

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0677022	(X3) Date Survey Completed 02/05/2019
Name of Provider or Supplier Memphis Children's Clinic	Street Address, City, State 6615 Kirby Center Cove, Memphis, 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
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Services Laboratory Personnel form (CMS 209), the laboratory's proficiency testing records and interview with the lead testing personnel, the laboratory failed to rotate proficiency among testing personnel who perform patient testing for urine colony count and throat culture in 2017 and 2018. The findings include: 1) Review of the CMS 209 form revealed the names of eight testing personnel (providers) who perform patient testing for urine colony count and throat culture. 2) Review of the laboratory's proficiency testing records revealed attestation statements for urine colony count and throat culture signed by testing personnel number eight for testing events 2017-2, 2017-3, 2018-1, 2018-2, and 2018-3. 3) Interview with the lead testing personnel on February 5, 2019 at 12:30 p.m. confirmed the laboratory failed to rotate proficiency testing for urine colony count and throat culture among all testing personnel in 2017 and 2018.</p>
D3031	<p>RETENTION REQUIREMENTS 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>

This STANDARD is not met as evidenced by:
 Based on review of the laboratory's quality control records, proficiency testing records, and interview with the lead testing personnel, the laboratory failed to retain manufacturer assay sheets for complete blood count (CBC) controls for five of twelve control lot numbers in 2017 and 2018, and failed to maintain a paper trail for provider responses for proficiency testing in 2017 and 2018. The findings include: 1) Review of the laboratory's quality control records revealed that the following lot number manufacturer assay sheets were not retained: lot numbers 069400, 079400, 089400-in use on 7.30.17; 067800, 077800-in use on 10.2.18. 2) Review of the laboratory's proficiency testing records revealed there was no paper trail for provider responses for Urine Microscopy and Pinworm Prep for 2017 events two and three, and 2018 event two. 3) Interview with the lead testing personnel on February 5, 2019 at 4:00 p.m. confirmed the laboratory failed to retain quality control and proficiency testing records for at least two years. Five of twelve manufacturer assay sheets for CBC controls in 2017 and 2018, and provider responses for microscopy proficiency testing in 2017 and 2018 were not retained. _____

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, the Centers for Medicare and Medicaid Services form (CMS 209), the competency assessment policy, and interview with the lead testing personnel, the laboratory's policy for competency assessment failed to include all six criteria for assessing personnel competency, and failed to include competency assessment for providers performing urine microscopy, pinworm prep, urine colony count, and throat culture. The findings include: 1) Review of the laboratory procedure manual revealed the following six criteria were not included in the competency assessment policy: 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. 2) Review of the CMS 209 revealed the names of eight providers who perform urine microscopy, pinworm prep, urine colony count, and throat culture. 3) Review of the laboratory policy for competency assessment revealed that the competency assessment policy did not include competency assessments for the providers performing urine microscopy, pinworm prep, urine colony count, and throat cultures. 4) Interview on February 5, 2019 at 11:30 a.m. with the lead testing personnel confirmed the testing personnel competency policy did not include the six criteria for testing personnel competency assessment required by the Centers for Medicare and Medicaid Services (CMS), and failed to include competency assessment for providers performing moderately complex testing for urine microscopy, pinworm prep, urine colony count, and throat culture. _____

D5215

EVALUATION OF PROFICIENCY TESTING PERFORMANCE

CFR(s): 493.1236(b)(2)

The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).

This STANDARD is not met as evidenced by:

Based on review of the 2018 event two microbiology proficiency testing performance evaluation report 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 2018 event two microbiology proficiency testing performance evaluation report revealed a score of Not Graded (No consensus) for urine colony count for sample number UR-10. There was no evaluation of the results to determine the laboratory's accuracy. 2) Interview with the lead testing personnel on February 5, 2019 at 12:30 p.m. confirmed the laboratory failed to evaluate non-graded proficiency testing scores for 2018 microbiology event two for sample number UR-10.

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 observation of the laboratory, review of the manufacturer package insert and interview with the lead testing personnel, the laboratory failed to label complete blood count (CBC) controls with corrected expiration date in 2019. The findings include: 1) Observation of the laboratory on February 5, 2019 at 9:00 a.m. revealed CBC control vials (lot numbers 069100, 079100, 089100) in use labeled "2-1-19." 2) Review of the Beckman Coulter 4C-ES manufacturer package insert revealed the CBC controls are good for 35 days after opening for a maximum of 20 samplings. 3) Interview with the lead testing personnel on February 5, 2019 at 10:00 a.m. confirmed the laboratory did not label CBC controls with corrected expiration after opening in 2019.

