As part of the oral fluid clinical studies, information was collected from the participants regarding concurrent diseases or medical conditions, oral pathologies, non-HIV viral infections, and other factors (e.g., use of tobacco products, alcohol use, dental pathology, and oral infections). See the "Instructions for Use" section of this package insert.

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This test should be performed at temperatures in the range of 5-37°C (41-99°F). If stored refrigerated, ensure that the Divided Pouch is brought to operating temperature before performing Testing.

STEP 1: SPECIMEN COLLECTION and TEST PROCEDURE

1. Ensure prior to testing that the subject has not had anything to eat, drink or has chewed gum for at least 15 minutes. Have the subject wait for at least 30 minutes before testing.

STEP 1.A: FINGERSTICK WHOLE BLOOD

1. Using standard venous phlebotomy procedures, collect a whole blood sample using a tube containing any of the following anticoagulants: EDTA, sodium heparin, or sodium citrate.

STEP 1.B: PLASMA

1. Immediately insert the blood-filled end of the Loop all the way into the Vial (see picture 1). Do not remove the device from the vial while the test is running. Start the timer, or note the time. Do not remove the device from the vial to read the test. Do not expose the test to light while performing the test.

STEP 1.C: PLASMA

1. Using standard venous phlebotomy procedures, collect a whole blood sample using a tube containing EDTA anticoagulant. Other anticoagulants have not been tested and may give incorrect results.

STEP 1.D: PLASMA

1. Using standard venous phlebotomy procedures, collect a whole blood sample using a tube containing any of the following anticoagulants: EDTA, sodium heparin, or sodium citrate. Other anticoagulants have not been tested and may give incorrect results.

INTERPRETATION OF RESULTS – Place the result window

HIGH-REACTIVE – only the control window appears. One of these lines may be lighter than the other. This indicates a suitable sample was collected and the test functioned properly. The control line will appear on all valid tests, whether or not the result is reactive (see insert for OraQuick ADVANCE® HIV-1/2 Kit Controls).

REACTIVE – two lines appear. If two lines are visible in the result window, the test was performed properly. Informativeness of the lines does not necessarily indicate the presence of HIV-1 and/or HIV-2 antibodies. A control line in the ‘C’ area of the result window indicates a valid result. A valid result indicates a suitable sample was collected and the test functioned properly. If two lines appear, the result is positive. If there is no line in the area labeled ‘C’, the result is INVALID. A test result reported as ADVANCE® or ADVANCE® HIV-1/2 Kit Control gives this result (see insert for OraQuick ADVANCE® HIV-1/2 Kit Controls).

VALID

If two lines are visible in the ‘T’ area, the result is invalid. The test result should be reported as ADVANCE® or ADVANCE® HIV-1/2 Kit Control gives this result (see insert for OraQuick ADVANCE® HIV-1/2 Kit Controls).

NEUTRAL

If there is no line in the area labeled ‘C’, the result is neutral. The test result should be reported as ADVANCE® or ADVANCE® HIV-1/2 Kit Control gives this result (see insert for OraQuick ADVANCE® HIV-1/2 Kit Controls).

LIMITATIONS OF THE PROCEDURE

1. The OraQuick® ADVANCE® HIV-1/2 test kit was used to test a wide range of individuals from low-risk populations as well as individuals from high-risk populations. The test performed well across all populations and test conditions. This test has not been adequately evaluated in children under the age of 13.

2. The test is not a rapid test for emergency situations where quicker test results are needed. This test is not intended for use in emergency situations.

3. The test was developed for individuals who are currently or have been recently infected with HIV-1 and/or HIV-2. This test is not intended for use in emergency situations.

4. This test is not a rapid test for emergency situations where quicker test results are needed. This test is not intended for use in emergency situations.

5. The test was developed for individuals who are currently or have been recently infected with HIV-1 and/or HIV-2. This test is not intended for use in emergency situations.

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15. The test was developed for individuals who are currently or have been recently infected with HIV-1 and/or HIV-2. This test is not intended for use in emergency situations.

16. The test was developed for individuals who are currently or have been recently infected with HIV-1 and/or HIV-2. This test is not intended for use in emergency situations.