IMPACT OF THE ANALYTICAL OPTIMIZATION OF A CATION QUANTIFICATION METHOD BY CAPILLARY ELECTROPHORESIS USING RBG TOOL

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INTRODUCTION

The pharmacy at Clermont-Ferrand University Hospital produces parenteral nutrition (TPN) bags for neonatal patients. Currently, the cation release assay (K^+, Ca^{2+}, Na^+ and Mg^{2+}) is performed by capillary electrophoresis with conductivity detection (CE-C4D) and takes 8 min per bag.

Issue: **Current dosing times can delay patient care management in case of large production sessions.**

OBJECTIVE

The aim was to reduce **analysis time** while maintaining **analytical performance**, and to study the **ecological and economic impact** of this optimization using the **RGB method**.

MATERIALS AND METHODS

1. Method optimization

Method	Dilution	Rinse time	Savitzky–Golay filter (SG)
M1 : Initial method	With WFI	2 min	No
M2 : Optimized method	With histidine solution at 5 mg/mL	1 min	Yes

2. M1 and M2 comparison using the RGB method

- **RGB method**(1) : evaluates an analytical method according to three main attributes.
- **Determination of the limit of acceptability (LAV)** = 33,3% and of **satisfaction (LSV)** = 66,6%
- **Valeurs « W » et « w »** : coefficients de pondération

	RED : ANALYTICAL PERFORMANCE W=4	GREEN : SAFETY AND RESPECT FOR THE ENVIRONMENT W=3	BLUE : PRODUCTIVITY W=3
Parameters	Intermediate fidelity (CV) w=3; LAV = 5%; LSV = 2.5%	Computer energy consumption / year w=5; LAV = 149.9 kW.h ; LSV = 112.5 kW.h	Analysis time for a TPN bag LAV = 8 min; LSV= 6 min
	Accuracy (relatif biais) w=3; LAV = 7.5%; LSV = 5 %		
	Minimum resolution (MR) w=2; LAV = 1; LSV = 1.5	CE energy consumption / year w=5; LAV = 61 kW.h; LSV = 45.7 kW.h	
	Average asymmetry (AM) w=2; LAV = 0.31; LSV= 0.62		

- **Color Score (CS)** : quantitative measure of method conformity.
- **Method Brilliance (BM)** : weighted geometric mean of individual CS values, expresses the perfection or fiawlessness of the method.

3. Application for 2023

- **Limit Of Quantification (LOQ)** : used to determine the number of quantifiable bags
- **Analysis time** and **energy comsuption** comparison

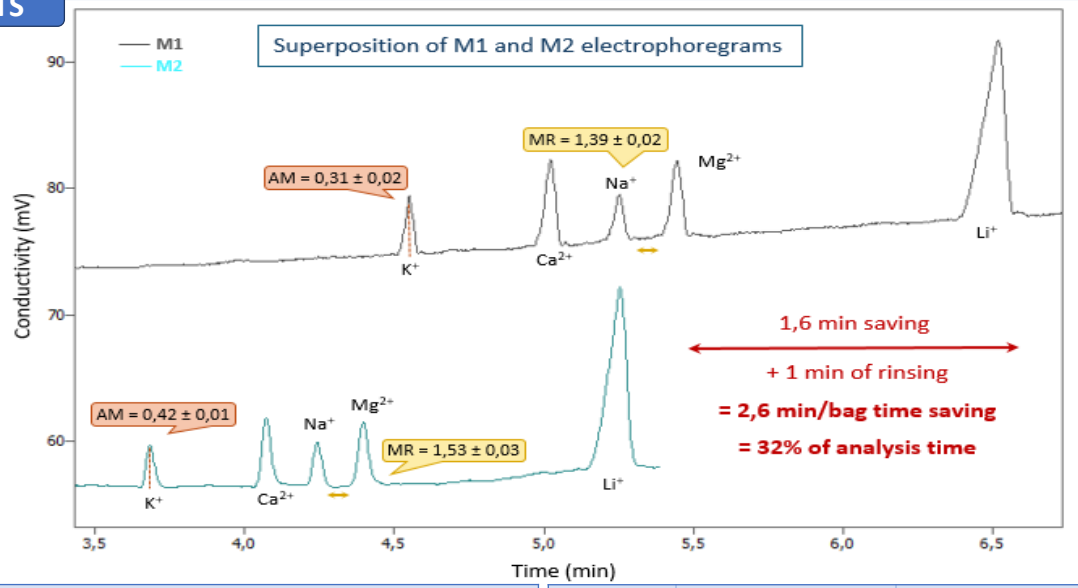
CONCLUSION

The superiority of M2 has been demonstrated according to RGB. However, the SG filter increases the LOQ of Mg^{2+}, reducing the number of quantifiable pockets. Combining M2 for high Mg^{2+} values with M1 for low values would make it possible to quantify all pockets and save 17h of analysis/year, or 23 kW.h .

(1) What Color Is Your Method? Adaptation of the RGB Additive Color Model to Analytical Method Evaluation Paweł M, Nowak and Paweł Koscielniak DOI: 10.1021/acs.analchem.9b01872

RESULTS

OPTIMIZATION



COMPARISON

	CS (%)			METHOD	OBTAINED COLOR	BRILLIANCE (BM)
	PERFORMANCE	ENVIRONMENT	PRODUCTIVITY			
M1	53.5 %	33.3 %	33.3 %	M1	GRAY	37.5 %
M2	50.4 %	75.0 %	75.0 %	M2	CYAN	67.9 %

M1 may be considered under certain conditions

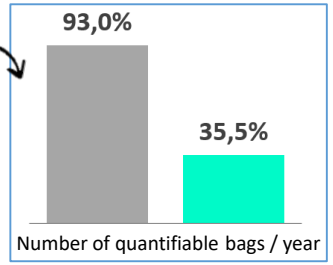
M2 may be the method of choice if analytical result quality requirements are less strict

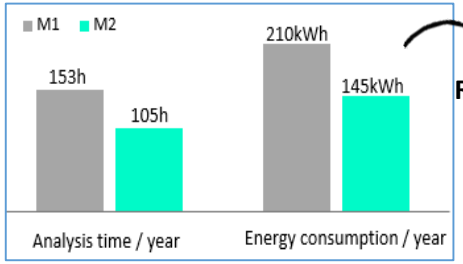
APPLICATION

LOQ of Mg^{2+}

M1 : 5 µM

M2 = 9 µM





Routine use: M1 + M2