

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D0521701	(X3) Date Survey Completed 11/19/2020
Name of Provider or Supplier Ada Pediatrics Pa	Street Address, City, State 650 N Cole Rd, Boise, ID	
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES 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 personnel training and competency assessment records, the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, and an interview with the Technical Consultant (TC), the laboratory failed to follow written policies and procedures to assess competency of testing personal at the 6 month interval. The findings include: 1. The CMS-209 form identifies seven (7) testing personnel who perform waived and moderate complexity testing. Two (2) of the seven (7) testing personal did not have documentation of 6 month competency assessment following their initial training. 2. An interview with the TC on 11/19/20 at 1:30 PM confirmed that there was not documentation for 6 month competency assessment for two (2) of the seven (7) listed testing personnel. 3. The laboratory reports performing 1,500 waived and 22 non-waived patient specimens annually.</p>
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on record review of the laboratory's policy and procedure manual and an interview with the Technical Consultant (TC), the laboratory director failed to</p>

approve, sign, and date the laboratory's policies and procedures as well as any changes in procedures. The findings include: 1. The laboratory director failed to approve, sign, and date all procedures in the laboratory's policy and procedure manual. 2. The laboratory director failed to approve, sign, and date the following procedures that had a revision date of May 21, 2020: "Protocol for Documenting Results," "Procedure for Lead Screening and Reporting," "Procedure for Collecting Blood Sample for HgB," "Procedure for Conducting a Streptococcus Test," "Procedure for Collecting a Clean Catch Urine," and "Urine Colony Count." 3. An interview with the TC confirmed the above findings on 11/19/20 at 1:45 PM 4. The laboratory reports performing 1,500 waived and 22 non-waived patient specimens annually

D5435

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(b)(2)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:
Based on an observation of the laboratory's incubator, record review of incubator temperature logs, and interview with the Technical Consultant (TC), the laboratory failed to perform and document periodic calibration checks of the thermometer in use in the incubator for urine colony counts. The findings include: 1. A direct observation of one (1) glass thermometer in use in the incubator for urine colony counts, had no documentation or record of periodic calibration. 2. A review of the incubator temperature log sheets revealed that there was no documentation of periodic thermometer calibration from the last survey on 05/11/18 to the current survey date of 11/19/20. 3. An interview with the TC on 11/19/20 at 2:30 PM confirmed that there was no documentation of calibration of the glass thermometer in use in the incubator for urine colony counts. 4. The laboratory reports performing 22 urine colony counts annually.