

# 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 measurements 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 procedure for 5 analytes, There are reference materials commonly used by several manufacturers and 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 been increasing. 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, with free access (7-30), this, is poorly known and poorly accessed by the end user of the clinical laboratory, (1),

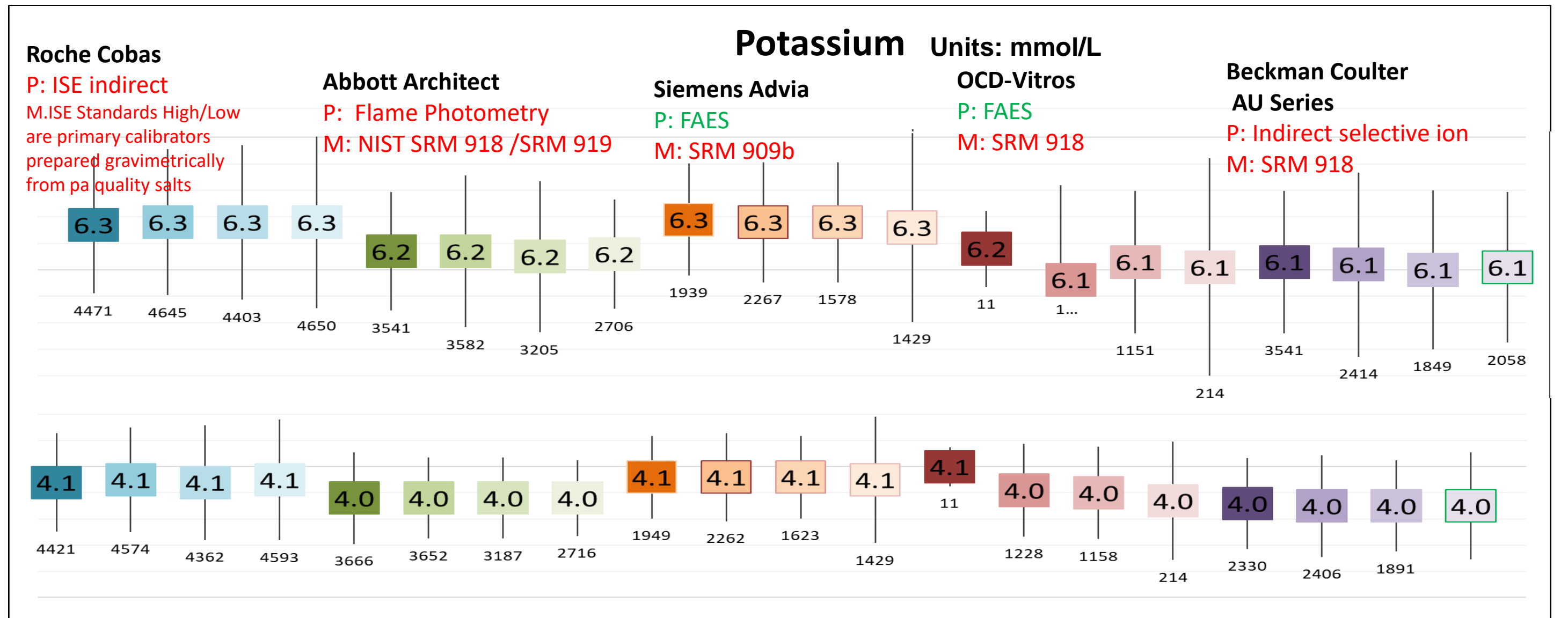
The excellent attitude of the colleagues in Colombia of the 5 IVD companies involved in this study was very valuable, they let us know how to access to the Traceability information..

