

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0902104	(X3) Date Survey Completed 09/25/2019
Name of Provider or Supplier Eastern Shore Children's Clinic	Street Address, City, State 7 Medical Park Drive, Fairhope, AL	
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
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>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 general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the personnel records, including training checklists and competency assessments, a review of the policy for personnel assessments, and interviews with the Clinic Manager (also Testing Personnel #9) and the Laboratory Director, the surveyor determined the laboratory failed to ensure testing personnel were trained, prior to assessing the competency (semiannually). This affected four of seventeen testing personnel, who perform moderate complexity testing in Hematology and Bacteriology. The findings include: 1. A review of the personnel records revealed the semiannual competency assessments for Testing Personnel (TP) #10, #12, #14, and #16 were done prior to the personnel being trained, according to the dates indicated on the training records/checklists. 2. According to TP #10's laboratory training checklist, the employee completed training on September 24, 2019. However the semiannual competency assessment was dated as performed on September 23, one day prior to the employee completing laboratory training. 3. TP #12 completed training on July 15, 2018; however had her "semiannual" competency assessed on July 2, 2018. 4. TP #14's "semiannual" competency was documented as being assessed on July 2, 2018; however the laboratory training was not completed until January 1, 2019, according to the personnel's laboratory training checklist. 5. TP #16's "semiannual" competency assessment was documented as being done on May 6, 2019; however the employee's laboratory training was not documented as being complete until September 23, 2019. 6. At 9:54 AM on October 2, 2019, the surveyor discussed with the Clinic Manager, the training and competency assessments of the</p>

testing personnel, specifically inquiring why the competency of the laboratory personnel was assessed, prior to the employee completing training. The Clinic Manager stated the personnel sometimes needed remedial training, prior to completion of initial training. A review of the training checklists revealed only one completion date for all tests performed by the laboratory personnel. There was no indication of what or which testing procedures the re-training was needed and which tests the personnel were assessed as being competent, not requiring remediation. The Clinic Manager stated the Laboratory Director performed the semiannual competency assessment from date-of-hire, regardless if training was completed or not. 7. At 1:00 PM On October 2, the surveyor explained to the Clinic Manager and the Laboratory Director the need to complete the training, prior to assessing the competency of an individual; and not expect an employee to be competent prior to being trained.

D5781

CORRECTIVE ACTIONS
CFR(s): 493.1282(b)(1)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:
Based on a review of the test menu with the Clinic Manager {also Testing Personnel (TP) #9}, upon initial tour of the laboratory, on October 2, 2019, a review of the incubator temperatures, a review of the Uricult procedure, and an interview with TP #9, the surveyor determined the laboratory failed to implement corrective actions, when the incubator temperatures exceeded the established acceptable ranges. This affected four days in 2019, from January to September 30. The findings include: 1. During the initial tour of the laboratory on October 2, 2019 at 9:30 AM, the Clinic Manager stated urine colony counts were performed using the Uricult test media and system. 2. A review of the Uricult (urine culture paddle) procedure revealed the culture specimen should be incubated at 35 to 37 degrees Celsius for 18-24 hours. 3. A review of the temperature logs revealed on March 29 and 30 of 2019, the incubator temperature was 40 degrees Celsius, exceeding the optimal temperature for specimen incubation. On May 17, 2019, the temperature was recorded as 42 degrees Celsius, and 45 degrees on July 12, 2019. The laboratory did not document corrective actions for the incubator temperatures found outside the acceptable limits. 4. In an interview on October 2, 2019 at 12:54 PM, the Clinical Manager reviewed the temperature logs and confirmed the unacceptable temperature recordings, without documented corrective actions.