**SAMPLE OFF-SITE TESTING PROTOCOL**

*Insert Agency Name* will provide the OraQuick® HCV Rapid Antibody Test in various off-site venues:

- Street Fairs or Community Events – in a NYS Limited Service Laboratory (LSL) approved room temperature space.
- Other organizations/agencies’ buildings meeting the protocol for Rapid HCV Antibody testing established in this manual.

**OFF-SITE TESTING ENVIRONMENT**

Staff member(s) conducting OraQuick® HCV Rapid Antibody Test will establish test area readiness including:

- Monitoring the environmental/operating temperature
- Ensuring proper lighting
- Ensuring proper work surface
- Ensuring hand washing facilities or hand sanitizer with 60% alcohol are available.
- Removing the OraQuick® HCV Rapid Antibody Test Kit(s) from the cooler; ensuring the test kit(s) comes to room temperature before opening and using.

*For Agencies conducting controls off-site:*

- Ensuring that an external control has been run according to the manufacturer’s instructions.
- Ensuring expected quality control results and recording them. Taking corrective action pursuant to a pre-established plan (if quality control results generated do not yield expected results).

**ENVIRONMENTAL/OPERATING TEMPERATURE**

The operating temperature for the OraQuick® HCV Rapid Antibody Test is 15°-37°C, 59°-99°F. The Program Director or an assigned staff person will verify the site temperature prior to testing.

To ensure that test area temperatures are within manufacturer recommended temperature ranges, a thermometer will be available at testing sites. Temperature readings will be taken prior to testing and recorded on the Test Site Temperature Log. *(An alternate policy would be to record temperatures on the off-site patient testing results log).*

In the event testing area temperatures fall outside the operating temperature 59°-99°F, testing will cease, a supervisor will be notified, and test kits will be returned to the agency. Controls will be run to ensure test kit integrity prior to returning to inventory.

*For Agencies conducting controls off-site:*

In the event testing area temperatures fall outside the operating temperature 59°-99°F, testing will cease, a supervisor will be notified, and corrective action will be taken. An adjustment to the environment (heat/air conditioning) will be made accordingly. Controls will be run and testing will resume per supervisory directive.

**LIGHTING**

Staff conducting the OraQuick® HCV Rapid Antibody Test will ensure lighting is acceptable for testing, direct observation will provide information for corrective action, include providing additional lamps, and adjustment to natural light (blinds, curtains) appropriately.
WORK SURFACE
Staff conducting the OraQuick® HCV Rapid Antibody Test will verify appropriate space and a flat surface is available in each testing site.

HAND WASHING FACILITIES
Staff conducting the OraQuick® HCV Rapid Antibody Test will verify hand washing facilities are in close proximity or that hand sanitizer containing 60% alcohol is available.

TRANSPORTING OF CONTROLS & TEST KITS
OraQuick® HCV Rapid Antibody Test Kit Controls will be stored in a cooler with ice pack and a thermometer to ensure the temperature remains within the limits of the acceptable range of 2°-8°C, 36°-46°F.

OraQuick® HCV Rapid Antibody Test Kits will be stored in a transportable container with a thermometer to ensure the temperature is within the limits of the acceptable storage temperature of 2°-37°C, 36°-86°F.

TRANSPORTING OF CLIENT DATA
- All client data is to be stored in a locked case at the off-site testing venue and during transport of documents from the off-site testing venue to Insert Agency Name.