## 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 special 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, (31-34). and The information for materials and reference methods was obtained from the JCTLM database. (35)

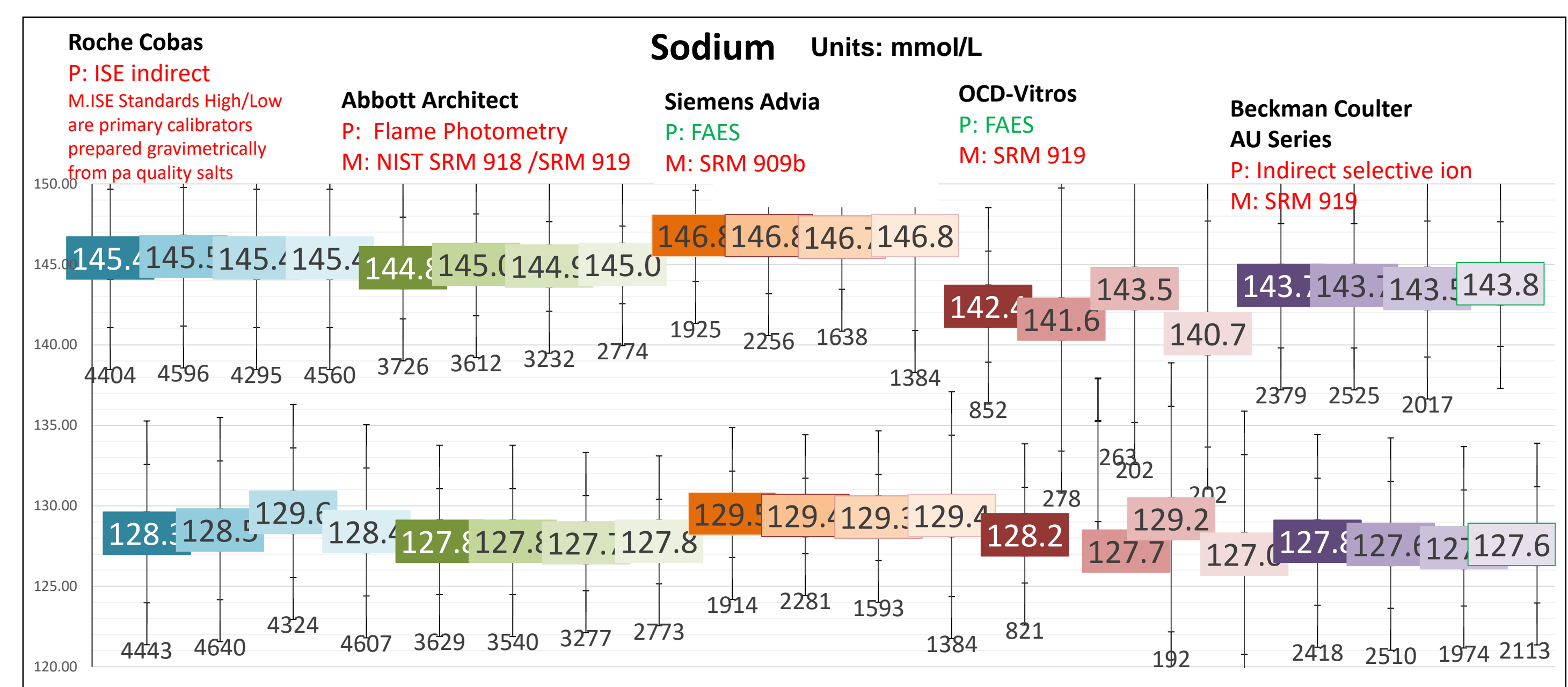
The information obtained from the Unity Worldwide Report was organized with means, standard deviation, SD coefficient of variation, CV, and number of points used to calculate means, SD and CV. These was plotted on a box plot by locating the average value in half, representing the standard deviation on 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 AU Series in purple.

The information for each measurement system was ordered with the corresponding color in darker to lighter tones from February, March, April and May 2019. The information corresponding to the material and procedure to which each manufacturer declares is traceable was placed on the box plots. (In green if it corresponded to any endorsed by the JCTLM, in red if it did not correspond, in purple if the information was not found )



**JCTLM Reference Procedure Approved:** FAES (Flame Atomic Emission Spectroscopy), Inductively Coupled Plasma-(Isotope Dilution) Sector Field Mass Spectrometry (ICP-(ID) SFMS), Inductively coupled plasma optical emission spectrometry (ICP-OES), ID/ICP-MS, Inductively Coupled Plasma Mass Spectrometry (ICP-MS), Ion chromatography, IDMS.

