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Performance qualification of automatic volumetric pipettes used in university hospitals in the DRC: Case of Kinshasa, Bukavu, and Kisangani

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ABSTRACT

Introduction
Automatic micropipettes are widely used in clinical biology for quantitative analyses in medical diagnostics. However, in many hospitals in developing countries, this equipment is often not verified for accuracy in collecting biological sample volumes. This oversight can result in biased diagnoses with significant public health consequences, such as misdiagnosing a healthy individual as ill, or vice versa.

Purpose
This study aimed to evaluate the performance of automatic volumetric micropipettes used in hospitals across three cities in the Democratic Republic of Congo (DRC): Bukavu, Kisangani, and Kinshasa.

Methods
Fifty micropipettes were collected from hospitals in these three major cities. All micropipettes were air-displacement type A, single-channel, with fixed and variable volumes. For each micropipette, 10 repeatable deliverable volumes were weighed. The mass of water obtained was converted to volume using the density of water at room temperature (approximately 1 g/mL at 20°C). Precision was evaluated using the coefficient of variation, while accuracy was determined by comparing the delivered volume to the nominal volume. The tolerances recommended by ISO 8655:2002 were applied in analyzing the results.

Results
The findings revealed that 12 out of 50 (24%) of the micropipettes analyzed were non-compliant. Non-compliance rates included 14% in Kinshasa and 10% in Bukavu, while all micropipettes from Kisangani were compliant.

Conclusion
This research highlights the importance of reinforcing staff skills regarding equipment performance verification. Ensuring the performance of micropipettes is crucial to the quality assurance systems in clinical biology laboratories, as it guarantees reliable medical diagnostic results and safeguards public health.

INTRODUCTION

Verifying the performance of automatic micropipettes involves ensuring that they operate accurately and reliably according to their intended use, laboratory requirements, and the manufacturer's specifications (Krishnan, et al., 2021; Majd, et al., 2010; Mangukiya, et al., 2016; Curtis, 2007; ISO, 2000; Epstein, et al., 2003; Almeida, et al., 2013; Batista, et al., 2008). Micropipettes or piston pipettes play a critical role in the qualitative and quantitative analysis of biological parameters. These devices are ideal for sampling small liquid volumes with high precision. However, errors in their performance can lead to harmful consequences for disease diagnosis in clinical biology. A person could be misdiagnosed as healthy when they are ill, or vice versa, due to unreliable micropipette performance (Magny, et al., 2001; Dumontet, et al., 2009).

In the Democratic Republic of Congo (DRC), the average income of the population makes patient care expensive, and diagnostic errors can result in therapeutic failures or even patient deaths. To safeguard public health and improve the reliability of diagnostic results in hospitals, it is essential to verify the performance of critical measuring instruments used by clinical biology laboratories, including High-Performance Liquid Chromatography (HPLC), capillary and gel electrophoresis, UV-Visible spectrophotometers, analytical balances, and automatic volumetric micropipettes. This study focuses on verifying the performance of automatic volumetric micropipettes used in hospitals in the cities of Bukavu, Kisangani, and Kinshasa in the DRC.

METHODS

Reagents

Distilled water was produced using a Durastill USA brand device from Durastill™ Water Systems (Melbourne, Australia).

Material

The analytical balances (with an accuracy of 0.01 mg) used were Adventurer™ Analytical brands from Servilab (Shandong, China), and the hygrometer and thermometer used were BIOBASE brands from Biobase Biozone Co., Ltd. (Shandong, China).

The automatic volumetric micropipettes analyzed in this study are listed in **Table I**. These include single-channel micropipettes with both fixed and variable volumes (air displacement, type A).

