

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D0869868	(X3) Date Survey Completed 09/06/2024
Name of Provider or Supplier Scott County Health Department	Street Address, City, State 600 West 4th Street, Davenport, IA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5002	<p>BACTERIOLOGY CFR(s): 493.1201</p> <p>If the laboratory provides services in the subspecialty of Bacteriology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1261, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: Based on observations made during the survey, review of the laboratory's Gram Stain procedure and Hardy Diagnostics Gram Stain Instructions for Use and interview with laboratory personnel identifier #1 (refer to the Laboratory Personnel Report); the laboratory failed to follow manufacturer's instructions for performing gram stains as specified in D5411.</p>
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on observations made during the survey, review of the laboratory's Gram Stain procedure and Hardy Diagnostics Gram Stain Instructions for Use, and interview with laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 10:45 am on 9/5/2024 the laboratory failed to perform gram stain testing following the manufacturer's instructions for two out of two years from 9/5/2022 - 9/5/2024. The findings include: 1. On 9/5/2024 a tour of the laboratory</p>

revealed that the laboratory used the Hardy Diagnostics gram stain kit (lot number A4331, expiration date 5/31/2025). 2. The Hardy Diagnostics Gram Stain Instructions For Use state: *Methanol fix slide by flooding with absolute methanol (95%) 1 - 2 minutes, then tilt the slide to drain off methanol and allow to air dry. DO NOT USE HEAT FIXATION. *Cover slide with Crystal Violet Reagent for one minute. *Rinse slide with deionized or tap water. *Cover slide with iodine reagent for one minute. *Gently rise the slide with deionized or tap water and allow to drain. *Tilt the slide and flood with a few drops of Decolorizer until no violet color runs off. This will usually take 10 seconds or less depending on the thickness of the specimen. Do not over decolorize. *Rinse slide gently with deionized or tap water. *Cover slide with Safranin, Advanced Counterstain, or Basic Fuchsin counterstain for one minute. *Rinse slide gently with deionized or tap water. The rinse water in this step should be slightly pink. Do not wash excessively. *Allow slide to drain and air dry or gently dry with a paper towel. 2. The laboratory's gram stain procedure stated the following steps: *Lab team member will determine whether to air dry smears on a flat surface, or place them on a 60 degree Celecric slide warmer until dry, depending on the amount of specimen. *Flood slide with crystal violet and let sit for 20 - 30 seconds. Rinse with a gentle stream of cool tap water. Gently shake off excess water. *Flood slide with iodine and let sit for 20 - 30 seconds. *Rinse with a gentle stream of cool tap water. Gently shake off excess water. *Flood slide with decolorizing solution until purple no longer runs from the thinnest part of the smear. *Rinse with a gentle stream of cool tap water. Gently shake off excess water. *Flood slide with Safranin and let sit for 20 - 30 seconds. *Rinse with a gentle stream of cool tap water. Gently shake off excess water. *Dry smear by blotting gently on a clean paper towel. 3. The laboratory had discrepancies from the Hardy Diagnostics Gram Stain Instructions For Use that included the smear fixation technique and staining times. 4. Laboratory personnel identifier #1 confirmed that the laboratory either heat fixed gram stain smears or did not fix the smears prior to gram staining.