**JCTLM Reference material Approved:** SRM 3141a, Potassium standard solution, SRM 918b, Potassium Chloride (Clinical Standard), HRM-2002A, Potassium, Calcium and Sodium in Frozen Human Serum, NIM CRM GBW09125, Electrolytes in Frozen Human Serum, JCCRM 111, electrolytes, DMR-57, Potassium spectrometric solution, NIM CRM GBW09124, Electrolytes in Frozen Human Serum, NIM CRM GBW09126, Electrolytes in Frozen Human Serum.



**JCTLM Reference Procedure Approved:** FAES (Flame Atomic Emission Spectroscopy), Gravimetry, Inductively Coupled Plasma-(Isotope Dilution) Sector Field Mass Spectrometry (ICP-(ID) SFMS), Inductively Coupled Plasma Mass Spectrometry (ICP-MS), ICP-OES, Inductively coupled plasma optical emission spectrometry (ICP-OES), Ion chromatography.

**JCTLM Reference Material Approved:** SRM 3152a, Sodium standard solution, JCCRM 111, electrolytes, SRM 919b, Sodium Chloride (Clinical Standard), DMR-56, Sodium spectrometric solution, NIM CRM GBW09124, Electrolytes in Frozen Human Serum, NIM CRM GBW09125, Electrolytes in Frozen Human Serum, NIM CRM GBW09126, Electrolytes in Frozen Human Serum, MRC 8937.0001, Sodium diclofenac.

## Results.

For **Magnesium** it 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 956 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 4-month, May of the 4 studied achieves harmonization with Roche Cobas and Beckman Coulter. Siemens Advia and OCD Vitros 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 **Chloride** 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 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 **Calcium**, 3 manufacturers are traceable to the SRM 956c 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 915, 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 918 and harmonization is observed in the values for the two levels evaluated. Siemens Advia is traceable to SRM 909b their values are harmonizable with Roche Cobas. The SRM 918b reference material is endorsed by the JCTLM, but none of the 3 manufacturers that are traceable to the SRM918 declare the lot.

For **Sodium**, 3 manufacturers, Abbott Architect, OCD-Vitros and Beckman Coulter AU Series are traceable to SRM 919, and harmonization is observed between the results of level 1 for BC and Abbott, OCD-Vitros despite being traceable to the same material presents results slightly different. Siemens Advia is traceable to SRM 909b and for Roche are primary calibrators prepared gravimetrically from pa quality salts

The SRM 919b reference material is endorsed by the JCTLM, but none of the 3 manufacturers that are traceable to the SRM919 declare the lot.

