New Raw Materials for the OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test Design

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Introduction

The OraQuick ADVANCE Rapid HIV-1/2 Antibody Test (OraQuick) is an FDA-approved direct antibody test used in human immunodeficiency virus type 1 (HIV-1) and type 2 (HIV-2) in-vitro diagnostic test for screening the detection of antibodies to HIV. The FDA approval of the OraQuick HIV-1/2 rapid test in 2004, and the availability of FDA-cleared rapid HIV-1/2 tests in many countries around the world, have made OraQuick the most sensitive and specific rapid test available. Of the four leading rapid HIV-1/2 tests available, the OraQuick was the next to market, and its development was funded in part by voluntary contributions from the Bill & Melinda Gates Foundation.

Specific objectives of this testing campaign were to design and implement a new generation of OraQuick test, which included an enhanced package of materials and methods to improve test performance, including testing for the presence of interfering substances from individuals with potentially interfering medical conditions, testing for specimens with varying reactivity in EIA assays and FDA-approved HIV rapid tests. Sample 109-13 was characterized as an HIV-1 Western Blot indeterminate with GS HIV-1/2 lines positive and OraQuick negative. The OraQuick result was confirmed by a rapid EIA (BioRad HIV-1/2+O) which was negative. The modified avidin replacement test did not have interference from the interfering substances as suggested by the OraQuick negative result. This indicated that these do not represent an actual differential reduction in sensitivity.

Results

In 2013, OraQuick Technicians reviewed 565 approval testing failures that had been included in a formal material and process change early in 2013 testing at OraQuick (ADVANCE® HIV-1/2 Section). Testing failures were assigned a unique number. There were five Panel Member reactivity types, and each reactivity type was tested in each of the five Panel Member Test Kit Types, and nine times with each of the five Panel Member reactivity types per site. There were three testing sites, with three operators per site. Each of the three replacement validation lots were evaluated with results in 20 minutes; accurate, results with >99% sensitivity and specificity across all specimen types and versatile, testing platform suitable for both clinical and non-clinical settings.

The OraQuick HIV-1/2 rapid test has the following Package Insert Claims.

- Sensitivity: For individuals with a potentially interfering medical condition, testing for specimens with varying reactivity in EIA assays and FDA-approved HIV rapid tests. Sample 109-13 was characterized as an HIV-1 Western Blot indeterminate with GS HIV-1/2 lines positive and OraQuick negative. The OraQuick result was confirmed by a rapid EIA (BioRad HIV-1/2+O) which was negative. The modified avidin replacement test did not have interference from the interfering substances as suggested by the OraQuick negative result. This indicated that these do not represent an actual differential reduction in sensitivity.

- Specificity: Most sensitive test available. OraSure Technologies Inc. has been a leader in the rapid diagnostic testing industry in the United States since 1997. In 2004, and has successfully conducted more than 35 million tests over the past 13 years with its laboratory partners.

- Conclusions: There were 405 Panel Members tested (81 per each PM reactivity type) with 100% concordance between both tests.