# VISUAL REFERENCE PANEL

**For Use Under Emergency Use Authorization (EUA) Only**

**All new operators must be able to correctly interpret all devices provided within the OraQuick® Ebola Visual Reference Panel prior to using the OraQuick® Ebola Rapid Antigen Test.**

**Failure to read at low intensities can result in the inability to detect specimens near the limit of detection of the OraQuick® Ebola Rapid Antigen Test and may result in false negative results.**

**This package insert and the OraQuick® Ebola Rapid Antigen Test package insert must be read completely before using the product. Follow the instructions carefully; failure to do so may cause an inaccurate test result.**

## NAME AND INTENDED USE

The OraQuick® Ebola Visual Reference Panel is intended to assist new operators in becoming proficient at reading specimens with antigen levels near the limit of detection of the device. The OraQuick® Ebola Visual Reference Panel is comprised of OraQuick® Ebola Rapid Antigen Test devices that have been designed to represent reading intensities of limit of detection, low positive, and negative test results. The limit of detection test device is indicative of specimens with antigen levels at the limit of detection of the device.

It is the responsibility of each laboratory using the OraQuick® Ebola Rapid Antigen Test to establish an adequate quality assurance program to ensure proficiency of new operators in their ability to interpret test results. The clinical performance of this device was established based on an operator's ability to read visual intensities at the "T" Zone at all levels including very weak lines representing low antigen levels.

## SUMMARY AND EXPLANATION OF THE EBOLA VISUAL REFERENCE PANEL

The OraQuick® Ebola Visual Reference Panel consists of three devices that have been manufactured to represent limit of detection, low positive, and negative test results. The devices are specifically formulated and manufactured to assist new operators in becoming proficient at reading specimens with antigen levels near the limit of detection of the device. The Ebola Limit of Detection Device has a very faint purple line at the Test (T) Zone. The Ebola Low Positive Device has a purple line at the Test (T) Zone. The Ebola Negative Device does not have a purple line at the Test (T) Zone. All devices have a purple line at the Control (C) Zone. Refer to *Test Result and Interpretation of Test Result* section of the OraQuick® Ebola Rapid Antigen Test package insert for instructions on how to interpret the devices.

***This panel is to be used to assist new operators with becoming proficient at reading and interpreting OraQuick® Ebola Rapid Antigen Test results at or near the limit of detection of the device. The OraQuick® Ebola Visual Reference Panel is NOT to be used as a quality control device to set intensity values used as a cutoff for reading and interpreting OraQuick® Ebola Rapid Antigen Test devices. Any line at the T Zone is considered a positive result regardless of how faint the line appears.***

## MATERIALS PROVIDED

### OraQuick® Ebola Visual Reference Panel

The Foil Pouch contains a package insert and three devices (one Ebola Limit of Detection Device, one Ebola Low Positive Device and one Ebola Negative Device) as described below.

**Ebola Limit of Detection Device**

One OraQuick® Ebola Rapid Antigen Test device that has been manufactured at a predetermined reactivity level to produce a positive test result consistent with the limit of detection of the device.

**Ebola Low Positive Device**

One OraQuick® Ebola Rapid Antigen Test device that has been manufactured at a predetermined reactivity level to produce a positive test result.

**Ebola Negative Device**

One OraQuick® Ebola Rapid Antigen Test device that has been manufactured to produce a negative test result.

## MATERIALS REQUIRED AND PROVIDED in the OraQuick® EBOLA Visual Reference Panel

- Foil Pouch containing three predetermined OraQuick® Ebola Rapid Antigen Test devices representing limit of detection, low positive and negative test results
- Package Insert

## MATERIALS REQUIRED BUT NOT PROVIDED

- Latex, vinyl, or nitrile disposable gloves

## WARNINGS

- **This package insert must be read completely before using the product.**
- **Adequate lighting is required for reading and interpreting the OraQuick® Ebola Visual Reference Panel and the OraQuick® Ebola Rapid Antigen Test.**
- **Follow the *Test Result and Interpretation of Test Result* section of the OraQuick® Ebola Rapid Antigen Test package insert for instructions on how to interpret the devices.**
- **The OraQuick® Ebola Visual Reference Panel when stored protected from light (either pouched or unpouched) is stable for 5 months. If not protected from light or stored above indicated temperature, the unpouched device should be discarded after 15 days.**
- **The OraQuick® Ebola Visual Reference Panel is NOT to be used as a quality control device to set intensity values used as a cutoff for reading and interpreting OraQuick® Ebola Rapid Antigen Test devices. Any line at the T Zone is considered to be a positive result regardless of how faint the line appears.**
- **All testing MUST be conducted under appropriate biosafety conditions in accordance with CDC guidelines. All study personnel conducting testing MUST read and be familiar with Universal Precautions[1], Infection Control for Viral Hemorrhagic Fevers in the African Health Care Setting[2] and in Information for Healthcare Worker in the United States (http://www.cdc.gov/vhf/ebola/healthcare-us/index.html) depending upon their location of testing.**

