The relationship between Metrological Traceability and Comparability of results for 5 analytes in 5 laboratory measurement systems

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Abstract.
This work presents the results obtained for 4 months in 5 measurement systems with the same material. “Bio-Rad Lyphochek Assayed Chemistry Control” lot 26430 in 2 levels and their relationship with the Metrological traceability for material and primary calibrators of each system. There are reference materials commonly used in Colombia, although they are not always traceable to those endorsed by the JCTLM (the highest hierarchical order available), the results are harmonized in several cases. The use of third opinion quality control materials, which can be used cross-sectionally in various measurement systems of various manufacturers, becomes a valuable tool to assess harmonization between the results obtained in different measurement systems.

Introduction.
More and more publications related to metrological traceability are found (1-6) and the awareness of their importance to achieve reliable and harmonizable results has increased. Although much more promotion and dissemination of the concept and its applications are lacking, because in spite that the information about the materials to which the tests in the clinical laboratory are traceable is located in the web page of the majority of these IVD companies, we have free access (7-30), this, is poorly known and poorly accessed by the end user of the clinical laboratory, (1).

The excellent attitude of the colleagues in Colombia of the 5 IVD companies involved in this study was very valuable, they let us know how to access to the Traceability information.

Materials and Methods
The measurement systems included in this study were Roche (Cobas), Ortho-Clinical Diagnostics-OCD (Vitros), Siemens Healthineers (Advia), Abbott (Architect) and Beckman Coulter. The information for materials and methods reported by each manufacturer for the analytes of interest was obtained from the inserts package of the tests and calibrator, and specific documents produced by each manufacturer. The values were obtained from the monthly Bio-Rad Unity Worldwide Report for “Bio-Rad Lyphochek Assayed Chemistry Control” lot 26430, for February, March, April and May 2019 (31) and The information for materials and reference methods was obtained from the JCTLM database (35).

The information obtained from the Unity Worldwide Report was organized with means, standard deviation, SD coefficient of variation, CV, and number of points used to calculate means, SD and CV. The information reported on a box plot by locating the average value in half, representing the standard deviation on the whiskers and placing the number of points used in the calculation of these statistics. The information obtained for Roche Cobas was graphed in blue, for Abbott Architect in green, Siemens Advia in orange, OCD Vitros in Brown and Beckman Coulter with purple.

Results.
For Magnesium is observed that the results of Roche Cobas, and Beckman coulter AU series are harmonizable during the 4 months and the 2 measurement systems are traceable to the same SRM 915 material. Although the manufacturer Roche Cobas does not declare the specific lot. Abbott Architect is traceable also to SRM 956, although it also does not declare the lot and only in the 4th month, May of the 4 studied achieves harmonization with Roche Cobas and Beckman Coulter.

For Chloride 5 of the 5 manufacturers report harmonizable values for the two concentration levels and 4 of the 5 are traceable to the same material, the SRM 919, however with OCD-Vitros they are observed consistently during the 4 months lower values than for the other manufacturers, None of the manufacturers are traceable to the same SRM 929 material, but their results for level 2 are not harmonizable. None of the 5 manufacturers of the study is traceable to any of the materials endorsed by the JCTLM.

For Calcium, 3 manufacturers are traceable to the SRM 956 Roche Cobas and Beckman Coulter, and although Abbott does not declare the lot of the SRM 956 to which it is traceable, harmonization of the results obtained by these 3 measurement systems is observed. Two others are traceable to SRM 919, Siemens Advia and OCD Vitros, harmonization is observed for level 2, but at level 1 OCD present lower values. None of the manufacturers is traceable to any of the materials endorsed by the JCTLM. In other words, there is harmonization but no traceability at the highest hierarchical order available.

For Potassium, 3 of the 5 manufacturers are traceable to SRM 919 and harmonization is observed in the values for the two levels evaluated. Siemens Advia is traceable to SRM 909. However, in both cases, the material is not traceable to Roche Cobas.

Conclusions
IVD Manufacturers are increasingly aware of the importance of declaring the traceability of their tests to reference materials and procedures, although at the local level, specifically in Colombia, this information, although freely accessible, is not processed among end users. The use of Bio-Rad’s third opinion quality material among other additional advantages allows visualizing the harmonization of the results obtained by different measurement systems. In many different tests, harmonization is observed, but not necessarily traceability at the highest hierarchical order available.