Table 1:
The Automatic Volumetric Micropipettes Studied

N°	Brand	Batch	Volume	University Hospitals City
1	Oppendorf Research	1312776	10-100	Bukavu
2	DLAB	YL18CAH035623	5-50	Bukavu
3	FINNPIPETTE	MOB 29	10	Bukavu
4	ThermoElectron	MOB 29A	10-100	Bukavu
5	FINNPIPETTE	YE209AS0033299	20-200	Bukavu
6	ThermoElectron	YE209A003	100-1000	Bukavu
7	FINNPIPETTE	YL18CAH0034521	100-1000	Bukavu
8	ThermoElectron	V38657	5-50	Bukavu
9	FINNPIPETTE	MH75880	10-100	Bukavu
10	ThermoElectron	YL227AR0022620	20-200	Bukavu
11	DLABS	34783	250	Bukavu
12	FINNPIPETTE	NH23648	100-1000	Bukavu
13	FINNPIPETTE	MH76258	100-1000	Bukavu
14	MILLENNIAL	1312776	10-1000	Bukavu
15	EPPENDORF	YL18CAH035623	5-50	Bukavu
16	FINNPIPETTE	MOB 29	10	Bukavu
17	FINNPIPETTE	MOB 29A	10-100	Bukavu
18	Oppendorf Research	YE209AS0033299	20-200	Bukavu
19	Acura 825	22081938CE	20-200	Kinshasa
20	Discorevy Confort	40751080	20-200	Kinshasa
21	Pipetman	J21483J	20-200	Kinshasa
22	Humapette	F004923	20-200	Kinshasa
23	Eppendorf Research	5531131	20-200	Kinshasa
24	Acura 825	220722258	5 -50	Kinshasa
25	Discorevy Confort	40431039	2-20	Kinshasa
26	Finnpipette	99104450	2-20	Kinshasa
27	VWR	742232632	2-20	Kinshasa
28	Acura 825	22081055CE	100-1000	Kinshasa
29	Discorevy Confort	040461728CE	100-1000	Kinshasa
30	Pipetman	J25211J	100-1000	Kinshasa
31	Ald pipettes	KA0020452	100-1000	Kinshasa
32	Accumax	ID466176CE	100-1000	Kinshasa
33	Humapettes	F007422	100-1000	Kinshasa
34	Socorex/Acura 815	NL18092072	100	Kinshasa
35	Pipetman	14-17668	100	Kinshasa
36	Pipetman	D10057M	200	Kinshasa
37	Pipetman	D10569M	200	Kinshasa
38	Eppendorf Research	14890	200-500	Kinshasa

Methods

Gravimetry

This is the method recommended by ISO 8655:2002 (ISO, 2002).

Initial Weighing

Place a clean, dry container on the scale and tare the previously qualified scale (ISO, 2002).

Liquid Delivery

- Use a new pipette tip.

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- Aspirate the volume of water corresponding to the nominal capacity of the pipette (for example, 50 µL).
- Variable volume pipettes are tested at three different volumes, each with 10 repetitions: the nominal volume, 50% of the nominal volume, and the lower limit of the useful volume range or 10% of the nominal volume.
- Dispense the water into the container weighed on the scale (ISO, 2002).

Weighing

- Note the mass displayed on the scale.
- Repeat this for 9 repetitions to ensure accuracy (ISO, 2002).

Volume Conversion

- Measure the temperature of the test liquid and the atmospheric pressure at the start and end of the qualification test.
- Convert the mass of water obtained into volume using the density of water at room temperature (approximately 1 g/mL at 20°C) (ISO, 2002).

Precision and Accuracy Criteria

Precision criteria were based on the coefficient of variation (CV) of repeated measurements, while accuracy was calculated by comparing the delivered volume to the nominal volume. The tolerances recommended by ISO 8655:2002 standards were applied for the analysis of the results (ISO, 2002).

RESULTS

Visual Inspection of Automatic Volumetric Micropipettes

We analyzed 50 micropipettes from the three major cities of the Democratic Republic of the Congo, including 21/50 (42%) from Kinshasa, 18/50 (36%) from Bukavu, and 11/50 (22%) from Kisangani. All these air displacement micropipettes (type A) were single-channel, with fixed volumes (7/50, i.e., 14%) and variable volumes (43/50, i.e., 86%). These pipettes came from different biochemistry and microbiological laboratories of the university hospitals in these three cities.

Precision

Table 2 shows the accuracy test results of the studied volumetric automatic micropipettes.

Table 2:
The Precision Test Results of the Volumetric Automatic Micropipettes Studied

N°	Sample volume	Number of corresponding volumes	Precised		Non-precised	
			Group	*Percentage*	*Group*	*Percentage*
1	2	2	1	50.0	1	50.0
2	5	4	2	50.0	2	50.0
3	10	6	4	66.7	2	33.3
4	20	15	12	80.0	3	20.0
5	50	7	5	71.4	2	28.6
6	100	31	26	83.9	5	16.1
7	200	13	10	76.9	3	23.1
8	500	19	15	78.9	4	21.1
9	1000	18	15	83.3	3	16.7
10	2500	1	1	100.0	0	0.0
11	5000	1	1	100.0	0	0.0
12	2	2	1	50.0	1	50.0
Total		**117**	**92**	**78.6**	**25**	**21.4**

Accuracy

Table 3 shows the results of testing the accuracy of the studied volumetric automatic micropipettes.