## Conclusions

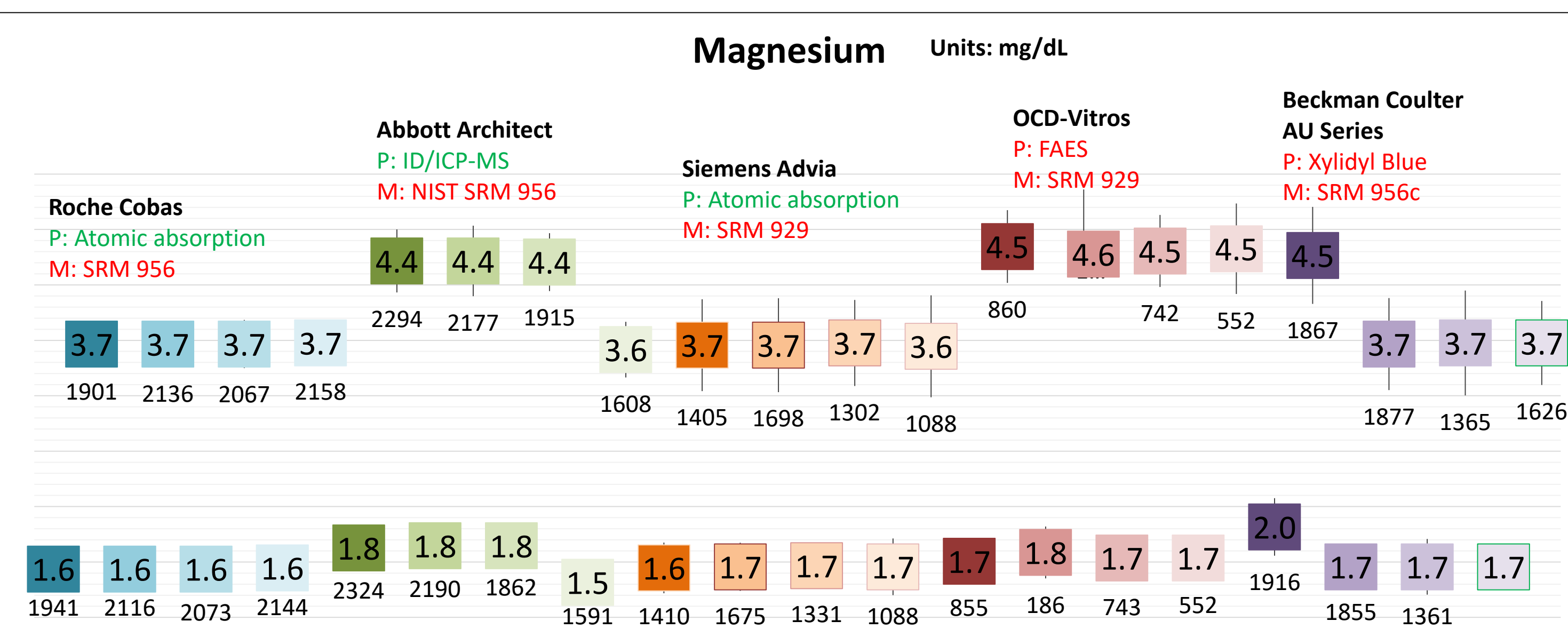
IVD Manufacturers are increasingly aware of the importance of declaring the traceability of their tests to reference materials and procedures, although at the local level, specifically in Colombia, this information, although freely accessible, is not promoted among end users.

The use of Bio-Rad's third opinion quality material among other additional advantages allows visualizing the harmonization of the results among various measurement systems. The Bio-Rad UNITY interlaboratory comparison report is a valuable tool in the evaluation of 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.

