Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D1011038	01/18/2022
Name of Provider or Supplier	**Street Address, City, State**	
Purohit Pediatric Clinic	516 Quintard Avenue, Anniston, 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
D0000	
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory 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 general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on reviews of Quality Assurance (QA) records, personnel records and an interview with the Clinic Manager (Testing Personnel #1), the laboratory failed to implement additional training strategies for the testing personnel to ensure errors in the performance of Hematology testing did not continue to occur in 2019, 2020, and 2021. The findings include: 1. A review of 2019-2021 QA records revealed approximately twenty days when the Clinic Manager documented problems related to QC issues, including, A) Failure of the testing personnel to review each level of QC to insure there were no flags and all parameters were within acceptable ranges B) Failure to run all three levels of QC, as per laboratory policy C) Failure to check the QC expiration date; the surveyor noted three days when the testing personnel utilized expired controls. (Refer to D5417.) D) Failure to perform and document corrective action (service or maintenance) when the high control was run multiple times and still not within acceptable ranges. 3. The surveyor further noted the QA records documented three days when Medonic maintenance was not performed and documented, and one day when the background count during the start-up was not within acceptable limits. 4. The only corrective action for the above problems was to "counsel" the testing personnel, and to review patient results on 7/30/2019 when only one level of QC was acceptable. 5. A review of testing personnel records revealed

	training was incomplete, not well-documented, and there was a lack of technical supervision of the training by the Technical Consultant. (Refer to D6045.) 6. During an interview on 1/18/2022 at 1:20 PM, the surveyor reviewed the above records with the Clinic Manager (Testing Personnel #1), and explained the multiple problems over time with various testing personnel indicated the laboratory had a systemic problem in the training methodology. As corrective action to prevent the problems from recurring, the laboratory needed to implement a more complete a training strategy that included instruction by a technically qualified individual, emphasizing areas where the laboratory had noted multiple problems (Medonic QC and maintenance). .
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on a review of Hematology quality control (QC) records, Quality Assurance (QA) records, and an interview with the Clinic Manager (Testing Personnel #1), the laboratory failed to implement additional procedures and training to ensure testing personnel checked expiration dates and did not use expired QC material. Expired controls were used three days of patient testing by two different testing personnel in 2021. The laboratory further failed to document remedial action for eleven patients tested on days when expired QC was utilized. The findings include: 1. A review of Hematology QC records revealed expired controls were used on 3/14/2021 by a previous testing personnel no longer employed, and on 6/17 - 6/18/2021 by Testing Personnel #5. 2. A review of personnel records revealed no remedial training was implemented to ensure other new testing personnel were aware of the necessity to review expiration dates before running the daily QC. (Refer to D6045.) 3. A review of the Medonic M Series daily test log revealed patient testing was performed as follows: A) Two patient CBC's (Complete Blood Counts) on 3/25/2021 B) Seven CBC's on 6 /17/2021, and C) Two CBC's on 6/18/2021. 4. A review of the QA records revealed the only corrective action was review of controls the day before and the day after the 3 /25/2021 incident. There was was no documentation of the Laboratory Director's review of the patient CBC's performed on the above dates to ensure patient care was not compromised. 5. During an interview on 1/18/2021 at 4:50 PM, the surveyor reviewed and confirmed the above noted findings with the Clinic Manager. .
D6045	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(7) (b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; This STANDARD is not met as evidenced by: Based on reviews of personnel files, Quality Assurance (QA) records, and interviews with the Clinic Manager (Testing Personnel #1), the Technical Consultant (also the Laboratory Director), failed to provide technical supervision and ensure training was

