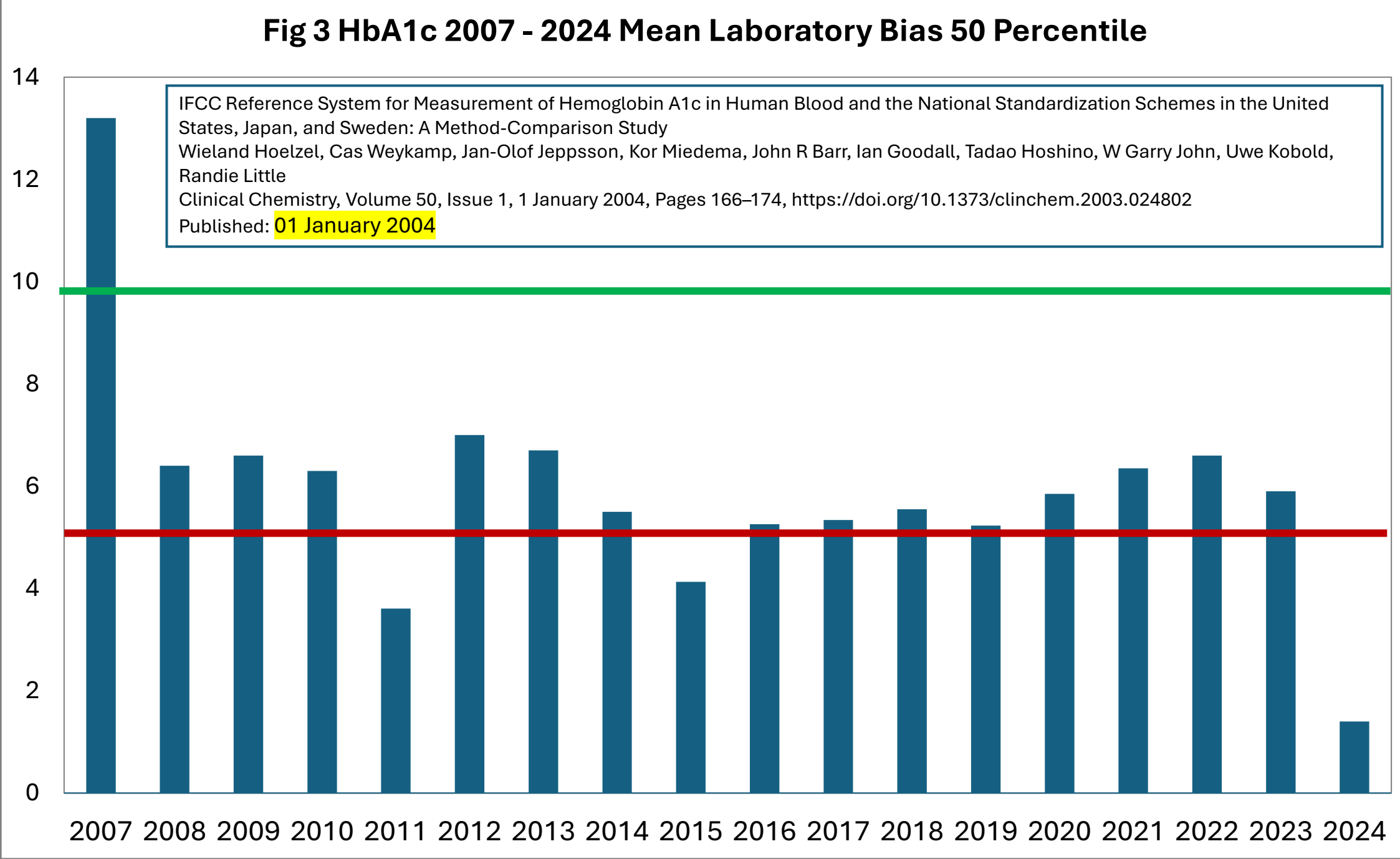
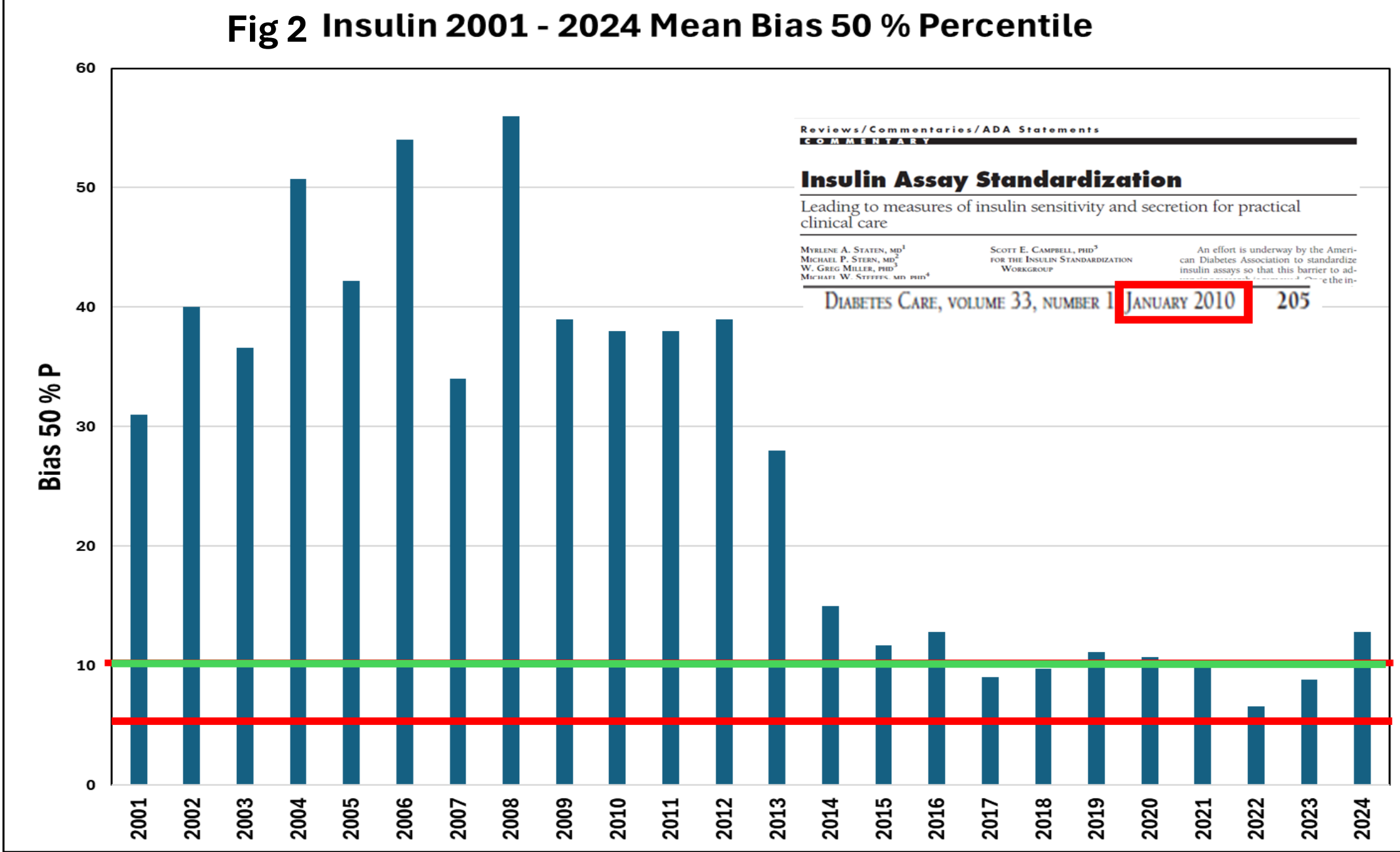
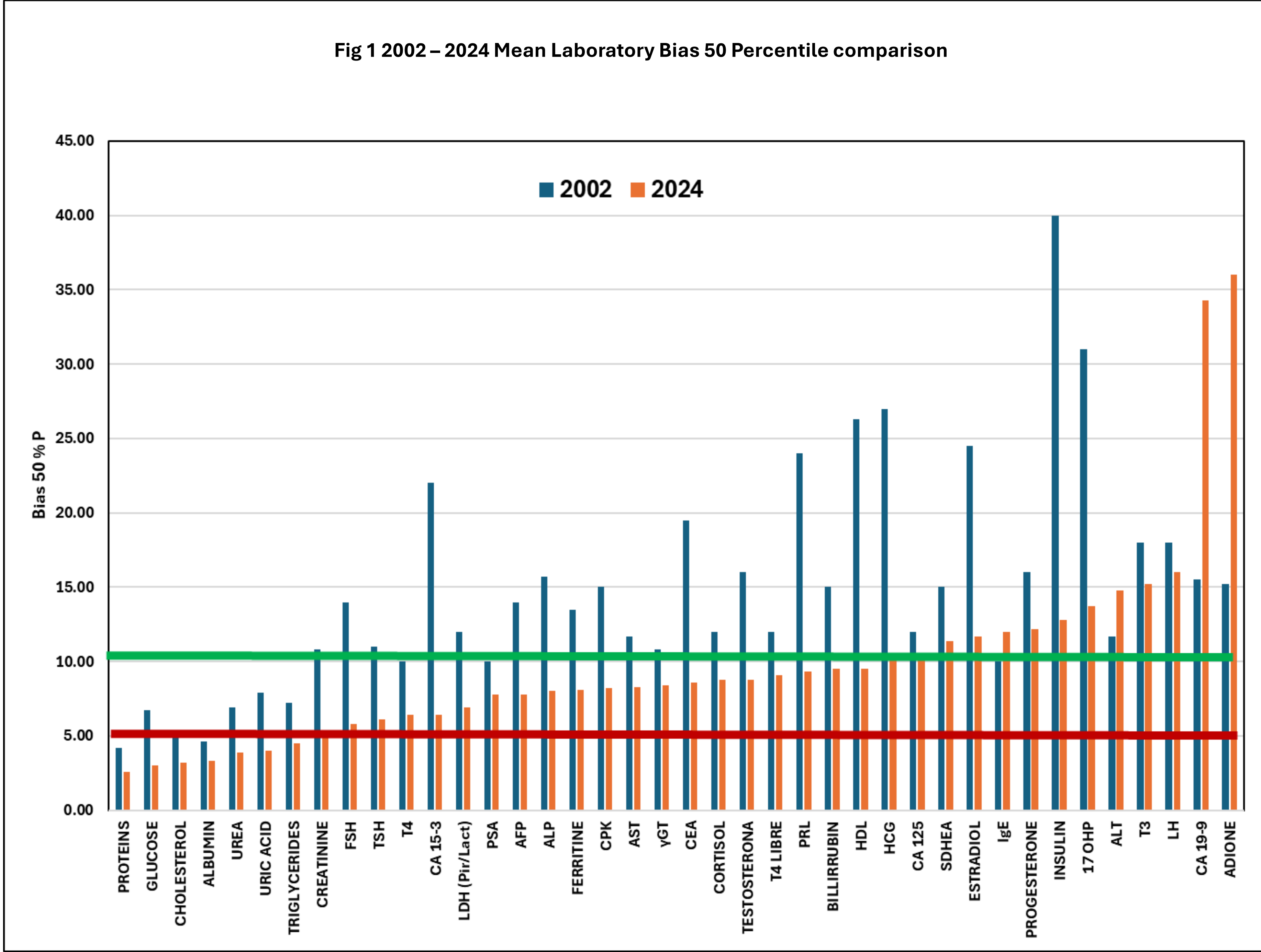


EQAS collaboration with clinical laboratories in evaluating measurands traceability and harmonization along 22 years

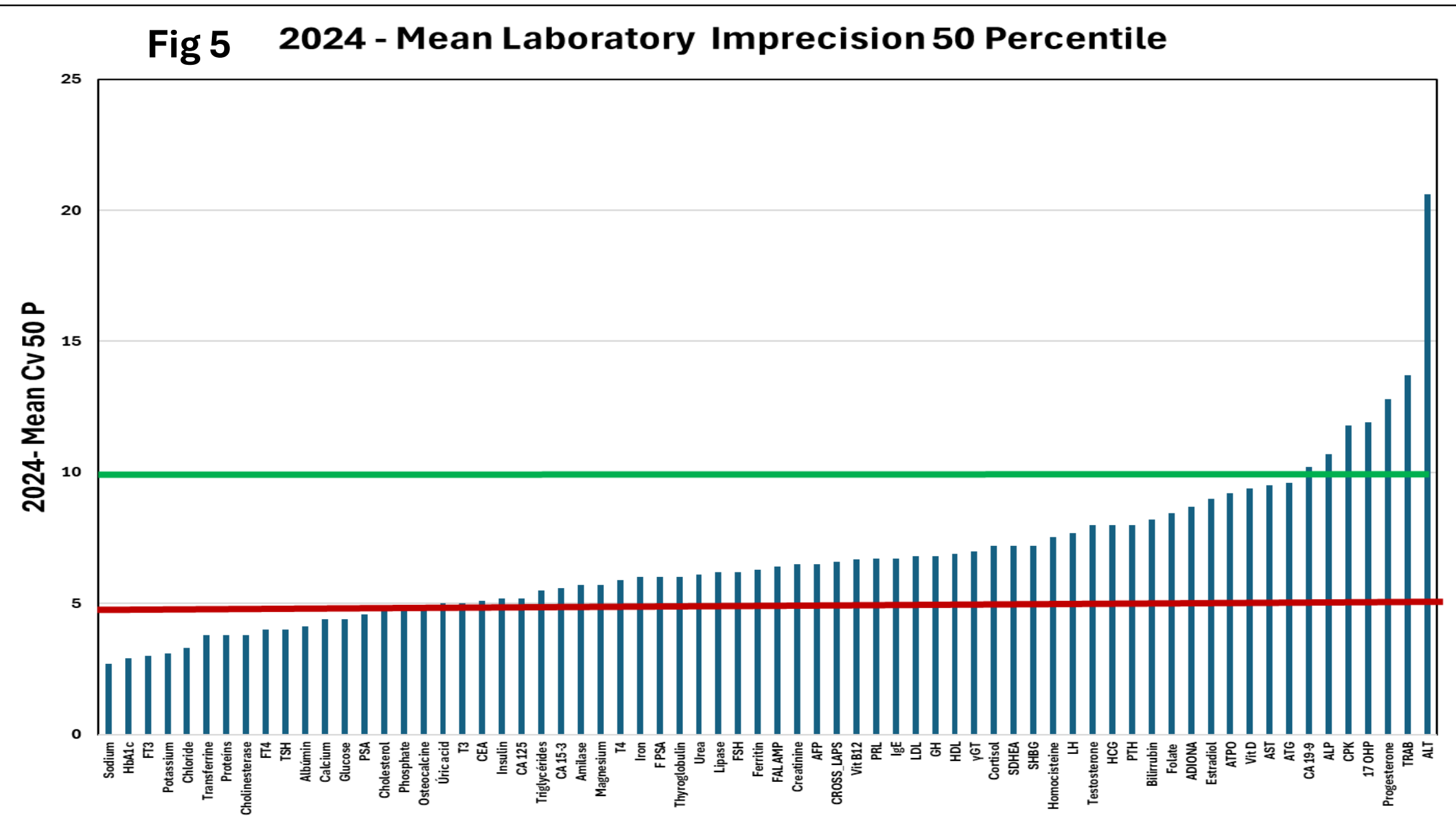
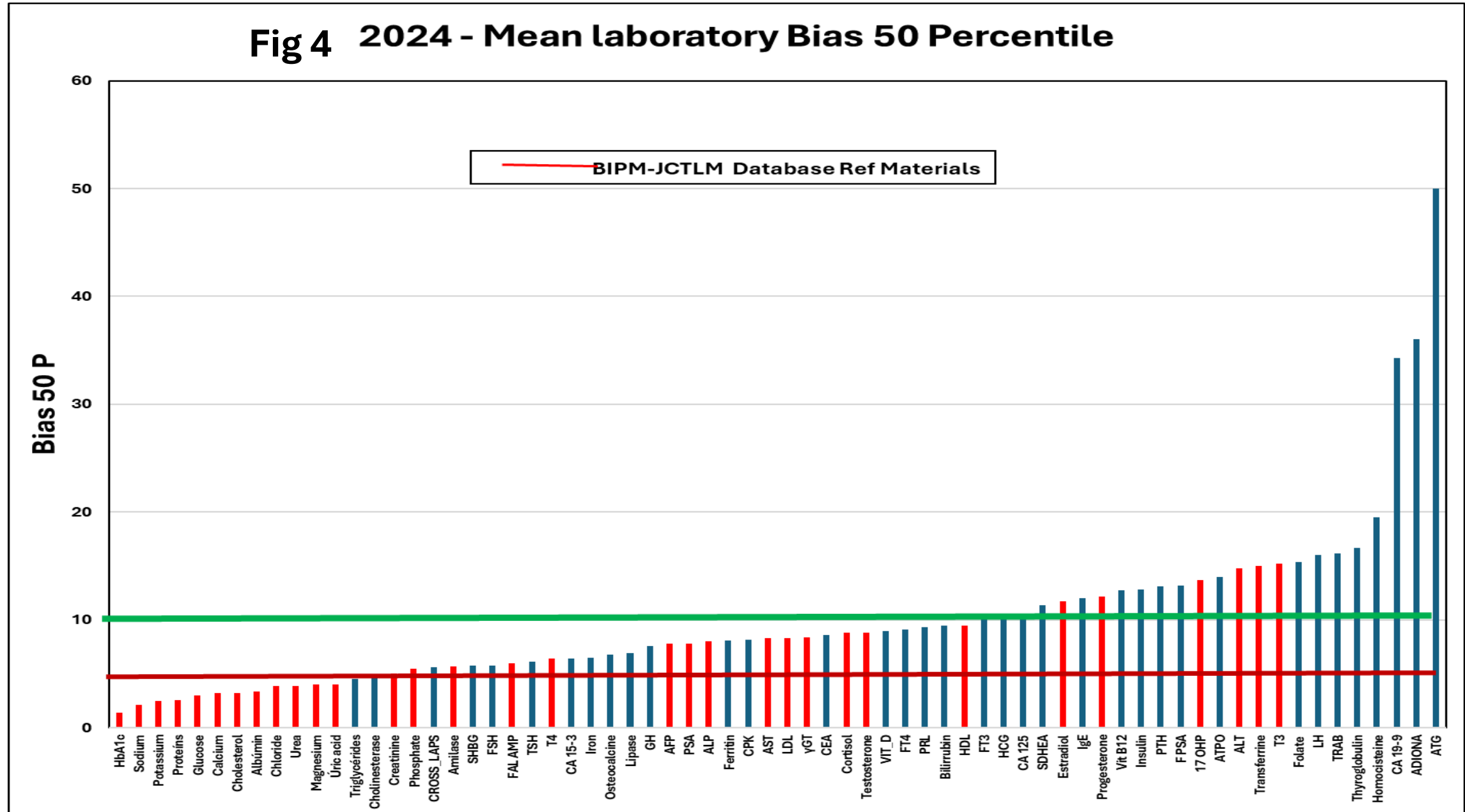
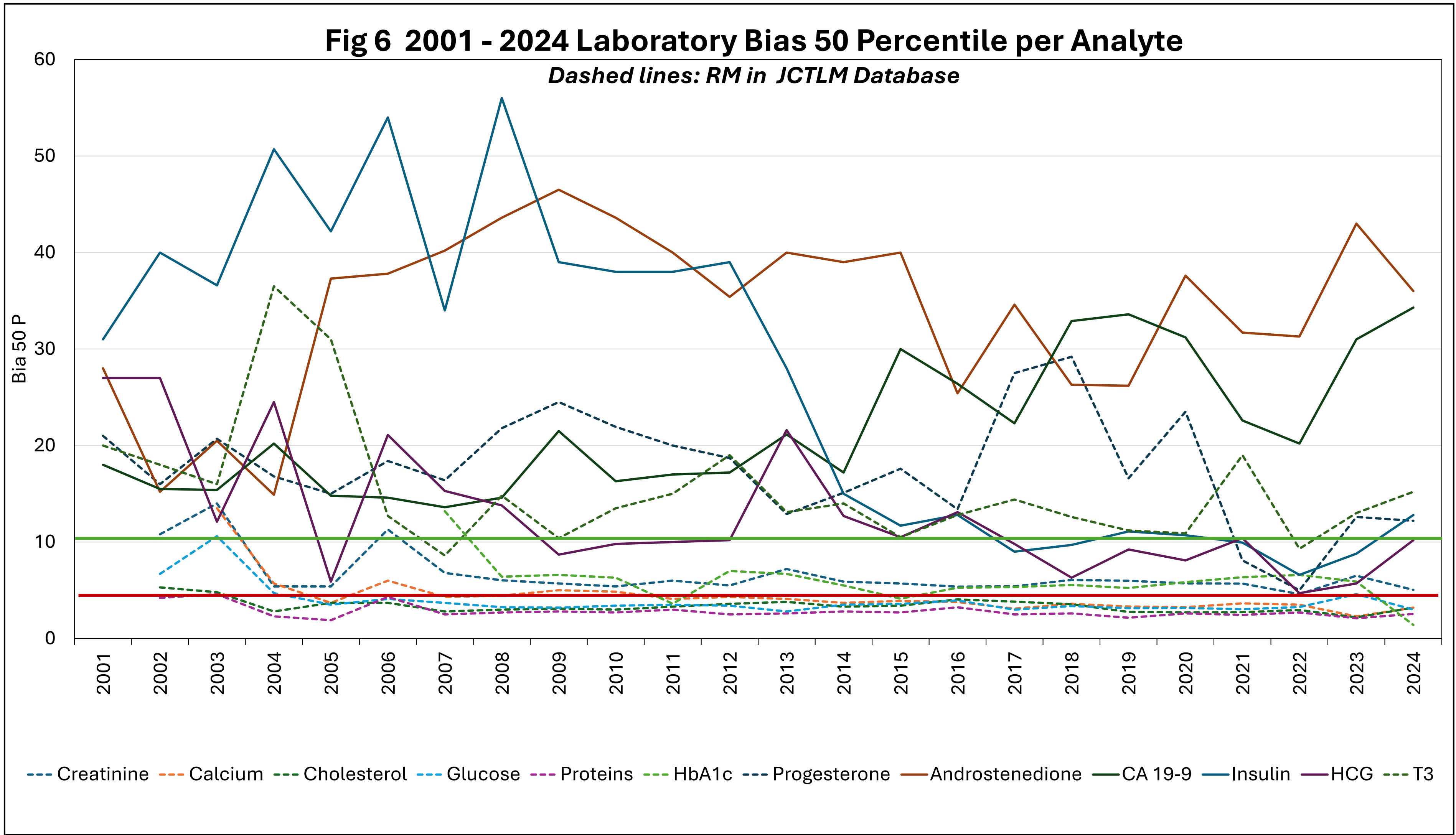
Quiroga S. Del Vecchio L. Torres M. EQAS Programa Buenos Aires (ProgBA) Instituto Universitario CEMIC, IUC. Galván 4102 (1431FWO) CABA Buenos Aires. Argentina squiroga@cemic.edu.ar

Scope: Laboratory medicine has a very important role in clinical diagnosis and follow up. Nevertheless, clinical labs are not