

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).

1. Method 1603: *Escherichia coli* (*E. coli*) in Water by Membrane Filtration Using Modified membrane-Thermotolerant *Escherichia coli* Agar (Modified mTEC) (September 2014). U.S. Environmental Protection Agency. EPA-821-R-14-010.
2. Method 1103.1: *Escherichia coli* (*E. coli*) in Water by Membrane Filtration Using membrane-Thermotolerant *Escherichia coli* Agar (mTEC) (March 2010). U.S. Environmental Protection Agency. EPA-821-R-10-002.
3. Method 1604: Total Coliforms and *Escherichia coli* in Water by Membrane Filtration Using a Simultaneous Detection Technique (MI Medium) (September 2002). U.S. Environmental Protection Agency. EPA-821-R-02-024.
4. 9213 D – Natural Bathing Beaches (2007). In: Standard Methods for the Examination of Water and Wastewater, 22nd Edition (Rice E.W., et al., Ed.), 9-46 – 9-48. Washington, DC: American Public Health Association. (2012).
5. 9222 B – Standard Total Coliform Membrane Filter Procedure (1997), followed by 9222 G – MF Partition Procedures (1997) using NA-MUG media. In: Standard Methods for the Examination of Water and Wastewater, 21st Edition (Eaton A.D., et al., Ed.), 9-60 – 9-65, and 9-70 – 9-71, respectively. Washington, DC: American Public Health Association. (2005).
6. D 5392-93 – Standard Test Method for Isolation and Enumeration of *Escherichia coli* in Water by the Two-Step Membrane Filter Procedure. In: Annual Book of ASTM Standards, Volume 11.02. ASTM International. (1996, 1999, 2000).
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.

1. TECTA™ EC/TC medium and the TECTA™ Instrument: A Presence/Absence Method for the Simultaneous Detection of Total Coliforms and *Escherichia coli* (*E. coli*) in Drinking Water. (2014).
2. Modified Colitag™ Test Method for the Simultaneous Detection of *E. coli* and other Total Coliforms in Water. ATP D05-0035. (2009).
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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