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 review of patient number four test report, urine colony count patient test logs, urine colony count quality control records, and interview with the lead testing personnel, the laboratory failed to perform quality control for urine colony count media for lot number 8D20A in 2018 with 58 patient tests performed. The findings include: 1) Review of patient number four test report revealed patient testing for urine colony count on October 10, 2018. 2) Review of the urine colony count patient test log revealed media lot number 8D20A in use at the time of patient number four testing. The lot number was in use from 8.27.18 to 11.26.18 with 58 patient tests performed. 3) Review of the urine colony count quality control records revealed no quality control records were available for media lot 8D20A. 4) Interview with the lead testing personnel on February 5, 2019 at 4:00 p.m. confirmed quality control records were not located for urine colony count media lot number 8D20A, with patient testing performed. _____

D5787

TEST RECORDS
 CFR(s): 493.1283(a)

The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).

This STANDARD is not met as evidenced by:
 Based on review of the laboratory's proficiency testing records, quality control records, and interview with the lead testing personnel, the laboratory failed to identify testing personnel and culture read dates/times for proficiency testing in 2018, and the identity of personnel performing quality control for the throat culture system in 2019. The findings include: 1) Review of the laboratory's proficiency testing records revealed the following: Microbiology 2018 Event two: Urine colony count test record log-no identity of testing personnel for any of the five samples, no record of the read date/time. Original proficiency testing results for sample numbers UR-06, UR-07, UR09 were marked through and changed with no identity of the person who changed the original results. Throat culture log-no identity of testing personnel for any of the five samples, no record of the read date/time. Microbiology 2018 Event three: Urine colony count and throat culture record log-no identity of testing personnel providing the final test result. 2) Review of the laboratory's quality control records for throat culture system revealed no identity of the personnel who performed the quality control in January 2019. 3) Interview with the lead testing personnel on February 5, 2019 at 4:00 p.m. confirmed the laboratory failed to identify the testing personnel and culture read dates/time for proficiency testing in 2018, and the identity of testing personnel performing quality control for the throat culture system in 2019.

D6019

LABORATORY DIRECTOR RESPONSIBILITIES
 CFR(s): 493.1407(e)(4)(iv)

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)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:

Based on review of the laboratory procedure manual, the laboratory's proficiency testing records and interview with the lead testing personnel, the laboratory director failed to ensure an approved corrective action plan was followed for unacceptable or unsatisfactory results in 2017 and 2018. The findings include: 1) Review of the laboratory procedure manual revealed no procedure or corrective action plan was present for addressing unacceptable or unsatisfactory proficiency testing results. 2) Review of the laboratory's proficiency testing records revealed the following: 2017 event two microbiology-Unacceptable scores for urine colony count for UR-09 and UR-10, resulting in an overall score of 60%, with no investigation into the cause of the failures. 2017 event three microbiology-Unacceptable score for urine colony count for UR-15 with no corrective action documented. 2018 event two microbiology-Unacceptable score for UR-07. No corrective action performed. 2017 event two hematology-Unacceptable score for HEM-08 monocyte %, unacceptable score for HEM-06 for red blood cell count. No corrective action performed. 3) Interview with the lead testing personnel on February 5, 2019 at 12:30 p.m. confirmed the laboratory does not have a proficiency testing corrective action plan for unacceptable or unsatisfactory proficiency testing results and the laboratory director failed to ensure corrective actions were performed for unacceptable proficiency testing results for complete blood count and microbiology in 2017 and 2018.

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 form (CMS 209), laboratory testing personnel records, and interview with the lead testing personnel, the technical consultant failed to ensure competency assessment was performed for providers performing urine microscopy, pinworm prep, urine colony count, and throat culture in 2017, 2018, and 2019. The findings include: 1) Review of the CMS 209 revealed the names of eight providers who perform urine microscopy, pinworm prep, urine colony count, and throat culture. 2) Review of the laboratory testing personnel records revealed no competency assessment documents were available for providers performing moderately complex testing for urine microscopy, pinworm prep, urine colony count, and throat culture in 2017, 2018, and 2019. 3) Interview with the lead testing personnel on February 5, 2019 at 11:30 a.m. confirmed no competency assessment documents were available for providers performing moderately complex testing in 2017, 2018, and 2019.