## PRECAUTIONS

### Safety Precautions

- Dispose of all OraQuick® Ebola Visual Reference Panel devices in a biohazard container. The OraQuick® Ebola Visual Reference Panel does not contain potentially infectious materials; however, the devices will be used in areas containing infectious materials and should be discarded in a biohazard container.
- Use of Visual Reference Panels manufactured by any other source will not meet the requirements for an adequate quality assurance program for the OraQuick® Ebola Rapid Antigen Test.

## STORAGE INSTRUCTIONS

Store the OraQuick® Ebola Visual Reference Panel at 15°-30°C (59°-86°F). Do not use the OraQuick® Ebola Visual Reference Panel beyond the expiration date printed on the foil pouch. Open the OraQuick® Ebola Visual Reference Panel pouch only when qualifying new operators in interpreting test results. Reseal and store the devices in their original foil pouch at 15°-30°C (59°-86°F) after use. If not protected from light or stored above indicated temperatures, the un-pouched device should be discarded after 15 days.

## DIRECTIONS FOR USE

### Test Procedure

**Note: The OraQuick® Ebola Visual Reference Panel should be read and interpreted in the same location that testing and interpreting the OraQuick® Ebola Rapid Antigen Test occurs.**

1. Open the foil pouch containing the OraQuick® Ebola Visual Reference Panel.
2. Pull out the three devices contained within the foil pouch.
3. Note the date the pouch was opened on the device labels or the pouch label.
4. Follow the *Test Result and Interpretation of Test Result* section of the OraQuick® Ebola Rapid Antigen Test package insert for instructions on how to interpret the devices.
5. Store the OraQuick® Ebola Visual Reference Panel Devices in the original re-sealable foil pouch at 15 - 30°C (59 - 86°F).

## EXPECTED RESULTS

### Ebola Limit of Detection Device

The OraQuick® Ebola Limit of Detection Device has been manufactured to have a very faint line at the Test (T) Zone. A line should be present in the Result Window in both the C Zone and the T Zone. This indicates a weakly positive test result consistent with the limit of detection of the device. The C Zone and the T Zone lines will not be the same intensity.

### Ebola Low Positive Device

The OraQuick® Ebola Low Positive Device has been manufactured to have a line at the Test (T) Zone. A line should be present in the Result Window in both the C Zone and the T Zone. This indicates a positive test result. The C Zone and the T Zone lines will not be the same intensity.

### Ebola Negative Device

The OraQuick® Ebola Negative Device has been manufactured to have a line at the Control (C) Zone. A single line should be present in the Result Window in the C Zone and NO line should be present in the T Zone. This indicates a negative test result.

**NOTE: If a new operator is unable to interpret all devices provided as part of the OraQuick® Ebola Visual Reference Panel, they are not considered to be proficient at reading and interpreting the OraQuick® Ebola Rapid Antigen Test. Failure to read at low intensities can result in the inability to detect specimens near the limit of detection of the OraQuick® Ebola Rapid Antigen Test and may result in false negative results.**

## LIMITATIONS

The OraQuick® Ebola Visual Reference Panel is for use only with the OraQuick® Ebola Rapid Antigen Test.

## BIBLIOGRAPHY


1. CDC, Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and other Bloodborne Pathogens in Health-Care Settings. MMWR 1988; 37(24):377-388.
2. Infection Control for Viral Haemorrhagic Fevers in the African Health Care Setting. Centers for Disease Control and Prevention and World Health Organization. Atlanta, Centers for Disease Control and Prevention, 1998: 1-198. WHO, September 2014: Ref: WHO/HIS/SDS/2014.4


## EXPLANATION OF SYMBOLS

| | | | |
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| LOT | Batch Code | IVD | *In Vitro* Diagnostic Medical Device |
| REF | Catalog Number | | Manufacturer |
| | Caution, Consult Accompanying Documents | | Temperature Limitation |
| PN | Part Number | | Use By |

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