Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D2123820	01/24/2022
Name of Provider or Supplier	**Street Address, City, State**	
Central Pediatrics & Internal Medicine, Pa	3040 Eastway Drive, Suite A, Charlotte, NC	

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
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on review of laboratory records and manufacturer's IFU(instructions for use), interview with the TC(technical consultant), and absence of documentation 1/24/22, the laboratory failed to follow manufacturer's instructions for the SARS-CoV-2 rapid antigen testing performed to ensure authorized Fact Sheets for patients and providers were included with the SARS-Cov2 test result reports and all operators were appropriately trained in performing and interpreting the test results.. Findings: The laboratory began testing for SARS-CoV-2 using rapid antigen test kits in June 2021. Review of laboratory records revealed the laboratory had manufacturer's IFU for the Quidel Quickvue SARS Antigen test and the Indicaid Covid- 19 antigen test on file. 1. The laboratory failed to ensure authorized Fact Sheets for patients and providers were included with SARS CoV-2 test result reports. Review of the IFU for the Quidel Quickvue SARS Antigen test revealed on pages 7- 8 and the Indicaid Covid- 19 antigen test revealed on pages 14-15 "Conditions of Authorization for the Laboratory and Patient Care Settings....Authorized laboratories using your product must include with test result reports, all authorized fact sheets..." Interview with TC at approximately 1:45pm confirmed the laboratory does not provide the fact sheets with test result reports. 2. The laboratory failed to ensure all operators of the SARS-CoV-2 rapid antigen test kits were appropriately trained in performing and interpreting the test results. Review of the IFU for the Quidel Quickvue SARS Antigen test and the Indicaid Covid-19 antigen test also revealed under Conditions of Authorization for the laboratory and Patient Care Settings, "...all operators using your product must be appropriately trained in performing and interpreting the results of your product..."

	Review of laboratory records revealed there was no documentation that testing personnel were trained to perform and interpret the test results of the Quidel Quickvue SARS Antigen test or the Indicaid Covid-19 antigen test.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of laboratory records, review of laboratory's policies and procedures, and interview with the TC(technical consultant) 1/24/22, the laboratory's procedure manual was not complete and current for the testing performed. Findings: The laboratory began testing for SARS-CoV-2 using rapid antigen test kits in June 2021. Review of laboratory records revealed the laboratory had manufacturer's IFU for the Quidel Quickvue SARS Antigen test and the Indicaid Covid- 19 antigen test on file. 1. The procedure manual did not include a step-by-step procedure for reporting SARS-CoV-2 test results to public health authorities. Interview with the TC at approximately 9:40am confirmed the laboratory does not have a procedure for reporting results for SARS-CoV-2.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of manufacturer's operating manual, observation, review of laboratory records, the absence of documentation, and interview with the TC(technical

	consultant) 1/24/22, the laboratory failed to define and monitor the conditions required for accurate and reliable test performance. Findings: Review of the Medonic hematology analyzer's procedure manual revealed the Boule Con-Diff tri-level controls and Boule Calibrator are stored refrigerated at 2-10 degrees C(Celsius). During tour of the laboratory at approximately 9:15am and 2:30pm, the surveyor observed the Boule controls, calibrator and urine controls located in the laboratory refrigerator. Review of the laboratory's temperature logs revealed documentation for the refrigerator temperatures monitored for a vaccine refrigerator located in the laboratory. The surveyor observed at approximately 2:30pm, a refrigerator temperature log beside the laboratory refrigerator for December 2019 only. There was no other documentation for the laboratory's refrigerator where the controls and calibrators were stored from January 2019 to January 2022, a period of 36 months. At approximately 2:30pm, the TC stated it did not appear the laboratory had monitored the temperatures of the laboratory's refrigerator where the controls and calibrators were stored.
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 review of 2019, 2020, and 2021 hematology QC(quality control)and patient records, and review of the manufacturer's QC assay sheets 1/24/22, the laboratory failed to discard control materials that had exceeded the expiration date. Findings: Random review of 2019, 2020, and 2021 hematology QC and manufacturer's control assay sheets revealed the Boule Con-diff controls lot numbers expired and were in use for the following: a. Control lot numbers # 21813-01(low) expired 5/2/19, #21813-02 (normal) expired 5/6/19, and #21813-03(high) expired 5/2/19 and were in use 5/3/19 to 5/29/19. Review of patient records revealed approximately 62 patients were tested 5 /3/19-5/29/19. b. Control lot numbers #22105-01(low) expired 9/22/21, #22105-02 (normal) expired 9/21/21, and #22105-03(high) expired 9/23/21 and were in use 9/22 /21 to 9/25/21. Approximately 16 patients were tested 9/23/21-9/24/21.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions and review of the Medonic Hematology laboratory records 1/24/22, the laboratory failed to perform and document maintenance on the Medonic Hematology analyzer as required by the manufacturer. Findings: Review of the Medonic M- series Hematology analyzers Procedure manual revealed, "Maintenance: Daily cleaning should be performed according to the Medonic M Series User's Manual. Instrument maintenance is performed monthly and semi-annually according to the manufacturer's instructions,

