M Dialysis Calibration Verification Test Kit

INTENDED USE:
Calibration Verification Test Kit solutions are intended for *in vitro* diagnostic use in the quantitative determination of linearity, Calibration verification and verification of reportable Range for the M Dialysis 600, ISCUS and ISCUS^{flex} Microdialysis Analyzers, for the following (have FDA clearance) analytes:

Glucose
Lactate
Pyruvate
Glycerol
Glutamate

Each test set consists of one bottle each of Levels I through V. Each bottle contains 2.5 mL.

SUMMARY:
Each ***Calibration Verification Test Kit*** contains all Analytes that have FDA clearance for analyses in the M Dialysis microdialysis Analyzers. Multiple levels are provided to establish the relationship between theoretical and actual performance of each of the included analytes.

The ***Calibration Verification Test Kit*** will assist in the documentation of linearity, calibration verification and verification of linear range.

CalVer Solution:
Calibration Verification Kit Solutions are prepared in Ringer's solution.

Analyte/ Unit of measure:

D-Glucose mg × dL^{-1}
L-Lactate mmol × L^{-1}
Glycerol µmol × L^{-1}
Pyruvate µmol × L^{-1}
Glutamate µmol × L^{-1}

Nonreactive Ingredients:
D-Glucose, L-Lactate sodium salt, Glycerol, Pyruvic acid sodium salt, Glutamic acid, Chlorides of sodium, potassium and calcium. Preservative added.

Precautions and Warnings:
For In Vitro Diagnostic Use

Symbol declaration

Use by
LOT **Batch code**
Storage temperature
Consult instructions for use
IVD **In vitro diagnostic device**

WARNING:
Do not Pipette by mouth. Exercise normal precautions required for handling laboratory reagents.

Opened vials should be handled with care to avoid risk for evaporation and/or contamination.

STORAGE AND STABILITY
Calibration Verification Test Kits are stored at 4° to 8°C. ***Do NOT store in a freezer.*** Test sets are stable until the expiration date printed on the bottle. Opened vials should be used within 2 weeks.

PREPARATION
Prior to use, remove the ***Calibration Verification Test Kit*** from storage and allow samples to equilibrate to room temperature (18 to 25°C). Invert each bottle several times gently before aspirating sample.

Replace Rubber stopper, and cap opened bottles tightly, return to 4 to 8°C refrigerator immediately after testing

ASSAY:
Pipette 50 µL of each level into a Microvial. Analyze each level in 5 replicates. (See Attached instructions for use)

CALCULATION OF RESULTS:
Each set of ***Calibration Verification Kit*** material is prepared to cover a significant portion of the linear range. An assigned value sheet is included with each ***Calibration Verification Kit.*** The following are examples for determining Pass/Fail and calculating Theoretical Values.

Example 1:

Acceptable Performance

Target Value (µmol/L)	Mean Result (µmol/L)	Acceptable Criteria	Acceptable Range (Target +/- Criteria)	Pass ?
Level I = 10	9.9	+/- 10%	9 - 11	Y
Level II = 40	42.3	+/- 10%	36 - 44	Y
Level III = 120	128.6	+/- 10%	108 - 132	Y
Level IV = 260	256.3	+/- 10%	234 - 286	Y
Level V = 660	709.3	+/- 10%	594 - 726	Y

Unacceptable Performance

Target Value	Mean Result (µmol/L)	Acceptable Criteria	Acceptable Range (Target +/- Criteria)	Pass ?
Level I = 10	9.8	+/- 10%	9 - 11	Y
Level II = 40	38.7	+/- 10%.	36 - 44	Y
Level III = 120	133.9	+/- 10%	108 - 132	N
Level IV = 260	254.4	+/- 10%	234 - 286	Y
Level V = 660	671.2	+/- 10%	594 - 726	Y

Example 2:

For each analyte, plot the expected (Theoretical) value on the x-axis versus the recovered (Experimental) value on the y-axis using standard linear graph paper.

If the system is linear the plot should approximate a straight line. The point at which the line is no longer straight can be used to determine the limit of linearity or the upper limit of reportable range.

Linear regression should be interpreted using standard statistical analysis and the results should be compared with the instrument linearity for each analyte tested. The degree of acceptable non-linearity is an individual judgment based on clinical significance and medical decision levels.

LIMITATIONS:
Calibration Verification Test Kit solutions are not intended for use as routine quality control materials or as calibration materials.

EXPECTED VALUES
Each set of ***Calibration Verification Kit*** material is manufactured such that an exponential relationship exists among levels 2 through 5.

Contact M Dialysis
For technical assistance or to place an order, please call (866) 868-9236

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