OraQuick® Rapid Antibody Test HCV

VISUAL REFERENCE PANEL

All new operators MUST be able to correctly interpret all devices provided within the OraQuick® HCV Visual Reference Panel prior to using the OraQuick® HCV Rapid Antibody Test.

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

This package insert and the OraQuick® HCV Rapid Antibody 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® HCV Visual Reference Panel is intended to assist new operators in becoming proficient at reading specimens with antibody levels near the limit of detection of the device. The OraQuick® HCV Visual Reference Panel is comprised of OraQuick® HCV Rapid Antibody Test devices that have been designed to represent reading intensities of limit of detection, low reactive, and non-reactive test results. The limit of detection test device is indicative of specimens with antibody levels at the limit of detection of the device.

It is the responsibility of each laboratory using the OraQuick® HCV Rapid Antibody 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" line at all levels including very weak lines representing low antibody levels.

SUMMARY AND EXPLANATION OF THE HCV VISUAL REFERENCE PANEL

The OraQuick® HCV Visual Reference Panel consists of three devices that have been manufactured to represent limit of detection, low reactive, and non-reactive test results. The devices are specifically formulated and manufactured to assist new operators in becoming proficient at reading specimens with antibody levels near the limit of detection of the device. The HCV Limit of Detection Device has a very faint reddish-purple line at the Test (T) Zone. The HCV Low Reactive Device has a reddish-purple line at the Test (T) Zone. The HCV Non-Reactive Device does not have a reddish-purple line at the Test (T) Zone. Refer to *Test Result and Interpretation of Test Result* section of the OraQuick® HCV Rapid Antibody 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® HCV Rapid Antibody Test results at or near the limit of detection of the device. The OraQuick® HCV 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® HCV Rapid Antibody Test devices. Any line at the T Zone is considered to be a reactive result regardless of how faint the line appears.

MATERIALS PROVIDED

OraQuick® HCV Visual Reference Panel

The Foil pouch contains a package insert and three devices (one HCV Limit of Detection Device, one HCV Low Reactive Device and one HCV Non-Reactive Device) as described below:

HCV Limit of Detection Device

One OraQuick® HCV Rapid Antibody Test device that has been manufactured at a predetermined reactivity level to produce a reactive test result.

HCV Low Reactive Device

One OraQuick® HCV Rapid Antibody Test device that has been manufactured at a predetermined reactivity level to produce a reactive test result.

HCV Non-Reactive Device

One OraQuick® HCV Rapid Antibody Test device that has been manufactured to produce a non-reactive test result.

MATERIALS REQUIRED AND PROVIDED in the OraQuick® HCV Visual Reference Panel

- Foil Pouch containing three predetermined OraQuick® HCV Rapid Antibody Test devices representing limit of detection, low reactive, and non-reactive test results
- OraQuick® HCV Visual Reference Panel 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® HCV Visual Reference Panel and the OraQuick® HCV Rapid Antibody Test.**
- **Follow the Test Result and Interpretation of Test Result section of the OraQuick® HCV Rapid Antibody Test package insert for instructions on how to interpret the devices.**
- **The OraQuick® HCV Visual Reference Panel when stored protected from light (either pouched or unpouched) is stable for 5 months. If not protected from light, the unpouched device should be discarded after 15 days.**
- **The OraQuick® HCV 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® HCV Rapid Antibody Test devices. Any line at the T Zone is considered to be a reactive result regardless of how faint the line appears.**
- **Before proceeding with testing, all operators MUST read and become familiar with Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis A Virus, Hepatitis B Virus, and other Bloodborne Pathogens in Health-Care Settings.[1]**

PRECAUTIONS

Safety Precautions

- Dispose of all OraQuick® HCV Visual Reference Panel devices in a waste container according to the expiration date printed on the foil pouch.
- Use of Visual Reference Panels manufactured by any other source will not meet the requirements for an adequate quality assurance program for the OraQuick® HCV Rapid Antibody Test.

STORAGE INSTRUCTIONS

Store the OraQuick® HCV Visual Reference Panel at 15-30°C (59-86°F). Do not use the OraQuick® HCV Visual Reference Panel beyond the expiration date printed on the foil pouch. Open the OraQuick® HCV 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, the un-pouched device should be discarded after 15 days.

DIRECTIONS FOR USE

Test Procedure

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

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

EXPECTED RESULTS

HCV Limit of Detection Device

The OraQuick® HCV 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 reactive test result. The C Zone and the T zone lines will not be the same intensity.

HCV Low Reactive Device

The OraQuick® HCV Low Reactive 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 reactive test result. The C Zone and the T Zone lines will not be the same intensity.

HCV Non-Reactive Device

The OraQuick® HCV Non-Reactive 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 non-reactive test result.

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

LIMITATIONS

The OraQuick® HCV Visual Reference Panel is for use only with the OraQuick® HCV Rapid Antibody 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.

EXPLANATION OF SYMBOLS

LOT	Batch Code	IVD	*In Vitro* Diagnostic Medical Device
REF	Catalog Number	KIT CTRLS	Kit Controls
	Caution, Consult Accompanying Documents		Manufacturer
CONTENTS	Contents	PN	Part Number
CONTROL –	Control Negative		Temperature Limitation
CONTROL +	Control Positive		Use By
DEV SOL VIAL	Developer Solution Vial		

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