

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0703618	(X3) Date Survey Completed 05/16/2019
Name of Provider or Supplier Little Rock Pediatric Clinic	Street Address, City, State 500 South University, Suite 615, Little Rock, AR	
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: . Through a review of the Quality Assessment Plan, Proficiency Testing (PT) records for 2018 and 2019, Survey exception reports and interviews with staff, it was determined the Laboratory failed to prevent the recurrence of problems in the General Laboratory Systems. As evidenced by: A. A review of the Laboratory's Quality Assessment Plan for Proficiency Testing revealed: "Each proficiency report generated by a PT program must be reviewed, dated and signed by laboratory director or technical consultant. Any unacceptable result will be investigated and the corrective action resulting from identified problems will be documented on the Survey Exception Report." B. A review of PT records for 2018 and 2019 revealed the laboratory failed Wet Prep analysis in three of three Proficiency Testing events. The laboratory scored 0% in the second and third proficiency testing event of 2018 and 0% for the 1st proficiency testing event of 2019. C. A review of the laboratory's survey exception report for the second PT event of 2018 revealed: Synopsis of Investigation by the technical consultant (as listed on CMS form 209) test completed by laboratory personnel #4(as listed on CMS form 209) "went over how to identify Clue Cells and to look for Bacteria in background and "fuzzy" edges." Also under the section Evidence of Successful Corrective Action "went over Clue Cells with laboratory personnel #4 (as listed on CMS form 209) and easy ways to identify them." D. A review of the laboratory's survey exception report for the third PT event of 2018 revealed: Synopsis of Investigation by the technical consultant (as listed on CMS form 209) 0% scored obtained in the third PT event Clue Cell was due to clerical error.</p>

Also, under the section Evidence of Successful Corrective Action "went over with staff to double check all results when reporting have a second reviewer verify results." E. A review of the laboratory's survey exception report for the first PT event of 2019 revealed: Synopsis of Investigation by the technical consultant (as listed on CMS form 209) "this is the third failure for wet preps, again missing Clue Cells. Testing person is no longer employed. The photograph was not real clear so "best guess was employee-only one cell to look at." Also under section Evidence of Successful Corrective Action: "went over Clue Cells with all laboratory personnel and how to recognize them all patients for wet prep testing in 2018 (five of five patients) and 2019 (six of six patients) reviewed." F. The Laboratory's Quality Assessment Plan did not prevent recurrence of problems in the second and third proficiency testing event of 2018, or the first proficiency testing event of 2019. G. In an interview on 5/16/2019 at 1100, the technical consultant (as listed on form CMS 209) confirmed the laboratory failed to prevent the recurrence of problems in the General Laboratory System.