

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  16D1094654	<b>(X3) Date Survey Completed</b>  10/07/2022
<b>Name of Provider or Supplier</b>  All Ages Pediatrics, Pc	<b>Street Address, City, State</b>  301 W 2nd Street, Suite 1, Ottumwa, IA	
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>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies, procedures, and personnel records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 1:00 pm on 10/7/2022, the laboratory failed to follow written policies and procedures for performing testing personnel competency for four out of four testing personnel from 3/24/2021 - 10/7/2022. The findings include: 1. The Quality Assessment procedure states, "Competency testing will be done twice yearly for new employees and once yearly for all other employees." 2. The following personnel had initial training performed: *Identifier #2, initial training 3/1/2021; *Identifier #3, initial training 7/30/2021; *Identifier #4, initial training 2/4/2022; *Identifier #5, initial training 6/15/2021. 3. At the time of the survey, the laboratory did not have six month and (when applicable) annual competency for testing personnel identifiers #2 - #5.</p>
<b>D5413</b>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in</p>

electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on lack of room temperature records, review of the Clinical Laboratory Improvement Amendments (CLIA) application (Form CMS-116), Biofire operator's manual and confirmed by laboratory personnel #1 (refer to the Laboratory Personnel Report) at approximately 1:45 pm on 10/07/2022; the laboratory failed to document the laboratory room temperature for 22 out of 22 days in May 2022. The findings include: 1. The CLIA application (Form CMS-116) states the hours of laboratory testing are 8:00 am - 5:00 pm Monday through Friday. 2. The Biofire operator's manual states that test cartridges are to be stored between 15 degrees - 25 degrees Celsius. 3. At the time of the survey, the laboratory did not document the Biofire cartridge (laboratory) room temperature for the following dates: 5/2 - 5/6/2022, 5/9 - 5/13/2022, 5/16 - 5/20/22, 5/23 - 5/27/22, 5/30/2022 and 5/31/2022.

**D5445**

**CONTROL PROCEDURES**

CFR(s): 493.1256(d)(1)(2)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of the Biofire Individualized Quality Control Plan (IQCP) and quality control records and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 1:45 pm on 10/7/2022, the laboratory failed to perform a positive and negative control with each new lot and/or shipment of respiratory panel cartridges for two out of two lot numbers used from 5/4/2022 - 7/1/2022. The findings include: 1. The Biofire IQCP states the laboratory will perform a positive and negative control with each new lot number and/or shipment of respiratory panel cartridges. 2. On 5/4/2022, the laboratory performed a negative control for lot number - 2CYA22 of respiratory panel cartridges. The laboratory did not perform a positive control. 3. On 7/1/2022, the laboratory performed a negative control for lot number - 2DKG22 of respiratory panel cartridges. Additionally, the laboratory performed a positive control for the virus SARS-CoV-2. The respiratory panel tested for 19 different viruses and bacteria, the laboratory did not perform a positive control for the remaining 18 viruses and bacteria. 4. At the time of the survey, no additional quality control records could be found for lot numbers 2CYA22 and 2DKG22 of respiratory panel cartridges.