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Verification of serum protein electrophoresis on the Cappilarys 2 Flex Piercing automaton

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ABSTRACT

Introduction: The verification/validation of analytical equipment and methods is both part of this reasoning and an indispensable condition for their use and is one of the priorities of the medical biologist. The aim of our study is to verify the electrophoresis of serum proteins on the Cappilarys 2 Flex Piercing automaton.

Materials and methods: The evaluation methodology concerned the scope A which is based on the recommendations of the Valtec protocol of the French Society of Clinical Biology, as well as those of the SH-GTA O4 protocol of the COFRAC (Comité français d'accréditation). We studied the repeatability on normal and pathological serum samples, and the reproducibility on normal and pathological internal quality control samples.

Results: The values of the coefficient of variation of repeatability and reproducibility obtained by our study for each serum protein fraction (Albumin, Alpha-1, Alpha-2, Beta-1, Beta-2, Gamma globulins), are overall satisfactory and are in accordance with the requirements issued by the supplier and those issued by RICOS. In addition, these results are consistent with those of other similar studies.

Discussion and conclusion: This type of study will provide a solid basis for the realization of an accreditation procedure for the tests used in our laboratory. For any laboratory wishing to be accredited according to the ISO 15189 standard, the validation/verification of methods is a determining criterion. It is an essential step to be taken before the implementation of the newly acquired equipment.

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Abbreviations

COFRAC, Comité français d'accréditation; CV, Coefficient of variation; IQC, Internal quality control; QC, Quality control; GBEA, Guide de Bonne Exécution des Analyses de biologie Médicale.

Introduction

The concept of quality in medical laboratories corresponds to a set of conditions for the accuracy and reliability of test results. Indeed, in order to be used in clinical practice or in public health, it is essential that the results obtained by medical laboratories are as accurate as possible (1, 2). To achieve this, it is necessary to master and correctly execute all the steps of the macro-analysis process that constitutes this complex laboratory system, including the pre-, per- and post-analysis phases (1, 3). The objective of this approach is to enable the laboratory to meet regulatory and normative quality standards and to meet the appropriate care needs of its patients. The verification/validation of equipment and analytical methods is part of this approach and is an essential condition for their use. The medical biologist is required to make the best choice of instruments and to objectively justify his decisions, in accordance with the "Guide de Bonne Exécution des Analyses de biologie Médicale" (GBEA), which has governed Moroccan medical analysis laboratories since November 2010 (4), and the ISO 15189 standard concerning their possible accreditation (5). The objective of our study is to verify the electrophoresis of serum proteins on the Cappilarys 2 Flex Piercing automaton.

Materials and Methods

Our study was carried out on the Capillarys 2 Flex Piercing automaton from Sebia for the qualitative and quantitative analysis of serum and urine proteins. The different fractions studied are separated according to their charge in an alkaline buffer (pH 9.4). The serum samples used in our study, one normal and one pathological serum were randomly selected from the routine tests received in the laboratory. The evaluation methodology concerned scope A which is based on the recommendations of the Valtec protocol of the French Society of Clinical Biology, as well as those of the SH-GTA O4 protocol of the COFRAC (Comité français d'accréditation) (7, 8).

Repeatability

Repeatability corresponds to the realization of an analysis of the same sample under the same conditions (operator, reagent lot, instrument, calibration).

For the study of repeatability, two serum samples were chosen, normal and pathological (hyper gammaglobulins), with respect to the reference values mentioned in table 1.We performed ten runs for each level (normal and pathological), and we calculated for each level the mean, the standard deviation, and the coefficient of variation (CV).

Table 1. Reference values of the different protein fractions for normal serum (Serum protein = 70 g/L).

Protein fractions	Reference value (6)
Albumin	39-46.3 (55.7-66.14%)
α1-globulins	2.1-3.4 (3-4.85%)
α2-globulins	5-8.3 (7.14-11.85%)
β1-globulins	3.3-5 (4.71-7.14%)
β2-globulins	2.2-4.5 (3.14-6.42%)
γ-globulins	7.8-13.2 (11.14-18.85%)

Reproducibility

Reproducibility includes the analysis of the same sample by varying at least one of the conditions (operator, time, batches of reagents ...). For reproducibility, two levels of internal quality control are chosen, normal and pathological (hyper gammaglobulins). Thirty runs were performed for each level (normal and pathological), and the mean, standard deviation, and coefficient of variation were calculated for each level.

Statistical analysis

Statistical analysis of the results was performed using Excel® Microsoft® 2016 software, by calculating CVs and comparing them with the CVs reported by the provider and RICOS. We note that the French Society of Clinical Biology has not published any values in this sense.

