CHECKLIST FOR LIMITED SERVICES LABORATORIES SUBMITTING HCV RAPID TESTING PROTOCOLS TO THE CLINICAL LABORATORY EVALUATION PROGRAM (CLEP) FOR REVIEW

1. OVERVIEW

This section should include a brief description of the organization's policy for when HCV testing is performed. The facility's laboratory director must review and approve its policy and procedures for HCV screening.

NOTE: Procedures should include standing orders to screen individuals using a point-of-care device if a health care provider is not present at the time of the screening to order the test, steps for diagnostic testing of rapid reactive results and linkage to follow-up care.

2. EQUIPMENT AND MATERIALS REQUIRED

All equipment used to perform testing should be included in this section (e.g., kit, quality control, space where testing is performed, disposable workspace cover, etc.).

3. ENVIRONMENTAL CONDITIONS

This section should include:

- ☐ Reference to performing testing under adequate lighting conditions.
- ☐ How the laboratory monitors and documents ambient temperature to assure that testing is performed at the temperature conditions required by the manufacturer.
- ☐ How the laboratory stores reagents and quality materials and how the temperatures are monitored to make certain that these materials are stored at the temperatures required by the manufacturer.
- ☐ List of site(s) where testing will occur, including off-site screenings, such as health fairs or home visits.

4. QUALITY CONTROL

This section should include:

- ☐ A description of the quality control materials used.
- ☐ An explanation of when and under what circumstances quality control is performed (e.g., on each new test kit, with each new operator, etc.).
- ☐ An explanation of next steps if the quality control is not within the manufacturer's acceptable range (e.g., rerun quality control, open new quality control, contact the manufacturer, etc.).

5. COLLECTION REQUIREMENTS AND SPECIMEN REJECTION CRITERIA

This section should include:

- ☐ A description of how specimens are collected.
- ☐ An explanation of when specimens are invalid and a follow-up plan of action for next steps (e.g., collect another specimen, etc.)

6. RECORD KEEPING

This section should describe how the laboratory records kit lot numbers and quality control results for each day's runs.

7. RESULTS AND INTERPRETATIONS

This section should include:

- ☐ A description of how results are reported including the result obtained.

8. REFERRAL FOR HCV DIAGNOSTIC TESTING AND LINKAGES TO CARE

This section should include:

- ☐ A description of how clients will be referred for HCV diagnostic testing (i.e., HCV RNA by PCR).
- ☐ How patients are linked to follow-up care.