.

After reconstitution & frozen once: all analytes stable for 30 days at -20 °C, except bilirubin will be stable for 8 hours at 2 - 8 °C & 15 days at -20 °C stored protected from light. Store control tightly capped and protected from light when not in use.

Recovery of the BioCal calibrator is within \pm 5% of initial value.

MATERIALS REQUIRED BUT NOT PROVIDED

Volumetric Pipette, Meril AutoQuant/AriQuant system pack reagents, Meril AutoQuant autoanalyzer and General laboratory equipment.

WARNINGS AND PRECAUTIONS

- All human material should be considered potentially infectious and handled appropriately by entitled and professionally educated person.
- Do not pipette by mouth. Exercise the normal precautions required for handling laboratory.
- Perform the test according to the general "Good Laboratory Practice" (GLP) guidelines.

CALIBRATION

Use BioCal calibrator as specified in the respective pack inserts of Meril AutoQuant/ AriQuant system pack reagents.

LIMITATIONS

This product should not be used past the expiration date. If there is evidence of microbial contamination or excessive turbidity in the reconstituted calibrator, discard the vial.

Different lot numbers of this calibrator should not be interchanged, as the values assigned vary from lot to lot.

WASTE DISPOSAL

This product is made to be used in professional laboratories. Please consult local regulations for correct waste disposal

REFERENCES

- NCCLS. Clinical and Laboratory Standards EP 25A Volume 29 No. 20; Approved Guideline.
- NCCLS. Clinical Laboratory Safety, Approved Guideline

 Second Edition.
- Data on file: Meril Diagnostics.

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