Results

Repeatability study

The results of statistical calculations of repeatability (mean and coefficients of Variation) are given in Table 2 for normal sera and Table 3 for pathological sera, with comparison to the supplier's (Sebia) standards, and to RICOS standards.

Table 2. Results of the repeatability study for normal serum, by serum protein electrophoresis on Capillarys 2 Flex Piercing (9).

Serum Protein	Average %	CV % laboratory	CV % supplier (Sebia)	CV % (RICOS)
Albumin	64.6	1.73	2.00	1.20
α1-globulins	4.1	2.95	7.00	4.28
α2-globulins	7.77	1.88	7.00	4.90
β1-globulins	5.74	1.56	7.00	3.83
β2-globulins	4.33	1.89	7.00	3.83
ɣ-globulins	13.46	1.94	4.00	5.48

CV, Coefficient of variation.

Table 3. Results of the repeatability study for pathological serum by serum protein electrophoresis on Capillarys 2 Flex Piercing (9).

Serum Protein	Average %	CV % laboratory	CV % supplier (Sebia)	CV % (RICOS)
Albumin	38.8	1.9	2,00	1.20
α1-globulins	6.8	2,85	7.00	4.28
α2-globulins	9.6	1,92	7.00	4.90
β1-globulins	5.5	1,73	7.00	3.83
β2-globulins	6.3	2,36	7.00	3.83
ɣ-globulins	33	1,98	4.00	5.48

CV, Coefficient of variation.

Study of the reproducibility

The results of the statistical calculations of reproducibility (means and CVs) are shown in Table 4 for normal serum and Table 5 for pathological serum.

Table 4. Results of the reproducibility study for normal internal quality control (IQC), by serum protein electrophoresis on Capillarys 2 Flex Piercing (9).

Serum Protein	Average %	CV % laboratory	CV % supplier (Sebia)	CV % (RICOS)
Albumin	65.1	0.98	1.20	1.6
α1-globulins	4.6	2.56	4.00	5.7
α2-globulins	5.3	1.87	3.00	5.2
β1-globulins	4.12	1.96	5.00	5.1
β2-globulins	4.65	2.1	3.80	5.1
ɣ-globulins	16.23	1.91	2.10	7.3

CV, Coefficient of variation.

Table 5. Results of the intermediate fidelity study for pathological internal control by serum protein electrophoresis on Capillarys 2 Flex Piercing (9).

Serum Protein	Average %	CV % laboratory	CV % supplier (Sebia)	CV % (RICOS)
Albumin	35,6	1,1	1,20	1,6
α1-globulins	6,2	2,3	4,00	5,7
α2-globulins	9,1	1,98	3,00	5,2
β1-globulins	6,3	1,79	5,00	5,1
β2-globulins	5,3	2,04	3,80	5,1
ɣ-globulins	37,5	1,94	2,10	7,3

CV, Coefficient of variation.

Discussion

We compared both the results of our study with the values reported by the vendor in their technical documentation and with RICOS (9). To obtain a good clinical interpretation, a CV value of 5% was chosen as the limit of acceptability for each protein fraction, independently of the concentration of the QC or the biological sample used, as in other studies (10-12).

The CV values that were obtained by the method repeatability study are overall satisfactory and are in accordance with the requirements issued by the supplier and those issued by RICOS. In addition, these results are also similar to those of other studies including a study performed at the Military Hospital of Instruction Mohammed VI in Rabat (13).

The reproducibility results were compared to the supplier values and RICOS acceptable limits, respectively. In agreement with other works (6-9), a limit CV for reproducibility of 5% was chosen for all protein fractions. The CVs achieved according to the values declared by the supplier are excellent; they are also lower than the acceptable limits proposed by RICOS. The values obtained are in agreement with other studies (10- 14).

The results are consistent with the values stated by the supplier and by RICOS. The central laboratory of the University Hospital Mohammed VI of Oujda has adopted a quality policy including a process of verification of methods according to scope A, and an accreditation process. This kind of study will provide a solid basis for the realization of an accreditation procedure for the tests used in our laboratory.

Conclusion

For any laboratory wishing to be accredited according to the ISO 15189 standard, method validation/verification is a determining factor. It is an essential step to be taken before the implementation of the newly acquired equipment. It concerns many sectors as indicated in the quality standards. The verification showed that the performances of the controlled automaton were satisfactory for all the evaluated parameters and in conformity with the requirements of the standards.

Declarations

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None.

Conflicts of interest

The authors declare that they have no conflicts of interest in relation to this article.

Authors' contributions

The authors acknowledge having actively participated in the work, having read the content of the article and having given their agreement to this content.

Ethics approval

The study was conducted in accordance with the Declaration of Helsinki.

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