FDA FACT SHEET
Produce Safety Rule (21 CFR 112)

EQUIVALENT TESTING METHODOLOGY FOR AGRICULTURAL WATER

FDA has determined that the following quantification methods are scientifically valid and at least equivalent to the method of analysis in § 112.151(a), “Method 1603: *Escherichia coli* (E. coli) in Water by Membrane Filtration Using Modified membrane-Thermotolerant *Escherichia coli* Agar (Modified mTEC)” (December 2009), in accuracy, precision, and sensitivity in quantifying generic *Escherichia coli* in agricultural water when used in connection with the criteria described in § 112.44(a) or § 112.44(b).


7. Hach Method 10029 for Coliforms – Total and *E. coli*, using m-ColiBlue24 Broth PourRite Ampules.

8. IDEXX Colilert Test Kit, but only if using IDEXX Quanti-Tray/2000 for quantification.

9. IDEXX Colilert-18 Test Kit, but only if using IDEXX Quanti-Tray/2000 for quantification.

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With regard to criteria described only in § 112.44(a), FDA has determined that the following presence/absence methods are scientifically valid and at least equivalent to the method of analysis in § 112.151(a), “Method 1603: *Escherichia coli* (*E. coli*) in Water by Membrane Filtration Using Modified membrane-Thermotolerant *Escherichia coli* Agar (Modified mTEC)” (December 2009), in accuracy, precision, and sensitivity in detecting generic *Escherichia coli* in agricultural water.


3. IDEXX Colilert Test Kit

4. IDEXX Colilert-18 Test Kit

5. IDEXX Colisure Test Kit

6. E*Colite Bag or Vial Test for Total Coliforms and *E. coli* in Potable Water. Charm Sciences, Inc.

7. 101298 Readycult Coliforms 100. EMD Millipore (division of Merck KGaA, Darmstadt, Germany).

**For more information:**
- FSMA Final Rule on Produce Safety.
  https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm

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