	performed and documented as per CLIA requirements before testing personnel began patient testing. This affected four of four new testing personnel listed on the Form CMS-209 (Laboratory Personnel Report). The findings include: 1. A review of the Form CMS-209 (Laboratory Personnel Report) revealed four out of ten testing personnel were employed since the previous survey on 4/10/2019. 2. A review of testing personnel training records revealed the following: A) The "Lab Training" sheet, which included the following: a) "CBC [Complete Blood Count]/Controls /Calibration" b) "Bilirubin Controls" c) The sheet listed also waived tests, and training for other areas that do not fall under CLIA regulations such as "Vision Test", "Hearing Test", "TB [Tuberculin] Test". Next to each of the above blocks, another testing personnel had initialed the training, however there was no indication of how the training was performed. The Clinic Manager signed and dated the form; there was no documentation the Technical Consultant had reviewed and approved the training. B) Attached to the "Lab Training" sheet was a "M Series Checklist" for the Medonic Hematology analyzer, however there was no documentation of who had performed the training and there was no documentation the Technical Consultant had reviewed and approved the training. C) The surveyor further noted there was no documentation of Richert Bilirubinometer (a moderate-complexity test) training except for the box on the "Lab Training" sheet which did not document training on the Bilirubin test performance, trouble-shooting or sources of error. 2. A review of 2019-2021 QA records revealed approximately twenty days when the Clinic Manager documented problems related to QC issues, including, A) Failure of the testing personnel to review each level of QC to insure there were no flags and all parameters were within acceptable ranges B) Failure to run all three levels of QC, as per laboratory policy C) Failure to check the QC expiration date; the surveyor noted three days when the testing personnel utilized expired controls. (Refer to D5417.) D) Failure to perform and document corrective action (service or maintenance) when the high control was run multiple times and still not within acceptable ranges 3. The surveyor further noted the QA records documented three days when Medonic maintenance was not performed and documented, and one day when the background count during the start-up was not within acceptable limits. 4. During an interview on 1/18/2022 at 1:20 PM, the surveyor reviewed the above records with the Clinic Manager (Testing Personnel #1), and explained the multiple problems over time with various testing personnel indicated the laboratory had a systemic problem in the training methodology, including a lack of technical supervision by the Technical Consultant. The laboratory needed to develop a training strategy that included instruction by a technically qualified individual, emphasizing areas where the laboratory had noted multiple problems (QC and maintenance). The laboratory further needed to develop a more complete checklist for training on the Reichert Bilirubinometer. .
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on reviews of personnel files and an interview with the Clinic Manager (Testing Personnel #1), the Technical Consultant (also the Laboratory Director), failed to provide technical supervision in evaluating the semi-annual competencies for five of ten testing personnel listed on the Form CMS-209 (Laboratory Personnel Report).

	The findings include: 1. A review of personnel records revealed no documentation of the Technical Consultant's review and approval of semi-annual competencies for five of ten testing personnel in 2019, 2020 and 2021. Semi-annual competencies for Testing Personnel #2, #5, #7, #9, and #10 were performed by the Clinic Manager (Testing Personnel #1) who has a high school diploma, and does not qualify as an individual able to fulfill the responsibilities performed by a Technical Consultant. 2. During and interview on 1/18/2022 at 1:20 PM, the above noted findings were reviewed and confirmed with the Clinic Manager. .
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on reviews of personnel files and an interview with the Clinic Manager (Testing Personnel #1), the Technical Consultant (also the Laboratory Director), failed to provide technical supervision in evaluating the annual competencies for eight of ten testing personnel listed on the Form CMS-209 (Laboratory Personnel Report). The findings include: 1. A review of personnel records revealed no documentation of the Technical Consultant's review and approval of annual competencies for eight of ten testing personnel in 2019, 2020 and 2021. Annual competencies were performed by the Clinic Manager (Testing Personnel #1) who has a high school diploma, and does not qualify as an individual able to fulfill the responsibilies performed by a Technical Consultant. 2. During and interview on 1/18/2022 at 1:20 PM, the above noted findings were reviewed and confirmed with the Clinic Manager. SURVEYOR ID# 32258 Licensure and Certification Surveyor