Table 3:
The Results of Testing the Accuracy of the Studied Volumetric Automatic Micropipettes

N°	Sample volume	Number of corresponding volumes	Accurate		Non-accurate	
			Group	*Percentage*	*Group*	*Percentage*
1	2	2	2	100.0	0	0.0
2	5	4	3	75.0	1	25.0
3	10	6	5	83.3	1	16.7
4	20	15	12	80.0	3	20.0
5	50	7	4	57.1	3	42.9
6	100	31	22	71.0	9	29.0
7	200	13	9	69.2	4	30.8
8	500	19	16	84.2	3	15.8
9	1000	18	16	88.9	2	11.1
10	2500	1	1	100.0	0	0.0
11	5000	1	1	100.0	0	0.0
12	2	2	2	100.0	0	0.0
Total		**117**	**91**	**77.8**	26	**22.2**

Conformity

Figure 1 shows the compliance results of the volumetric automatic micropipettes studied, and **Table 4** relates the compliance against the university hospital cities.

Figure 1:
The Results for Compliance of the Sampling Volumes Studied (**A**) and Those for Compliance of the Automatic Volumetric Micropipettes (**B**)

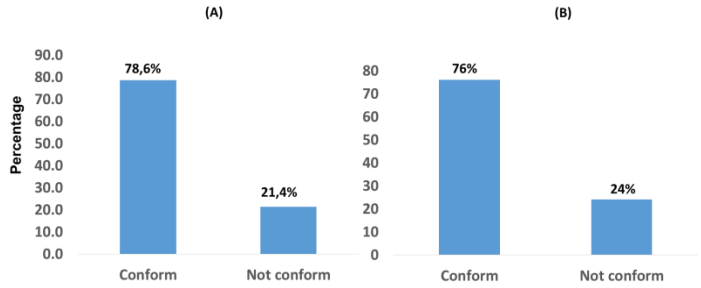

Table 4:
Compliance Results of Automatic Volumetric Micropipettes According to University Hospitals

N°	University Hospitals	Conform		Not conform	
		Group	*Percentage*	*Group*	*Percentage*
1	Kinshasa	14/21	28	7/21	14
2	Bukavu	13/18	26	5/18	10
3	Kisangani	11/11	22	0/11	0
	Total	**50**	**76**	**50**	**24**

Table 5:
Results of micropipette FINNPIPETTE (100 -1000µl) from Bukavu qualification

Collection (µL)	**100µl**	**500µl**	**1000µl**
	Weight (mg)	*Weight (mg)*	*Weight (mg)*
Collection 1	95,9	540,9	988,9
Collection 2	98,1	496,7	952,6
Collection 3	95,2	489,8	958,1
Collection 4	95,6	489,2	985,4
Collection 5	95,7	475,1	965,2
Collection 6	95,9	491,4	979,2
Collection 7	97,4	493,7	967,4
Collection 8	96,3	539,4	991,2
Collection 9	98,3	575,2	979,7
Collection 10	93,7	585,1	988,9
Mean (µl)	96,2	517,7	975,7
Theorical Volume (µl)	100	500	1000
SD (µl)	1,40	39,4	13,9
Precision (RSD%)	1,5	7,6	1,4
Intermediate precision (Bias relatif en %)	3,8	3,5	2,4

DISCUSSION

This study shows that 21.4% and 22.2% of the sample volume studied were respectively non-precise and not exact. This situation could serve as the basis for unreliable results in certain diagnostics in medical laboratories (Magny, et al., 2001; Dumontet, et al., 2009). **Figure 1** shows that 24% of the micropipettes analyzed were non-compliant, with 14% and 10% in Kinshasa and Bukavu, respectively. All the micropipettes analyzed from Kisangani were compliant, possibly because they were newly purchased. It should be noted that the non-conformity of these micropipettes may be attributed to lack of maintenance, inappropriate use, or the age of the equipment.

Furthermore, most of the laboratories that supplied these micropipettes are not accustomed to checking the performance of the equipment they use in clinical biology. These results will encourage these laboratories to establish a system for monitoring the performance of equipment used in quality control.

CONCLUSION

The main objective of this study was to verify the performance of automatic volumetric micropipettes used in some hospitals in three cities in the Democratic Republic of the Congo—Bukavu, Kisangani, and Kinshasa—with the aim of contributing to improving the reliability of diagnostic results in these hospitals. We analyzed 50 micropipettes from these three major cities of the Democratic Republic of the Congo. All these air displacement micropipettes (type A) were single-channel, with fixed volumes (7/50, i.e., 14%) and variable volumes (43/50, i.e., 86%).

The tolerances recommended by ISO 8655: 2002 standards were applied in the analysis of the results. The results obtained show that 12/50 or 24% of the micropipettes analyzed were non-compliant. This unfortunate reality indicates that the quality assurance system is not yet functioning effectively in several university hospital laboratories, which could negatively impact diagnostic results. It is essential that the bioanalysis laboratory located in university hospitals implement a system for regular verification of the performance of automatic volumetric micropipettes to ensure the reliability of diagnostic results and safeguard the health of the population.

Ethical Approval: Not applicable

Conflicts of Interest: None declared.

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