

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0677386	(X3) Date Survey Completed 03/21/2019
Name of Provider or Supplier Memphis Childrens Clinic	Street Address, City, State 7705 Poplar Ave Suite 230 Bldg B, Germantown, TN	
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
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing records, and interview with the lead testing personnel, the testing personnel performing urine colony count and throat cultures failed to sign proficiency testing attestation statements in 2017, 2018, and 2019. The findings include: 1. Review of the laboratory's proficiency testing records revealed that the attestation statements for the urine colony count and throat culture were not signed by the testing personnel performing the final read of the cultures for 2017 event two, 2018 events one, two and three, and 2019 event one. 2. Interview with the lead testing personnel on March 21, 2019 at 4:45 pm confirmed the attestation statements for urine colony count and throat culture were not signed by the testing personnel who perform the final read of the cultures in 2017, 2018, and 2019.</p>
D2010	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2)</p> <p>The laboratory must test samples the same number of times that it routinely tests patient samples.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing records, patient culture logs, and interview with the lead testing personnel, the laboratory failed to test proficiency</p>

testing samples the same number of times it tests patient samples in 2017 and 2018. The findings include: 1. Review of the laboratory's proficiency testing records revealed repeat testing of proficiency testing as follows: 2017 event two-Urine colony count performed on 6.28.2017, all five samples repeated on 7.05.2017. 2017 event three-throat culture performed on 10.09.17, two samples (TH-11 and TH-12) repeated on 10.11.17. 2. Review of random patient culture logs revealed no repeat testing of urine colony count or throat culture. 3. Interview with the lead testing personnel on March 21, 2019 at 4:45 pm confirmed the laboratory does not routinely perform repeat testing of patient urine colony count and throat culture and did not test proficiency testing samples the same number of times it tests patient samples in 2017 and 2018.

D2015

TESTING OF PROFICIENCY TESTING SAMPLES
CFR(s): 493.801(b)(5)(6)

(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's proficiency testing records and interview with the lead testing personnel, the laboratory failed to maintain a copy of all proficiency testing records for a minimum of two years in 2017 and 2018. The findings include: 1. Review of the laboratory's proficiency testing records revealed no urine colony count or throat culture logs documenting all testing steps as follows: No test logs for 2018 events one, two and three. No read date and time on the log for urine colony count and throat culture for 2017 event two. 2. Interview with the lead testing personnel on March 21, 2019 at 4:45 pm confirmed the laboratory did not maintain all proficiency testing records in 2017 and 2018.

D5209

PERSONNEL COMPETENCY ASSESSMENT POLICIES
CFR(s): 493.1235

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.

This STANDARD is not met as evidenced by:
Based on review of the laboratory procedure manual, testing personnel competency assessment records, and interview with the lead testing personnel, the laboratory failed to have a procedure to include all six criteria for assessing personnel competency. The findings include: 1. Review of the laboratory procedure manual revealed the following six criteria were not included in the procedure and competency documentation: direct observation of routine patient test performance; monitoring the

recording and reporting of test results; review of intermediate test results or worksheets, quality control records, proficiency testing results and preventative maintenance records; direct observation of performance of instrument maintenance and function checks; assessment of test performance through previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and assessment of problem solving skills. The competency assessment policy was titled "POLICY FOR COMPETENCY TESTING OF MEDICAL ASSISTANTS." The policy only applied to medical office assistants and did not include testing personnel who perform the final read of the urine colony count and throat culture. 2. Review of the 2017 and 2018 competency assessment records for testing personnel performing the final read of the urine colony count and throat culture revealed the competency assessment did not include all six elements. 3. Interview on March 21, 2019 at 4:45 pm with the lead testing personnel confirmed the testing personnel competency procedure did not include the six criteria for testing personnel competency assessment required by the Centers for Medicare and Medicaid Services (CMS) and did not include testing personnel who perform urine colony count and throat cultures.

D5213

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(b)(1)

The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's proficiency testing records and interview with the lead testing personnel, the laboratory failed to evaluate non-graded proficiency testing scores in 2018. The findings include: 1. Review of the laboratory's proficiency testing scores for 2018 microbiology event two revealed a score of "Not Graded" for sample number UR-10. There was no evaluation of the reported result to determine laboratory accuracy. 2. Interview with the lead testing personnel on March 21, 2019 at 4:45 pm confirmed the laboratory failed to evaluate non-graded proficiency testing scores for 2018 event two sample UR-10.

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 review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report (CMS209), the laboratory testing personnel competency assessment records, and interview with the lead testing personnel, the technical consultant failed to perform competency assessment for six of eleven personnel performing patient testing for urine colony count and throat culture, and three of four personnel performing patient testing for complete blood count (CBC). The findings include: 1. Review of the CMS209 revealed the names of eleven testing personnel who perform urine colony count and throat culture patient testing. 2. Review of the laboratory competency assessment records revealed no documentation of competency assessment

for testing personnel numbers four, five, six, seven, eight and nine who perform final read of urine colony count and throat culture in 2017, 2018, and 2019. 3. Review of the laboratory competency assessment records revealed no documentation of competency assessment performed by the technical consultant for testing personnel numbers one, two, and three who perform complete blood count testing in 2018 and 2019. 4. Interview with the lead testing personnel on March 21, 2019 at 4:45 pm confirmed the technical consultant failed to perform competency assessment for six of eleven testing personnel performing urine colony count and throat culture, and three of four testing personnel performing complete blood count testing in 2017, 2018, and 2019.