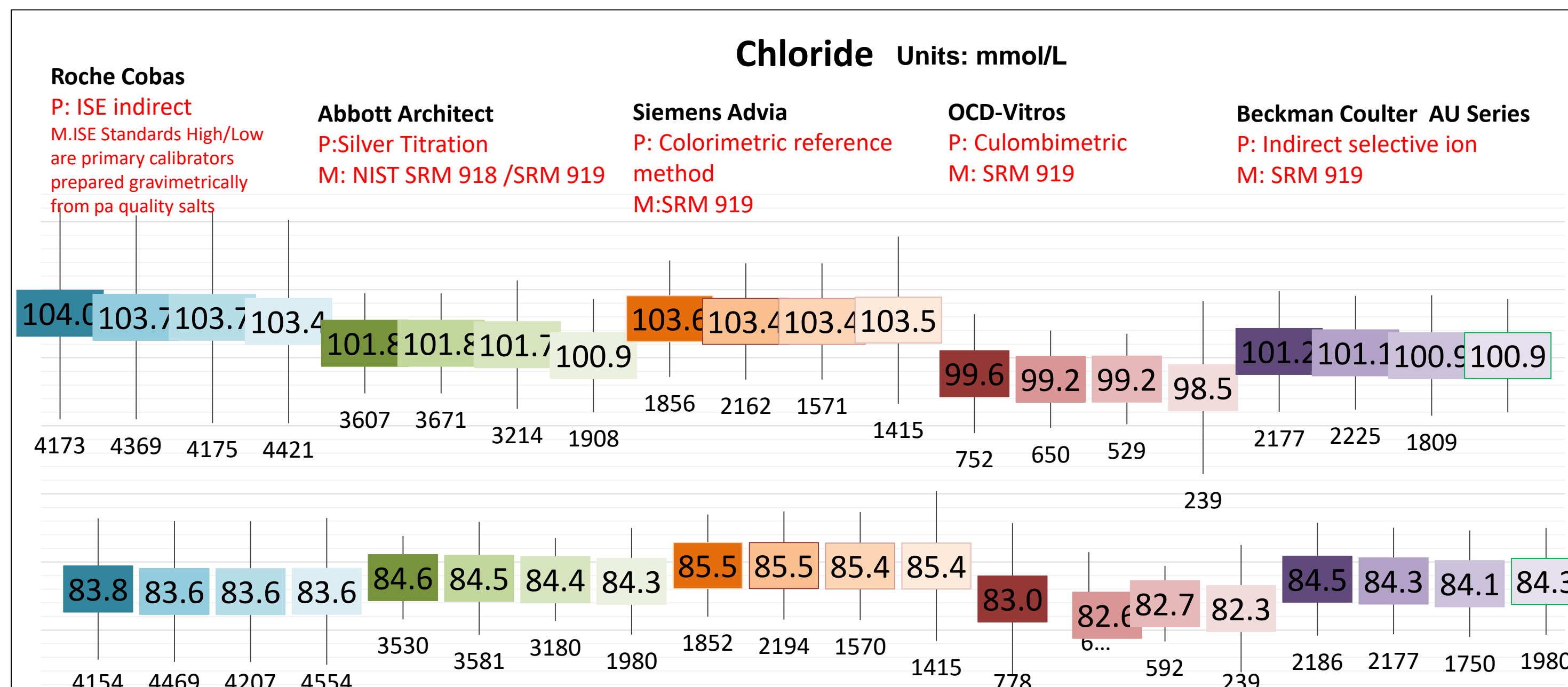
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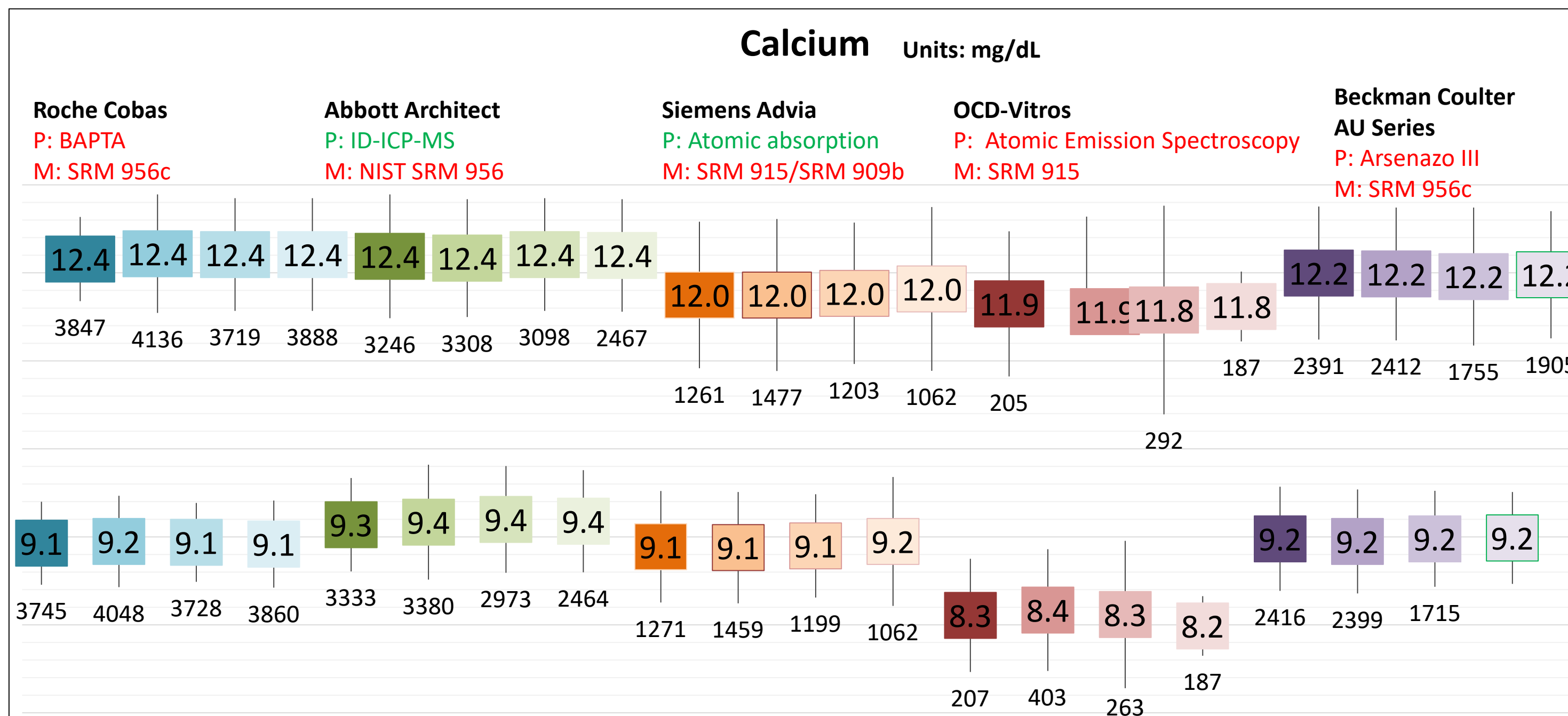
**JCTLM Reference Procedure Approved:** FAAS, Atomic absorption, Inductively Coupled Plasma-(Isotope Dilution) Sector Field Mass Spectrometry (ICP-(ID) SFMS), Inductively Coupled Plasma Mass Spectrometry (ICP-MS), Inductively coupled plasma optical emission spectrometry (ICP-OES), Ion chromatography, ID/ICP-MS, ID/TIMS.

