

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0315095	(X3) Date Survey Completed 11/09/2018
Name of Provider or Supplier Memphis Children's Clinic	Street Address, City, State 6385 Stage Rd, Suite 2, 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
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the 2017 and 2018 proficiency testing (PT) records and interview with testing personnel number one, the laboratory failed to document the PT results of the urine colony count culture onto the urine culture worksheet and the PT results of the throat culture onto the throat culture worksheet, in 2017 and 2018. The findings include: 1) Review of the 2017 events one, two, three, 2018 events one, and two PT records revealed the urine culture worksheets and the throat culture worksheets did not include the PT sample results; a separate sheet of paper contained the results of the PT samples with no date and no testing personnel initials. 2) Interview on November 9, 2018 at 11:30 a.m. with testing personnel number one confirmed the urine culture worksheets and the throat culture worksheets do not include the PT sample results. The 2017 and 2018 PT throat culture results and the urine colony count culture results were written on a separate sheet of paper for the providers to review.</p>
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 personnel records, the laboratory procedure manual and interview with the laboratory director, the laboratory failed to have a personnel competency assessment procedure to include the six competency assessment criteria. The findings include: 1) Review of the laboratory procedure manual revealed the personnel competency procedure and worksheet did not include the following six criteria for ensuring competency: direct observation of test performance; monitoring the recording and reporting of test results; review of intermediate test results; direct observation of instrument maintenance; assessment of test performance; and, assessment of problem solving skills. 2) Review of the 2017 and 2018 testing personnel competency records revealed no documentation for these six criteria included in the competency documentation for bacteriology and hematology specialties. 3) Interview on November 9, 2018 at 3:45 p.m. with the laboratory director confirmed the laboratory procedure for competency assessment did not include all six assessment criteria and was not in use during the 2017 and 2018 testing personnel competency performance.

D5400

ANALYTIC SYSTEMS

CFR(s): 493.1250

Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:

The laboratory failed to: follow the manufacturer instructions for inoculation of the sterile urine specimen (Refer to D5411 citation number one); failed to follow the manufacturer instructions for incubation of uninoculated quality control culture plates for 72 hours (Refer to D5411 citation number two); failed to follow the manufacturer instructions for reporting patient results (Refer to D5411 citation number three); failed to ensure the complete blood count (CBC) quality control (QC) was not in use after the expiration date (Refer to D5415); failed to document the urine culture quality control results with each new lot number (Refer to D5481); failed to identify and perform corrective action for CBC QC (Refer to D5791 citation number one); and, failed to identify and perform corrective action for urine culture QC (Refer to D5791 citation number two).

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:

CITATION NUMBER ONE: Based on observation of the laboratory, review of the Troy Biologicals, Inc Uri-Check Plus manufacturer instructions, and interview with testing personnel number one, the laboratory failed to follow the manufacturer instructions for inoculation of the sterile urine specimen to the culture media. The findings include: 1) Observation of the laboratory on November 9, 2018 at 9:00 a.m. revealed an incubator on the counter in use for patient testing. 2) Review of the Troy Biologicals, Inc Uri-Check Plus manufacturer instructions revealed the patient urine specimen is to be poured onto the culture media until the paddle culture media is covered, using sterile technique. 3) Interview on November 9, 2018 at 11:45 p.m. with testing personnel number one confirmed application of the patient urine specimen to the Uri-Check Plus paddle culture media is that a non-sterile pipette to used to collect the urine specimen from the sterile container then the urine specimen is dripped onto the culture media. CITATION NUMBER TWO: Based on observation of the laboratory, review of the Selective Streptococcus Agar (SSA) manufacturer instructions, the laboratory throat culture quality control (QC) records and interview with testing personnel number one, the laboratory failed to follow the manufacturer instructions for incubation of uninoculated quality control culture plates for 72 hours. The findings include: 1) Observation of the laboratory on November 9, 2018 at 9:00 a. m. revealed an incubator on the counter in use for patient testing. 2) Review of the SSA manufacturer instructions revealed, "5. incubate uninoculated representative plates at 35+/- 2*C for 72 h and examine for microbial contamination." 3) Review of the laboratory throat culture QC records revealed, "unplated plate w/NG >24H? y/n /inits", with no date and time of reading. 4) Interview on November 9, 2018 at 10:30 a. m. with testing personnel number one confirmed the sterile uninoculated QC culture plate is reported at 24 hours incubation along with the other QC plates, and not at 72 hour incubation. CITATION NUMBER THREE Based on observation of the laboratory, review of the Taxo Discs for Differentiation of Group A Streptococci manufacturer instructions, patient number two final report, and interview with testing personnel number one, the laboratory failed to follow the manufacturer instructions for reporting patient results as presumptive positive Streptococcus A culture. The findings include: 1) Observation of the laboratory on November 9, 2018 at 9:00 a.m. revealed an incubator on the counter in use for patient testing. 2) Review of the Taxo Discs for Differentiation of Group A Streptococci manufacturer instructions revealed, "It is recommended that any zone of inhibition, regardless of diameter, be reported as "beta-hemolytic Streptococcus, presumptively group A by bacitracin." 3) Review of patient number two final throat culture report revealed on 9-11-18 a throat culture was reported as, "Results: Positive per Dr. ..". 4) Interview on November 9, 2018 at 10:45 a.m. with testing personnel number one confirmed the throat culture patient report is not reported correctly, which should be reported as presumptive positive.

