

Accuracy evaluation of the "CareStart Rapid Test" rapid diagnostic test for glucose-6-phosphate dehydrogenase (G6PD) deficiency in the COVID-19 era: a preliminary study



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INTRODUCTION

The Coronavirus Sars-CoV-2 pandemic, which started in 2019 and still in progress, opened an important debate about the use of the Chloroquine and Hydroxychloroquine drugs as a treatment in Glucose-6-phosphate-dehydrogenase (G6PD) deficient patients affected from Covid-19. The aim of this study was to evaluate the performance of the "G6PDH CareStart Rapid Test" kit (Meridian Healthcare s.r.l.) in the laboratory of the "Fondazione Policlinico Universitario A. Gemelli IRCCS" Hospital in Rome (Italy), reference center for biochemical and molecular diagnosis of favism.

MATERIALS AND METHODS

For this study we included a total of 20 blood samples from patients with deficient, intermediate and normal G6PD activity. The G6PD activity was performed using the "Advia Chemistry XPT System" (Siemens) instrument (Fig. 1A) in association with the "G6P-DH" kit (Sentinel Diagnostics). The qualitative assay was processed with the "G6PD CareStart kit Rapid Test". The procedure of the "G6PD CareStart Rapid Test" kit involves the use of a lancing device, the subsequent blood collected through a mini-pasteur (provided by the kit) and the transfer of the blood drop (about 2 µl) in the «S» window and 2 drops of the Assay Buffer (equivalent to 100 µl) in the «A» window. After 10 minutes the result is visible: pink color for normal activity and white color for deficient samples (Fig. 1B). All samples were also evaluated at the molecular level, confirming the enzymatic deficiency with the identification of the molecular alteration in the G6PD gene.

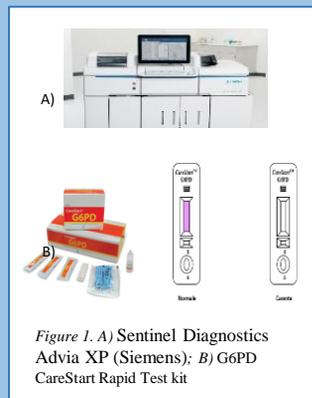


Figure 1. A) Sentinel Diagnostics Advia XP (Siemens); B) G6PD CareStart Rapid Test kit

RESULTS

In the 20 tests analyzed using the "G6PD CareStart Rapid Test" kit, 4 cards were processed without the use of pipettes, according to the protocol. These 4 cards were not readable due to an excessive saturation (Fig. 2A). The remaining 16 cards were processed through the use of pipettes and we found a perfect concordance between the G6PD activity and the result produced by the "G6PD CareStart Rapid Test": pink = not deficient (Fig. 2B), white = deficient (Fig. 2C). From the total of the readable cards, we found 6 samples with normal G6PD activity and 10 samples with deficient activity. The molecular test performed on the deficient samples identified the molecular alteration responsible for the deficiency.

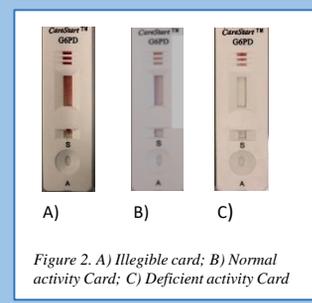


Figure 2. A) Illegible card; B) Normal activity Card; C) Deficient activity Card

DISCUSSION

The results of our study show that the "G6PD CareStart Rapid Test" kit (Meridian Healthcare s.r.l.) is fast and easy to use. Despite the concordance found between the G6PD activity and the qualitative result produced by the cards, it is still necessary to underline some critical issues: to produce ideal results, it was necessary to proceed with the use of pipettes, both for blood sampling and Assay Buffer. Without the use of pipettes, in fact, the card become saturated and it is difficult to interpret. Samples with normal or severely deficient activity produce a consistent and evident result that is easy to read by the operator. For borderline samples, evaluating the outcome of the card is difficult. This evidence suggests a use of a card reader (currently not available at the company) to produce a more confident result. Despite the above critical issues, we believe that the "G6PD CareStart Rapid Test" kit can be considered an excellent screening test. It is useful for quickly identifying a deficient G6PD patient, both in the emergency room and in the laboratory, especially in this period when the association between G6PD deficiency and Covid-19 infection is of vital importance.