

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 33D0161435	<b>(X3) Date Survey Completed</b> 08/04/2022
<b>Name of Provider or Supplier</b> Shaker Pediatrics Pc	<b>Street Address, City, State</b> 10 Century Hill Drive Suite 5, Latham, NY	
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>D3031</b>	<p><b>RETENTION REQUIREMENTS</b> 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 the review of the Uricult System Quality Control (QC) records for 2021 and 2022 and an interview with the laboratory testing person, the laboratory failed to retain the Uricult System Clinical Laboratory Standards Institute (CLSI) certificates for the calendar years 2021 and 2022. FINDINGS: 1. Review of the Uricult System QC records for the calendar years 2021 and 2022, the laboratory failed to retain the Uricult System CLSI certificates. 2. Testing person confirmed on August 4, 2022 at 10:30 AM that the laboratory failed to retain the Uricult System CLSI certificates.</p>
<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 competency assessment policy and the competency evaluation records for the calendar years 2020, 2021 and an interview with the testing person, the laboratory failed to follow their written competency evaluation policy for the one routine testing person for the calendar years 2020 and 2021. FINDINGS: The competency evaluation form currently in use to assess the testing person competency</p>

failed to include the six criteria to evaluate the testing person. a. The laboratory's competency evaluation policy includes the six required components for competency assessment, including training, six-month for the first year of testing and annually thereafter. The six required components are: 1. direct observation of routine patient test performance, including preparation. specimen handling and testing; 2. monitoring the recording and reporting of test results; 3. review of intermediate results of worksheets, quality control records, proficiency testing results, and preventive maintenance records; 4. direct observation of performance of instrument maintenance and function checks; 5. assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and, 6. assessment of problem solving skills.

**D5291**

**GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT**  
CFR(s): 493.1239(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.

This STANDARD is not met as evidenced by:  
Based on review of the Quality Assessment (QA) policy and a interview with the testing person, the laboratory failed to follow their establish QA policy and perform a annual QA review for the calendar years 2020 and 2021. FINDINGS: 1. The laboratory to follow their establish QA policy and perform a annual QA review for the calendar years 2020 and 2021. a. 2020 and 2021 annual QA review documentation was not available for review. 2. The testing person confirmed on August 4, 2022 at approximately 11:00 AM, the laboratory to follow their establish QA policy.

**D5413**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**  
CFR(s): 493.1252(b)

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

This STANDARD is not met as evidenced by:  
Based on review of the laboratory temperature procedure for the incubator, the incubator temperature records for the calendar years 2020, 2021 through survey date and interview with the testing person, the laboratory failed to follow the manufacturer's temperature requiremenst for throat culture and urine colony counts testing. FINDINGS: 1. The laboratory performs throat culture. The manufacturer of the throat culture media used for testing and the laboratory's temperature policy require that the incubator temperature to be in the range of 35-38 degree Celsius. 2. The incubator temperature was out of range for the following: 3 days in April 2020 @ 40C 17 days in December 2020 @ 40C January 1, 2021 through December 31, 2021 @ 40C January 1, 2022 through August 4, 2022 @ 40C 3. Approximately 1,500

	<p>patients were tested for urine colony counts and throat cultures during the above dates 4. The testing person confirmed on August 4, 2022 at approximately 11:30 AM that the the laboratory failed to follow the manufacturer's temperature requiremenst for throat culture and urine colony count testing.</p>
<p><b>D6000</b></p>	<p><b>MODERATE COMPLEXITY LABORATORY DIRECTOR</b> CFR(s): 493.1403</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on surveyor's findings and an interview with the testing person, the laboratory director failed to provide overall management of the laboratory. FINDINGS: The laboratory director failed to ensure that the laboratory: 1. Maintained their written QA policy for all phases of laboratory testing, Refer to D6021; 2. Established competency assessment policy was followed, Refer to D6054.</p>
<p><b>D6021</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(5)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's QA policy, lack of QA documentation and an interview the testing person, the laboratory director failed to follow the establish QA procedure for having an ongoing mechanism to monitor, assess, and when indicated correct problems identified in the general laboratory system. Refer to D5291 and D5413</p>
<p><b>D6054</b></p>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's competency assessment policy, competency evaluation form currently in use and and confirmed in an interview with the testing person, the laboratory director, acting as the technical consultant, failed to assess the testing person using the six criteria requirements. Refer to D5209</p>