

# FDA FACT SHEET

## Produce Safety Rule (21 CFR 112)

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### EQUIVALENT TESTING METHODOLOGY FOR AGRICULTURAL WATER

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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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