COM25-59797

A blood gas analyzer for parenteral nutrition bag analysis? Performance evaluation and method validation

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INTRODUCTION

The parenteral nutrition (PN) unit of our hospital produces binary PN bags. Until recently, electrolyte release control was performed using capillary electrophoresis, but the supplier discontinued its activity. After comparing different instruments, we selected a blood gas analyzer (BGA) which was originally designed for human biological samples. **Objective** : The aim of this study was to validate this analytical method.

MATERIALS & METHOD

	Solutions	Calibration points ; replicas	Calculus / Statistical tests used
Specificity	Pure solution of each electrolyte at concentrations equivalent to those in G6 PN bags	6 points calibration curve ; 5 replicas	Comparison of Linear Regression (LR) lines slopes (electrolyte alone *versus* in the matrix) using Student's t-test
Repetability / Intermediate precision (IP)	G6 & G13 standard PN bags	6 replicas ; IP evaluated during 3 days ;2 different operators	Mean ; Coefficient of variation (CV)
Linearity	A mixed cation solution was prepared	6 points calibration curve; 5 replicas	Linear Regression lines for each electrolyte/ Fisher's exact test to compare variances (theoretical *versus* measured concentrations)
Low Limit of Quantification (LLOQ)			LLOQ = 10 $sd/b1$ With sd: standard deviation and b1 : slope of calibration curve
Accuracy & trueness			Determination of confidence intervals (CI) and mean recovery (R)

Na, K and Ca measurement by potentiometry.

RESULTS

Specificity

Hypothesis testing:
H0: the slopes are not significantly different
H1: the slopes are significantly different

	Na alone	Na in G6 matrix
Slope	0,869	1,007
Standard deviation	0,11	0,053

t exp	1,13
t 5%, 8 ddl	2,571
p-value	0,29

$T_{exp}<T_{a5\%}$: Fail to reject H0 : the slopes are not significantly different for the Na

	K alone	K in G6 matrix
Slope	0,738	0,981
Standard devitaion	0,091	0,048

t exp	1,13
t 5%, 8 ddl	2,571
p-value	0,29

$T_{exp}<T_{a5\%}$: Fail to reject H0 : The slopes are not significantly different for the K

→ Absence of matrix effect

Repetability /IP

G6 / Operator 1/ 11. dec.24	Theoritical K (12,66 mmol/L)	Theoritical Ca (10,05 mmol/L)	Theoritical Na (31,44 mmol/L)
MEAN	12,73	8,41	32,35
SD	0,05	0,07	0,15
CV (%)	0,36%	0,88%	0,47%

G13 / Operator 1/ 11.dec.24	Theoritical K (22,08 mmol/L)	Theoritical Ca (17,54 mmol/L)	Theoritical Na (50,87 mmol/L)
MEAN	20,88	12,32	52,81
SD	0,04	0,20	0,79
CV (%)	0,18%	1,62%	1,49%

G6 / Operator 2/ 12.dec.24	Theoritical K (12,66 mmol/L)	Theoritical Ca (10,05 mmol/L)	Theoritical Na (31,44 mmol/L)
MEAN	12,75	8,56	32,56
SD	0,04	0,06	0,11
CV (%)	0,28%	0,68%	0,35%

G13 / Operator 2/ 12.dec.24	Theoritical K (22,08 mmol/L)	Theoritical Ca (17,54 mmol/L)	Theoritical Na (50,87 mmol/L)
MEAN	20,94	12,31	53,10
SD	0,06	0,07	0,09
CV (%)	0,29%	0,60%	0,17%

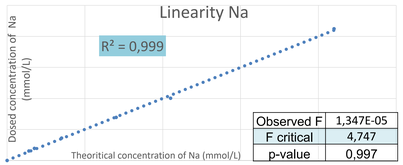
G6 / Operator 1/ 13.dec.24	Theoritical K (12,66 mmol/L)	Theoritical Ca (10,05 mmol/L)	Theoritical Na (31,44 mmol/L)
MEAN	12,78	7,84	32,63
SD	0,03	0,27	0,04
CV (%)	0,25%	3,38%	0,13%

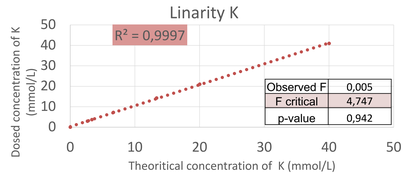
G13 / Operator 1/ 13.dec.24	Theoritical K (22,08 mmol/L)	Theoritical Ca (17,54 mmol/L)	Theoritical Na (50,87 mmol/L)
MEAN	20,81	12,48	53,06
SD	0,07	0,34	0,35
CV (%)	0,34%	2,74%	0,66%

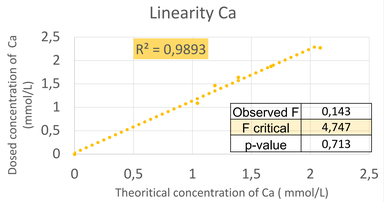
→ All CVs are < 10%

Linearity

Hypothesis testing:
H0: the relation between theoritical concentration and dosed concentration is linear
H1: the relation between theoritical concentration and dosed cocnentation is not linear







→ Observed F<F critical α5% : Fail to reject H0 : the relation between theoritical and dosed concentration is linear for Na, K and Ca

LLOQ

LLOQ Na (mmol/L)	0,53
LLOQ K (mmol/L)	0,49

→ Na is theoritically quantifiable up to 0,53 mmol/L and K up to 0,49 mmol/ L

Accuracy-Trueness

	Mean recovery R	Upper bound of CI R	Lower bound of CI R
Na	99,93	96,54	103,32
K	103,47	99,52	107,41

→ The value « 100 » is included in the R Confidence Interval limits

CONCLUSION-DISCUSSION

✓The specificity, repeatability, intermediate precision, and linearity for sodium and potassium allow us to validate the method.

✗ Additional tests are planned to validate this method for calcium dosage
✗ LLOQ theoritically calculated but not evaluated in practice

✓The method is validated for quality control of both standards and individualized PN bags

✓Method validated