

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D0387439	(X3) Date Survey Completed 02/11/2020
Name of Provider or Supplier William J Schulte, Md	Street Address, City, State 1603 Morgan Street Suite 6, Keokuk, 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
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on review of Selective Strep Agar (SSA) media logs, the media Individualized Quality Control Plan (IQCP) and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 10:30 am on 2/11/2020, the laboratory failed to retain the SSA media quality control certificates for seven out of 11 lot numbers of SSA media used from June 2019 - February 2020. The findings include: 1. The laboratory's media IQCP states, "Quality control certificates from the manufacturer will be retained for each lot and shipment of exempt media." 2. At the time of the survey, the laboratory did not retain the SSA media quality control certificates for the following lot numbers of media: *123310, expiration date 07/31/2019 *123976, expiration date 09/12/2019 *441219, expiration date 09/19/2019 *124402, expiration date 10/10/2019 *125244, expiration date 11/28/2019 *446500, expiration date 12/09/2019 *447700, expiration date 12/26/2019</p>
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on review of patient throat culture logs, Selective Strep Agar (SSA) media logs and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 11:00 am on 2/11/2020, the laboratory failed to ensure they did not use expired SSA media for two out of 14 patients who had throat cultures performed using lot number 441219 of SSA media. The findings include: 1. On 9/24/2019, the laboratory performed throat cultures using lot number 441219 of SSA media on patient identifiers A & B. 2. SSA media lot number 441219 expired on 9/19/2019.