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.
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

Have you seen our Blog? FDA Voice

---

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation’s food supply, cosmetics, dietary supplements, and products that give off electronic radiation, and for regulating tobacco products.

U.S. Food and Drug Administration
5001 Campus Drive
College Park, MD, 20740
www.fda.gov