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Findings in a metrological analysis of strips-test use in diabetes home-care control: a confirmation

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Recently a study by this author has been published [1] about critical inconsistencies affecting this extremely extended type of control in home care. It was shown that basically the tests could be false or inconclusive due to insufficient rules of normalization governing this kind of test. In particular, the meaning of the advised (marginal) use of “control solutions” is mistaken, by being considered only a qualitative check of the tester readings, with no correlation with the capillary-blood glucose-level measured values. Instead, according to basic standard rules governing the field of testing, that control solution has to be considered a “reference material”, and consequently the way to check the calibration of the testers—whose re-calibration should then be allowed when necessary (a feature presently not allowed). The previous study was conducted on 4 popular testers (among the dozens existing) and their strips for the pre-diabetes range only. Now an additional semi-professional one has been used for the same purpose, on the same patient—note that this study directly concerns the quality of the instruments, the testers, not the measurement on the glucose level in capillary blood of a population of patients.

A one-year use of the new tester showed a quite different situation of consistent readings, based on an off-shelf correct calibration of the tester—persisting during the tests’ full period. The previous ones, sparingly checked again with their respective strips, confirmed (a) their off-calibration condition in most cases, (b) the validity of the suggested method for recovering the calibration, and (c) the urgent need for an ISO specific normalization of the control-solution features and use. After a short recall of the previous findings, the paper compares them to new ones and discusses the resulting metrological/testing (and some clinical) consequences, also by comparing this study with previous ones in the literature.

Recent Publications

1. Steur, P. & Pavese, Franco. (2022). On the double heat capacity peak of oxygen solid-to-solid transition near 23.8 K. *Chemical Physics Letters*. 797. 139598. 10.1016/j.cplett.2022.139598.
2. Pavese, Franco. (2022). Review on questionable consistency issues between the CGPM Resolution 1 on revised SI (2018) and the 9th BIPM SI Brochure (2019). 10.1142/9789811242380_0004.
3. Pavese, Franco. (2022). Measurement in science: between Evaluation and Prediction. 10.1142/9789811242380_0021.

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