reference laboratories and do not use reference methods and/or reference preparations. They present the greatest uncertainty in hierarchical scale of traceability and cannot guarantee it by themselves. They must also be cost effective. There are several partners responsible for the quality and fitness of clinical results, such as reagent manufacturers, clinical labs and global standardization institutions. The Joint Committee on Traceability in Laboratory Medicine (JCTLM) is an international consortium that promotes the global standardization of clinical laboratory test results and provides information on reference materials, reference measurement procedures and reference services that are available around the world 1 . It was established in 2002 through a declaration of cooperation between BIPM, the International Federation of Clinical Chemistry & Laboratory Medicine (IFCC), and the International Laboratory Accreditation Cooperation (ILAC). Since its founding, the role of the JCTLM has expanded to become a global resource for implementing metrological traceability in laboratory medicine

Objetive: External Quality Assessment Schemes (EQASs) can identify where clinical suitability improvement of laboratory results is needed. The relationship between traceability and proficiency testing / EQAS has been extensively demonstrated. The aim of this work is to recognize quality improvements and pitfalls in standardization / homogenization. Since 2010, Buenos Aires EQAS (ProgBA-CEMIC),established in 1979, is a stakeholder of BIPM in JCTLM. Currently, ProgBA has approximately 800 Latin American participants in routine clinical chemistry and hormones and/or other areas. A review of cumulative results from surveys distributed from 2002 to 2024 of 65 clinical chemistry measurands was completed from all labs results, all participant´s mean laboratory bias 50 percentile per analyte respect to all-labs trimmed mean was calculated (Bias 50 P) as bias estimation. 5 (red line) and 10 (green line) percentage bias are shown in figures.



Results: Improvements throughout the 22 years´ period were identified in the measurement of HbA1c, insulin, HCG, calcium and creatinine. For instance, from 2002 to 2024 median all-laboratory % insulin bias decreased from 40 % to 12 %. Pitfalls were found in EQAS results of progesterone, antithyroid and anti- receptor antibodies, androstenedione, triiodothyronine and CA 19-9 among others. For instance, from 2002 to 2024, the median all-laboratory % CA 19-9 bias doubled from 15 % to 30 %. In this measurand group, triiodothyronine has reference methods and reference materials listed in JCTLM Data Base. Others have neither reference material nor reference method, as CA 19-9 and anti-thyroid antibodies. Some of these analytes are very important in clinical practice.



Conclusions: From cumulative results analysis, EQAS can overview which measurands need to be better standardized or homogenized, depending on their situation in the calibration hierarchy. The JCTLM must call attention to reagent manufacturers, reference materials producers and laboratories that develop reference methods to achieve the required harmonization and cooperate to increase adequate patient outcomes and safety.

References
1 JCTLM Database <https://www.jctlmdb.org/#/app/home>
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