Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0990431	03/22/2018
Name of Provider or Supplier	**Street Address, City, State**	
Internal Medicine And Pediatrics Of Cullman, Pc	1890 Al Highway 157, Suite 430, Cullman, 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
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on a review of the validation documentation and procedures for the Nano Tech Frend analyzer and an interview with the Technical Consultant and the Testing Personnel, the surveyor determined the laboratory failed to ensure the Laboratory Director signed and dated his review and approval of these new procedures before use by the testing personnel. The findings include: 1. A review of the verification procedures (performed 9/27 thru 10/4/2016) for Thyroid Stimulating Hormone (TSH), Free T4, and Prostatic Specific Antigen (PSA) on the Nano Tech Frend, revealed only the Technical Consultant's signature with the date 11/3/2016. There was no evidence the Laboratory Director had approved the new testing procedures. The laboratory had previously used the Mini Vidas for testing these analytes until September 2016. 2. During an interview on 3/22/2018 at 2:15 PM, the surveyor explained approval of new procedures cannot be delegated, and then asked if the Laboratory Director had signed and dated his approval of the tests performed on the Frend analyzer before patient testing began. The Technical Consultant explained she had approved, signed and dated the verification data, then the Director had "looked" at it, however he had not signed the documents. When asked the date when patient testing began, the Testing Personnel reviewed her records, and answered 11/11/2016, thus confirming the above noted findings. .
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially

	available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on a review of the 2016-2017 API (American Proficiency Institute) proficiency testing (PT) records, a lack of pipettor maintenance and calibration records, and interviews with the Technical Consultant, the surveyor determined the laboratory failed to implement a protocol for pipettor maintenance to insure accurate and reliable test results. The findings include: 1. A review of the API PT records revealed the laboratory failed Thyroid Stimulating Hormone (TSH) on Survey events 2016-Event #3 and 2017-Event #1. [This failure was previously written up by the CLIA Supervisor on 4/6/2017 during a CLIA PT desk review.] 2. A review of the Plan of Correction submitted by the facility on 4/18/2017 determined one of the causes of the failures was due to a pipettor, which was replaced with a new MLA calibrated pipettor. The facility stated this change corrected the problem. 3. During an interview on 3/22/2018 at 11:40 AM, when asked about the pipettor problems, The Technical Consultant stated they had determined one cause of their PT and QC problems was due to the "cheap pipettor" originally received with the Frend when it was installed. After the laboratory's investigation and multiple phone calls, Nano Tech (the manufacturer) sent the laboratory a new MLA calibrated pipettor. 4. During a second interview on 3/22/2018 at 3:50 PM, the surveyor then asked if the laboratory had implemented any pipettor calibration and maintenance protocols, since they knew pipettor problems could be a source of error in the test procedure. The Technical Consultant stated they had not. Thus the above noted findings were confirmed. .
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on reviews of the quality control records for the Nano Tech Frend analyzer, patient test volumes and interviews with the Technical Consultant and the Testing Personnel, the surveyor determined the laboratory failed to ensure two levels of quality control (QC) were performed each day of patient testing in the absence of an optional IQCP (Individualized Quality Assurance Plan) in 2017 and 2018. The laboratory further failed to document the lot numbers of the reagent cartridges on which QC was performed for 31 out of 62 QC testing events reviewed from January 2017 thru February 2018. The findings include: 1. In an interview on 3/22/2018 at 11: 30 AM, when asked about the frequency of QC testing for Thyroid Stimulating Hormone (TSH), Free T4, Prostatic Specific Antigen (PSA) and Testosterone performed on the Nano Tech Frend, the Technical Consultant stated the Testing Personnel performed two levels of QC every 30 days and with each new lot number of

	reagent cartridges as per manufacturer's instructions in the Operator's Manual. 2. A review of the QC records revealed the Testing Personnel documented the Frend QC on a different sheet for each analyte every month with directions at the top of the sheet, as follows: "Perform external QC every MONTH at the same time AND with [each] NEW LOT of test cartridges". The Testing Personnel documented the Lot #, expiration, acceptable ranges and results for two levels of QC, however there was no record of the lot # and expiration of the test cartridges on which the QC was performed. 3. During an interview on 3/22/2017 at 2:30 PM, the Testing Personnel was asked if there was documentation of the test cartridges lot numbers and when the QC was performed. The Testing Personnel stated this information was documented on the monthly Frend maintenance log. 4. A review of the dates, test, and cartridge lot #'s in the maintenance logs, when reviewed and compared with the tests and dates on the QC log revealed the Testing Personnel had failed to document the lot # of the test cartridge on which the QC was performed in 31 out of 62 (50%) of the QC testing events documented from January 2017 thru February 2018. 5. During an interview with the Testing Personnel and the Technical Consultant on 3/22/2018 at 3:50 PM, the surveyor asked if they realized they had documented the lot number of the test cartridges only 50% of the time. After a review of the records, the Testing Personnel confirmed she had failed to record many of the test cartridge lot #'s, and she needed a more efficient mechanism to capture this information. 6. As the interview continued, the surveyor explained that CLIA regulations also required two levels of QC each day of patient testing. However if a laboratory chooses to follow a manufacturer's recommendation of performing QC less frequently, the laboratory had the option of implementing an IQCP (Individualized Quality Control Plan) for the tests. The Technical Consultant stated she was not aware of the requirement to implement an IQCP to allow for decreased QC testing. When asked about patient testing, the Testing Personnel confirmed 1024 patient tests (as recorded on the Form CMS-116) had been performed on the Frend in 2017, and most patient testing had occurred on days when no QC had been run in 2017 and 2018. .
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on reviews of the quality control records for the Nano Tech Frend analyzer, patient test volumes and interviews with the Technical Consultant and the Testing Personnel, the surveyor determined the Technical Consultant failed to ensure the testing personnel performed two levels of quality control (QC) each day of patient testing in the absence of an optional IQCP (Individualized Quality Assurance Plan) to allow for decreased frequency of QC performance in 2017 and 2018. The Technical Consultant further failed to implement a mechanism of documentation to include the lot numbers of the reagent cartridges on which QC was performed for 31 out of 62 QC testing events reviewed from January 2017 thru February 2018. The findings include: 1. Refer to D5447. .
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 a review of the personnel records and an interview with the Technical Consultant and the Testing Personnel, the surveyor determined the Technical Consultant failed to perform the annual competency evaluations for one of one moderate-complexity testing personnel in 2017 and 2018. The findings include: 1. A review of the personnel files revealed the moderate-complexity Testing Personnel had annual competency evaluations performed on 3/2/2017 and 3/14/2018, however both had been signed by the Office Manager. 2. During an interview on 3/21/2018 at 10:30 AM, the Testing Personnel was asked if the Office Manager had the educational requirements equivalent to qualify as a Technical Consultant, plus the Laboratory Director's written delegation of this responsibility. The Testing Personnel stated she did not think so. The surveyor then explained the Office Manager did not meet CLIA requirements to assess competency for the moderate-complexity testing personnel. The Technical Consultant then stated she had not performed the evaluations, and it was an oversight. Thus the above noted findings were confirmed. SURVEYOR: Laura T. Williams, BS, MT (ASCP) Licensure and Certification Surveyor