

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0695974	(X3) Date Survey Completed 10/06/2020
Name of Provider or Supplier Shoreview Pediatrics Sc	Street Address, City, State 2524 E Webster Place #301, Milwaukee, WI	
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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of laboratory procedures and proficiency testing (PT) records and interview with the laboratory director, the laboratory has not verified the accuracy of the colony count for urine cultures twice annually in 2019 and 2020. Findings include: 1. Review of laboratory procedures show the laboratory evaluates colony counts to report urine culture results: *If the colony count is less than 10,000 colonies / mL (milliliter), the laboratory reports the culture as negative, *The culture result is questionable when the colony count is 10,000 to 100,000 colonies / mL, *The laboratory considers the culture positive when the culture grows greater than 100,000 colonies / mL. 2. Review of PT records showed the PT program only graded the 'growth' or 'no growth' determination for each sample; no evidence of laboratory evaluation of the colony count was present in 2019 or 2020. 3. Interview with the laboratory director on October 6, 2020 at 1:00 PM confirmed the laboratory did not verify the accuracy of the colony count on urine cultures twice annually in 2019 or 2020.</p>
D5449	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g)</p> <p>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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.</p>

This STANDARD is not met as evidenced by:
 Based on surveyor review of laboratory records and interview with the laboratory director, the laboratory failed to perform positive and negative external quality control testing each day of patient testing for Pertussis and Mycoplasma testing on the Alethia analyzer, and had not developed an Individualized Quality Control Plan (IQCP). Findings include: 1. Review of laboratory quality control records showed the laboratory did not perform external quality controls each day of patient testing. Review of other laboratory records showed no evidence of an IQCP for testing performed on the Alethia analyzer. 2. Interview with the laboratory director on October 6, 2020 at 1:00 PM confirmed the laboratory did not perform external quality controls each day of patient testing. Further interview confirmed the laboratory had not established an IQCP consistent with the requirements identified at 493.1256 as an equivalent quality control program. This is a repeat deficiency previously cited on April 5, 2018.

D5477

CONTROL PROCEDURES
 CFR(s): 493.1256(e)(4)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
 Based on surveyor review of quality control records and procedures, and interview with the laboratory director, the laboratory had not checked each batch of Uricult media before or concurrent with the initial use for its ability to support growth and, as appropriate, select or inhibit specific organisms, or produce expected biochemical responses. The laboratory did not have a current Individualized Quality Control Plan (IQCP). Findings include: 1. Review of quality control records for the Uricult test system showed no documentation of evaluation of each batch of media by the laboratory. 2. Review of laboratory procedures showed no evidence of an IQCP for the Uricult test system. 3. Interview with the laboratory director on October 6, 2020 at 1:00 PM confirmed the laboratory did not have an IQCP for the Uricult test system. Further interview confirmed the laboratory did not check each batch of media for its ability to support growth and, as appropriate select or inhibit specific organisms, or produce expected biochemical responses prior or concurrent with the initial use. This is a repeat deficiency previously cited on April 5, 2018.

D6030

LABORATORY DIRECTOR RESPONSIBILITIES
 CFR(s): 493.1407(e)(12)

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)(12) Ensure that policies and procedures are established for

monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:

Based on surveyor review of laboratory procedures and interview with the laboratory director, the laboratory had not developed a procedure for the evaluation of competency using the six assessment criteria required at 493.1413(b)(8). Findings include: 1. Review of laboratory procedures showed no evidence of a written policy or procedure for the evaluation of testing personnel competency using the six assessment criteria required at 493.1413(b)(8). 2. Interview with the laboratory director on October 6, 2020 at 1:00 PM confirmed a written policy for evaluation of testing personnel competency had not been developed. This is a repeat deficiency previously cited on April 5, 2018.