D5415

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

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:
Based on review of the April 2018 complete blood count (CBC) quality control (QC) records, the patient CBC testing logsheet and interview with testing personnel number one, the laboratory failed to ensure the CBC QC was not in use after the expiration date. The findings include: 1) Review of the April 24 and 25, 2018 CBC QC daily instrument printouts revealed lot number 078900 expiration date 4-23-18 was in use. 2) Review of the April 2018 patient CBC testing logsheet records revealed patient testing was performed and reported on April 24 and 25, 2018. 3) Interview on November 9, 2018 at 10:50 a.m. with testing personnel number one confirmed April 24 and 25, 2018 patient CBC testing was performed and reported when expired CBC QC was in use.

D5481

CONTROL PROCEDURES
CFR(s): 493.1256(f)(g)

(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on review of the 2017 and 2018 urine culture quality control (QC) records and interview with testing personnel number one, the laboratory failed to document the urine 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 2017 and 2018 urine 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 11:40 a.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 April 2018 CBC QC records revealed the printed CBC instrument summary report documented from April 2 through April 30, 2018, lot numbers low 069500, normal 079500, and high 089500 with expiration date 07-16-18, in use. 2) The April 1 to April 25, 2018 daily CBC QC instrument printouts revealed documented lot numbers low 068900,

normal 078900, and high 088900 expiration date 04-23-18, in use. 3) Review of the July CBC QC summary revealed the printed CBC instrument summary report documented from July 2 to July 31, 2018, lot numbers low 067600, normal 077600 and high 087600, expiration date 10-08-18, in use. 4) Review of the July 1 to July 16, 2018 daily CBC QC instrument printout revealed documented lot numbers Low 069500, normal 079500, and high 089500 expiration date 07-16-18, in use. 5) Review of the October 2018 CBC QC summary printout revealed October 1 to 31, 2018 lot numbers low 068300, normal 078300, high 088300 expiration date 01-14-19, in use. 6) Review of the October 1 to October 4, 2018 daily CBC QC instrument printouts revealed lot numbers low 067600, normal 077600 and high 087600, expiration date 10-08-18, in use. 7) Review of the April, July and October 2018 QA documentation revealed no identification and corrective action for the CBC QC summary printouts containing the incorrect lot numbers, expiration dates, QC acceptable ranges, and daily QC performance data. 8) Interview on November 9, 2018 at 3:35 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 11:45 a. m. with testing personnel number one confirmed the laboratory director reviews the monthly urine QC data, with no corrective action documented for the QC failures.

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:
CITATION NUMBER ONE: Based on observation of the laboratory, review of patient number one final complete blood count (CBC) report and interview with testing personnel number one, the laboratory failed to include a unique patient identifier on the patient CBC instrument printout. The findings include: 1) Observation of the laboratory on November 9, 2018 at 8:41 a.m. revealed a Beckman Coulter AcTdiff 2 instrument on the counter in use for patient testing. 2) Review of patient number one final CBC report dated 09-14-18 revealed the instrument printout did not include a unique patient identifier. 3) Interview on November 9, 2018 at 10:00 a.m. with testing personnel number one confirmed the patient unique identifier is supposed to be on the patient CBC instrument printout. CITATION NUMBER TWO: Based on review of the April, July and October 2018 CBC QC instrument printouts and interview with the laboratory director, the

laboratory failed to include the laboratory name and address on the CBC QC instrument printouts. The findings include: 1) Review of the April 25, July 16 and October 5, 2018 CBC QC instrument printouts revealed no laboratory name and address. 2) Interview on November 9, 2018 at 3:46 p.m. with the laboratory director confirmed the laboratory name and address was not included on the CBC QC instrument printouts.

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 review of testing personnel records, review of the urine culture quality control (QC) records, the throat culture QC records and interview with testing personnel number one and the laboratory director, the laboratory director failed to ensure testing personnel number one is competent for performing and reporting urine culture QC results and throat culture QC results results. The findings include: 1) Review of testing personnel number one records revealed on 7-31-18 documented competency for urine and throat cultures. 2) Review of the urine culture QC records revealed on June 28, 2018, no results were documented for the Escherichia coli and Pseudomonas aeruginosa QC and no date of the reading, with testing personnel number one initials for reporting. 3) Review of the throat culture QC records revealed on 7-9-18, 8-7-18 and 9-14-18 QC results were documented with no date of the reading of the Streptococcus pyogenes and Streptococcus agalactiae QC, with testing personnel number one initials for reporting. 4) Interview on November 9, 2018 at 10:10 a.m. with testing personnel number one confirmed she performed and documented the urine and throat culture QC, and that the competency is for inoculating the cultures not reading/reporting. 5) Interview on November 9, 2018 at 3:45 p.m. with the laboratory director confirmed the 2018 competency documentation is not for reading/ reporting the urine and throat culture QC.