Editorial

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Home pregnancy tests: quality first

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Some weeks ago, while discussing the possible use of rapid antigenic tests to replace traditional molecular testing for coronavirus 19 (COVID-19) screening, a famous virologist said “they would like to transform the molecular detection of SARS-CoV-2 into a home pregnancy test”.

Home pregnancy tests (HPTs) were introduced in late 1976 to enable women to check for their pregnancy status “in the privacy and comfort of their own home”, even if earliest written records of urine-based pregnancy tests come from ancient Egypt over 3000 years ago [1]. David Haarbarger and Tahir S. Pillay have described the history of the pregnancy hormones and the development of bioassays such as the Ascheim-Zondek, the Shapiro-Zwarenstein and the Galli Mainini tests. Only in 1960, Leif Wide and Carl Gemzell developed the first immunological pregnancy test [2], and 15 years later the Warner-Chilcott’s early pregnancy test received US Food and Drug Administration (FDA) approval. It should be emphasized that at that time the thermometer was the only home diagnostic tool and therefore, the “point-of-care” pregnancy test was a big breakthrough. The accuracy and quality of the test has been improved over time by introducing monoclonal antibodies and visual labels in immunochromatographic formats and it was reported that until 1988 almost one-third of women used home pregnancy tests [3].

However, despite the assumption of the “famous” virologist, not all “home pregnancy tests are created equal”, and both accuracy, sensitivity and reliability are not granted for all commercially available HPTs.

In this issue of the *Journal*, Catharine Surgeon and colleagues – as members of a panel of seven experts who convened to discuss the validation studies required to comply with the new regulations for HPTs in Europe – report on the recommendations proposed for best practice and encourage manufacturers to apply them in the implementation of the new In Vitro Diagnostic Regulation (IVDR) [4]. This information should also be made available to

notified bodies as a useful guide when evaluating the data of HPT performances.

The panel recommendations cover both pre-analytical, analytical and user assessments that should be undertaken, thus acknowledging current evidence on the importance of considering not only analytical performance characteristics but all other extra-analytical variables [5]. These recommendations are therefore valuable information for HPTs as well as for pregnancy tests intended for use by both laboratorians, health care professionals in hospitals and other healthcare settings.

To briefly summarize, the recommendations span from the right use of the nomenclature (recognition of gonadotropin isoforms that should be expressed in molar units) over pre-analytical requirements for urine collection and storage, to the evaluation of analytical imprecision, true-ness, sensitivity and interferences due to cross-reactions with other hormones (e.g. LH, hCGβcf etc.). In addition, clinical requirements for validation with data supporting manufacturer’s claims, as well as for diagnostic sensitivity, specificity, positive and negative predictive values are defined. The limitations of a specific HPT are clearly shown. Another important issue – the “easy to use” aspect – should be evaluated by involving a women representative of the lay users to provide evidence of the true value of the test in the “real world”.

This paper is highly appreciated, and its careful reading strongly suggested, because it provides useful information on combining an easy access to self-testing at home by lay users with the need to assure quality and reliability of laboratory results.

The approach used for HPTs should be the paradigm of recommendations for all other “point-of-care”, and “near-patient” laboratory tests, which should be decentralized to assure higher and better access to laboratory tests while granting quality and reliability. Laboratory tests are not commodities, and quality is still the most important issue as it strongly affects further diagnostic and therapeutic decisions, and in the case of HPTs, the true assessment of the clinical pregnancy status. Technological developments and professional advice should ensure quality when pregnancy tests are performed in the “privacy and comfort of women’s home”, as a fundamental part of “decentralized and user-centered” laboratory medicine.

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