**JCTLM Reference Material Approved:** SRM 3131a, Magnesium standard solution, BCR-304, calcium, magnesium and lithium in human serum, DMR-62, Magnesium spectrometric solution, NIM CRM GBW09124, Electrolytes in Frozen Human Serum, NIM CRM GBW09125, Electrolytes in Frozen Human Serum, NIM CRM GBW09126, Electrolytes in Frozen Human Serum, SRM 929a, Magnesium Gluconate.



**JCTLM Reference Procedure Approved:** Coulometry, Coulometric titration, ID/TIMS, Inductively Coupled Plasma Mass Spectrometry (ICP-MS), Inductively Coupled Plasma-(Isotope Dilution) Sector Field Mass Spectrometry (ICP-(ID) SFMS).

**JCTLM Reference Material Approved:** JCCRM 111, electrolytes, SRM 918b, Potassium Chloride (Clinical Standard), SRM 919b, Sodium Chloride (Clinical Standard), NIM CRM GBW09124, Electrolytes in Frozen Human Serum, NIM CRM GBW09125, Electrolytes in Frozen Human Serum, NIM CRM GBW09126, Electrolytes in Frozen Human Serum.



**JCTLM Reference Procedure Approved:** FAAS, Atomic absorption, Inductively Coupled Plasma-(Isotope Dilution) Sector Field Mass Spectrometry (ICP-(ID) SFMS), Inductively Coupled Plasma Mass Spectrometry (ICP-MS), Inductively coupled plasma optical emission spectrometry (ICP-OES), Ion chromatography, Isotope dilution ICP-MS, IDMS.

**JCTLM Reference material Approved:** SRM 3109a, Calcium standard solution, SRM 915b, Calcium carbonate (Clinical Standard), BCR-304, calcium, magnesium and lithium in human serum, HRM-2002A, Potassium, Calcium and Sodium in Frozen Human Serum, NIM CRM GBW09124, Electrolytes in Frozen Human Serum, NIM CRM GBW09125, Electrolytes in Frozen Human Serum, NIM CRM GBW09126, Electrolytes in Frozen Human Serum.