Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0957613	11/09/2018
Name of Provider or Supplier	**Street Address, City, State**	
Memphis Children's Clinic Pllc	3155 Kirby Whitten Road, Bartlett, 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
D5002	BACTERIOLOGY CFR(s): 493.1201 If the laboratory provides services in the subspecialty of Bacteriology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1261, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: The laboratory failed to document the urine culture quality control results (Refer to D5411); and failed to identify and perform corrective action (Refer to D5791 citation number two).
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 2018 and 2018 personnel records, the laboratory procedure manual and interview with testing personnel number one, the laboratory failed to have a procedure to include all six criteria for assessing personnel competency. The findings include: 1) Review of the 2017 and 2018 personnel records revealed no documentation of competency assessment for the six required criteria. 2) 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 est 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. 3) Interview on November 9, 2018 at 3:00 p.m. with testing personnel number one confirmed the testing personnel competency procedure did not include the six criteria for testing personnel competency assessment.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of the 2018 urine culture quality control (QC) records and interview with testing personnel number one, the laboratory failed to document the urine culture quality control results for Escherichia (E.) coli and Pseudomonas (P.) aeruginosa for each new lot number in 2017 and 2018. The findings include: 1) Review of the August and October 2018 urine culture QC records revealed documented new lot numbers, E. coli and P. aeruginosa QC organisms, date of incubation, with no documentation of the QC results. 2) Interview on November 9, 2018, at 2:30 p.m. with testing personnel number one confirmed the QC organisms are inoculated but no QC results are documented for each new lot number, in 2017 and 2018.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: CITATION NUMBER ONE: Based on review of the April, July and October 2018 complete blood count (CBC) quality control (QC) records, the April, July and October 2018 quality assessment (QA) records, interview with the laboratory director, the laboratory QA process was ineffective for identifying and correcting CBC QC documentation problems, when the printed CBC QC summary included QC data of different lot numbers, in 2018. The findings include: 1) Review of the December 5, 2017 to March 1, 2018 CBC QC summary records revealed low lot number 069000 in use from 12-05-17 to 03-01-18; normal lot number 079000 in use from 12-05-17 to 02-26-18; and, high lot number 089000 in use from 12-05-17 to 02-08-18. 2) Review of the February 15, 2018 daily CBC QC instrument printouts revealed documented new lot numbers low 069000, normal 079000, and high 089000 expiration date 05-07-18, began in use. 4) Review of the February 2018 QA documentation revealed no identification and corrective action for the CBC QC summary printouts containing the incorrect lot numbers, expiration date, QC acceptable ranges, and daily QC performance data. 5) Interview on November 9, 2018 at 4:00 p.m. with the laboratory

	director confirmed the identification and corrective action were not performed for the incorrect CBC QC summaries in 2018. CITATION NUMBER TWO: Based on review of the 2018 quality assessment (QA) records and interview with testing personnel number one, the laboratory failed to identify and perform corrective action when the urine sterility plate was not incubated for 72 hours and when the urine culture QC organism results were not documented, in 2018. The findings include: 1) Review of the 2018 QA records revealed monthly review by the laboratory director with no corrective action documentation for the urine culture media sterility plate not incubated for 72 hours and when the urine culture media QC organism results were not documented. 2) Interview on November 9, 2018 at 2:30 p.m. with testing personnel number one confirmed the laboratory director reviews the monthly urine culture QC data, with no corrective action documented when the urine culture organism results are not documented.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of the February and October 2018 CBC QC instrument printouts and interview with the laboratory director, the laboratory failed to include the laboratory address on the CBC QC instrument printouts. The findings include: 1) Review of the February 15 and October 25, 2018 CBC QC instrument printouts revealed no laboratory address. 2) Interview on November 9, 2018 at 3:46 p.m. with the laboratory director confirmed the laboratory address was not included on the CBC QC instrument printouts.