Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2044942	05/26/2021
Name of Provider or Supplier	**Street Address, City, State**	
Purohit Pediatric Clinic Roanoke	4441 Highway 431, Suite 1, Roanoke, 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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) 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 This STANDARD is not met as evidenced by: Based on a review of the American Proficiency Institute (API) proficiency testing records, a review of the quality control records and an interview with the laboratory manager, the surveyor determined the laboratory failed to rotate the testing of proficiency specimens, among all personnel who test patient specimens [Complete Blood Counts (Hematology)]. This affected 8 of 8 Hematology testing events from 2018 (Event #3), 2019 and 2020 (six events), and 2021(Event #1). The findings include: 1. A review of API proficiency testing records revealed Testing Personnel (TP) #1 signed the attestation statements for all eight Hematology testing events from 2018 (Event #3) - 2021 (Event #1). 2. The laboratory staff listed the same three qualified and trained individuals on the CMS form #209 (Laboratory Personnel Report) as on the previous survey conducted 12/19/2018. 3. At 10:55 AM on May 26, 2021, the surveyor asked the laboratory manager (also listed as TP #3) about proficiency testing rotation, inquiring if TP #1 was the only personnel who perform Hematology testing. The laboratory manager stated TP #1 was the primary testing personnel, although TP #2 was usually on-site, and assisted with laboratory testing (CBC testing), when the laboratory is busy. TP #3, the laboratory manager, usually worked another location. The laboratory manager stated the testing would be rotated. 4. A review of the quality control records, from 2019 - 2021, revealed TP #2 performed testing on the Hematology analyzer.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c)

	(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on a review of Quality Assurance (QA) records and an interview with the laboratory manager, the surveyor determined the laboratory failed to document all assessments of patient chart reviews, performed monthly. This affected the survey review period from January 2019 - April 2021. The findings include: 1. A review of the Policy and Procedure Manual revealed a policy for the Quality Assurance Program, which listed the following as categories to monitor: Personnel; Specimen Collection and Handling; Patient Test Management and Record Keeping; Quality Control; Laboratory Safety; Proficiency Testing; Patient Test Results and Record Retention. The monthly QA checklists were all marked as having been done, with a check-mark or not-applicable (N/A). 2. During an interview on May 26, 2021 at 12:30 PM, the surveyor inquired if the laboratory staff performed any patient chart reviews. The laboratory manager confirmed approximately ten to twelve random chart reviews were done each month, but there was no documentation of the assessments of the chart reviews.