

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 23D0858924	<b>(X3) Date Survey Completed</b> 02/24/2021
<b>Name of Provider or Supplier</b> Alger Pediatrics, P C	<b>Street Address, City, State</b> 733 Alger St Se, Grand Rapids, MI	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	D0000 A recertification survey was completed on February 24, 2021. During the survey, it was determined that Immediate Jeopardy (IJ) existed for the following condition-level deficiencies: Bacteriology- 42 CFR 493.1201
<b>D5002</b>	<p><b>BACTERIOLOGY</b> 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 document review and interview with the Office Manager and the Laboratory Director, the laboratory failed to meet Bacteriology requirements as specified in 493.1230 through 493.1256. Findings include: 1. The laboratory failed to follow the manufacturer's instructions for the Henry Schein OneStep+ Strep A Dipstick Test. Refer to D5411.</p>
<b>D5411</b>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> 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 record review and interview with the Office Manager (OM), the laboratory failed to follow the manufacturer's instructions for the Henry Schein OneStep+ Strep</p>

A Dipstick Test for 16 (14 rectal swabs and 2 vaginal swabs) of 16 swabs collected in 2 years of documents reviewed. Findings include: 1. A review of the manufacturer's instructions states, "The One Step+ Strep A Dipstick Test is for in vitro diagnostic use only. The test should be used for the detection of Strep A antigen in throat swab specimens only." 2. A review of the "Strep Culture" log revealed for 16 (14 rectal swabs and 2 vaginal swabs) of 16 swabs collected the manufacturer's instructions were not followed for an acceptable specimen source as follows: a. rectal swab 1/11/2019 - negative b. rectal swab 1/11/2019 - negative c. vaginal swab 11/20/2019 - negative d. rectal swab 11/11/2019 - positive e. rectal swab 11/1/2019 - positive f. rectal swab 3/8/2019 - negative g. rectal swab 5/2/2019 - positive h. rectal swab 1/13/2021 - negative i. rectal swab 12/24/2020 - negative j. rectal swab 1/8/2021 - negative k. rectal swab 11/21/20 - negative l. rectal swab 2/4/2020 - negative m. vaginal swab 1/17/2020 - negative n. rectal swab 1/13/2020 - negative o. rectal swab 1/10/2020 - positive 3. When queried on 2/24/2021 at 10:35 am, the OM was unaware that sources other than throat were being collected for the strep screen test. 4. A interview on 2/24/2021 at 10:35 am, the OM confirmed the laboratory was using specimen sources outside the manufacturer's instructions.

**D5785**

**CORRECTIVE ACTIONS**  
CFR(s): 493.1282(b)(3)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.

This STANDARD is not met as evidenced by:  
 . Based on record review and interview with the Office Manager (OM), the laboratory failed to document corrective action for improper temperature of the bacteriology incubator for 5 days (February 28 and 29, March 10, 11, and 19 2020) of 2 years of documents reviewed. Findings include: 1. A record review of the "Incubator Quality Control Record" log revealed for 5 days (February 28 and 29, March 10, 11, and 19 2020) of 2 years of documents reviewed the incubator was below the stated range of 35 degree C to 37 degree C and no corrective action was documented as follows: a. February 28, 2020 - temperature 34 b. February 29, 2020 - temperature 32 c. March 10, 2020 - temperature 32 d. March 11, 2020 - temperature 34 e. March 12, 2020 - temperature 34 2. A record review of the "Maintenance" policy states "If the temperature is not within the limits posted on the control record, adjust the temperature accordingly, documenting what time and you made the adjustment and at what time you rechecked the reading until the correct range is obtained, also notify the laboratory director and/or office manager." 3. A interview on 2/24/2021 at 11:40 am, the OM confirmed that no corrective action was documented for the incubator temperatures out of the stated range.

**D6046**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the Office Manager (OM), the TC failed to evaluate the competency of testing personnel (TP) performing the bacteriology throat culture testing for 6 (TP1 - TP6) of 6 testing personnel listed on the CMS-209 form. Findings include: 1. A record review of TP competency assessments revealed TP competencies were assessed by a co-worker for 6 (TP1 - TP6) of 6 TP listed on the CMS-209 who does not qualify as a Technical Consultant to perform competency assessments as follows: a. TP1 assessment dates of 5/1/2019 and 6/1/2020 b. TP2 assessment dates of 5/1/2019 and 5/14/2020 c. TP3 assessment dates of 4/30/2019 and 6/18/2020 d. TP4 assessment dates of 4/30/2019 and 5/22/2020 e. TP5 assessment dates of 4/30/2020 and 5/1/2020 f. TP6 assessment dates of 11/1/2019 and 5/12/2020 2. A interview on 2/24/2021 at 9:54 am, the OM confirmed the competency assessments were completed by a co-worker not qualified as a TC to perform competency assessments.