Program: Public Health Microbiology
SOP ID and Name: Shiga Toxin Quik Chek™ Rapid Test
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Purpose and Scope

Some strains of E. coli have the genes for and express the Shiga toxins *stx*1, *stx*2, or both *stx*1 & *stx*2. Both toxins can cause disease which often presents as bloody diarrhea, with *stx*2 having higher virulence and increased rates of kidney damage called hemolytic uremic syndrome (HUS). The CDC estimates that 265,000 people are infected with Shiga toxigenic E. coli (STEC) in the United States each year.

In this single-use rapid membrane enzyme immunoassay, direct fecal samples and cultures are tested to determine the presence or absence of *Stx*1 and *Stx*2 genes. First, sample is mixed with diluent and added to a cartridge. Then, wash buffer is added. The test is analyzed after a brief incubation period. It can display a qualitative positive result for *stx*1, *stx*2, both, or neither.

Two analysts will participate in testing a demonstration panel of known samples over two days. Results will be compared between analysts and days.

Equipment

Materials Provided in Shiga Toxin Quik Chek™ Kit (catalog #T30625)

- Membrane devices
- Diluent and dropper
- Wash Buffer and dropper
- Substrate
- Conjugate
- Positive Control
- Disposable plastic transfer pipettes

Materials Required but Not Provided

- Small Test Tubes
- Applicator sticks or swabs
- Timer
- Vortex

- Pipettor and tips
- Disposable gloves

Reagents

Materials Provided in TECHLAB Shiga Toxin Quik Chek™ Kit (catalog #T30625)

- Membrane devices
- Diluent and dropper
- Wash Buffer and dropper
- Substrate
- Conjugate
- Positive Control

TECHLAB Shiga Toxin Demonstration Panel (catalog #ED625)

Samples

A 10-sample demonstration panel from TECHLAB will be analyzed using the rapid test method. The panel contains samples of known results. The first analyst will test Group 1 on Day 1, and Group 2 on Day 2. The second analyst will test Group 2 on Day 1, and Group 1 on Day 2.

- Group 1
  - ED625A Stx1 (+), Stx2 (-) Reagent, 1 mL
  - ED625B Stx1 (-), Stx2 (+) Reagent, 1 mL
  - ED625C Stx1 (+), Stx2 (+) Reagent, 1 mL
  - ED625D Stx1 (-), Stx2 (-) Reagent, 1 mL
  - ED625E Stx1 (+), Stx2 (-) Reagent, 1 mL
- Group 2
  - ED625F Stx1 (-), Stx2 (+) Reagent, 1 mL
  - ED625G Stx1 (+), Stx2 (+) Reagent, 1 mL
  - ED625H Stx1 (-), Stx2 (-) Reagent, 1 mL
  - ED625I Stx1 (+), Stx2 (-) Reagent, 1 mL
  - ED625J Stx1 (-), Stx2 (+) Reagent, 1 mL

- TECHLAB details their testing of direct fecal and broth culture samples in the TECHLAB Shiga Toxin Quik Chek™ package insert.

Accuracy

Accuracy will be measured as agreement between the known results of the Demonstration Panel and the observed results by the analysts performing the tests. Acceptance criteria will be ≥95% agreement of results among all known samples and analyst results.

Precision

Precision will be measured as the degree of sample agreement between analysts. Acceptance criteria will be ≥95% agreement of results among analysts for all samples

Evaluation of measurement bias

The Quik Chek™ Rapid Test is a qualitative test, measurement bias is not applicable.

Analytical Sensitivity

The TECHLAB Shiga Toxin Quik Chek™ Rapid Test assay is FDA-cleared under Emergency Use Authorization and will not be evaluated for analytical sensitivity in this verification. A sensitivity study conducted by the manufacturer can be found in the attached package insert.

Analytical Specificity

The TECHLAB Shiga Toxin Quik Chek™ Rapid Test assay is FDA-cleared under Emergency Use Authorization and will not be evaluated for analytical specificity in this verification. A specificity study conducted by the manufacturer can be found in the attached package insert.

Reportable Range

Only detected or not detected results are reported, reportable range is not tested or defined further in this verification. Results may be detected for *Stx*1, *Stx*2, both or neither.

Linearity

The Quik Chek™ Rapid Test is a qualitative test, linearity is not applicable.

Reference Intervals

The Quik Chek™ Rapid Test is a qualitative test, reference intervals are not applicable.

Interlaboratory Comparison

This is an internal verification and will not use interlaboratory comparison.

Intralaboratory Comparison

Two analysts, Redacted and Redacted, will perform the verification over two days. Results comparison between analysts must show ≥95% agreement to be considered valid.

Calibration Procedures

There are no regular calibration procedures for this method. Please see next section for control procedures.

Control Procedures

Control samples will be run monthly, and when a new kit lot is put into use. The positive control included in each kit will be used as the positive control. 25 µL of Diluent will be used as the negative control.

Robustness

Verifications will be performed over two days to account for variations in temperature and humidity. Temperature and humidity will be recorded on each day of the verification.

Measurement Uncertainty

Two external control samples will be run monthly and with new kit lots. Only trained personnel who have completed a competency will be performing this assay. This ensures protocol and procedures are being performed correctly.

Verification of Spreadsheets, Commercial Software, and/or LIMS

Data will be recorded on two spreadsheets attached to CLM 1235. Quality control results will be recorded on Attachment B, and sample results will be recorded on Attachment C. Data will be reviewed and signed off by an analyst who is competent in the method.

Reference Documents:

- TECHLAB™ Shiga Toxin Quik Chek™ Package Insert
- TECHLAB™ Shiga Toxin Demonstration Panel Package Insert
- CLM 1235: Shiga Toxin Quik Chek™ SOP