	using the boule cleaning kit....All maintenance should be documented(a maintenance log is recommended), and the documentation saved for a minimum of 2 years." The Medonic M-series User's manual stated under Section 8: Cleaning, Maintenance, and transport, "This section contains information that is crucial for maintaining, transporting and storing the Medonic M-series...8.1 Daily Cleaning...Cleaning procedure. The daily cleaning only takes a few minutes, the instructions are as follows: Step 1. Clean the aspiration and pre-dilute probes using an alcohol wipe. 2. Remove possible traces of salt crystals or blood at the top of the aspiration and pre-dilute probes, probe rinse cup, and around the top of sampling device probe inlet(if applicable) using a paper tissue with a disinfecting solution." 1. Review of the Medonic laboratory records revealed there was no documentation for daily cleaning of the hematology analyzer since the laboratory began testing January 2019 until time of survey, a period of 36 months. The User's manual also stated under 8.2 Monthly Cleaning..."This section describes the cleaning procedure to be used to secure the correct function of the instrument on a monthly basis." Review of this section revealed the steps and actions for the monthly bleach cleaning procedure and clot prevention. 2. Review of the Medonic records also revealed monthly printouts from the analyzer with "bleach/clot prevention" handwritten on them. Review of the printouts revealed no documentation for the monthly cleaning procedures for the following: a. 3 months in 2019- 4/19-6/19; b. 3 months in 2020- 4/20, 9/20-10/20; c. 5 months in 2021- 4/21-6/21, 9/21-10/21.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's 2019, 2020, and 2021 hematology installation and quality control records, review of CMS(Centers for Medicare and Medicaid Services) Casper report 155D, review of 2019, 2020, and 2021 API(American Proficiency Institute) PT(proficiency testing) records, and interview with the Office manager 1/24 /22, the laboratory director failed to ensure the laboratory was enrolled in an HHS approved proficiency testing program for the 1st and 2nd Hematology events in 2019. Findings: Review of the laboratory's hematology installation and quality control records revealed the laboratory began CBC testing on the Medonic Hematology analyzer January 8, 2019. Review of the CMS Casper report 155D revealed PT scores for the 2019 3rd event, but no scores for 2019 1st and 2nd event. Review of the laboratory's PT records revealed no documentation for the 2019 1st and 2nd hematology test events. During the exit interview at approximately 3pm, the office manager confirmed the laboratory failed to enroll in PT on time for 2019.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform

	test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory's QA(quality assessment) policy, review of QA records, and absence of documentation 1/24/22, the laboratory director failed to ensure the quality assessment program was established and maintained to assure the quality of laboratory services provided. Findings: Review of the laboratory's QA policy revealed, "Periodically, various systems in the laboratory will be evaluated to assure the quality goals are met. If a problem is identified, corrective action will be taken to design and implement a solution that is approved by the Laboratory Director. Re-evaluation of the system will occur to determine the effectiveness of the new plan. Written records will be kept of the reviews, findings, and actions. System Review: Procedure manual * Personnel Assessment * Patient Test Management/Test Tracking * Relationship of Patient Information to Patient Results * Testing and Instrumentation Quality Control and Instrument Maintenance * Laboratory Incidents Management and Errors * Proficiency Testing * Communication * Complaints * Laboratory Safety...." Review of the laboratory's QA records revealed QA monitors completed by the laboratory's TC on 12/15/21 and 1/8/22. There was no other documentation on file to show the laboratory director had maintained the laboratory's QA program to evaluate the various systems to assure the quality goals were met from the time the laboratory began testing in January 2019 to December 2021, a period of 35 months.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on review of the laboratory's QA(quality assessment) policy, review of personnel records, and interview with the TC(technical consultant) 1/24/22, the laboratory director failed to ensure policies and procedures were followed to document training for 3 of 3 TP(testing personnel) and failed to ensure the competency of 2 of 3 TP was maintained as required in 2019, 2020, and 2021. Findings: Review of the laboratory's Quality Assessment policy revealed under Personnel Assessment, "Hiring of appropriately qualified personnel is essential for maintaining the highest standard of quality....Upon hire, each employee goes though an orientation period reviewing policies, procedures, instrumentation, and QC/QA in the laboratory. Documents this training is retained in the employee's personnel file. A documented competency evaluation is conducted at the end of the first three months

	(or six months) of employment and annually thereafter..." Review of the laboratory's personnel files revealed: 1. A training document that TP#1 and TP#2 were trained on the Medonic Hematology analyzer at time it was installed on 1/8/19. 2. TP#1 had competency evaluations on file dated 1/8/20, 7/8/20, 1/8/21, and 1/8/22. 3. TP#2 had competency evaluations on file dated 7/8/19, 1/8/20, 1/8/21, and 1/8/22. 4. TP#3 was hired October 2021. There was a training document on file for TP#3 dated 10/18/21. At approximately 1pm, the TC confirmed the training forms and competency evaluation forms on file for the 3 of 3 TP in 2019, 2020, and 2021 were completed in December 2021 during the TC's first visit to the laboratory. There was no additional documentation on file to show the laboratory director had followed policy to complete the training documents or competency evaluations for the TP when they were due to be completed.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on the review of personnel records 1/24/22 and the deficiency cited at D6065, the laboratory failed to ensure that 1 of 3 testing personnel(TP#3) met the minimum education requirements for performing moderate complexity testing.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on review of personnel records and interview with the office manager 1/24/22, the laboratory failed to verify that 1 of 3 TP (testing personnel #3) met the minimum education requirements for performing moderate complexity testing. Review of personnel records for TP#3 revealed a certification of translation accuracy for a degree obtained outside the United States. The certification of translation accuracy stated that the degree obtained was a "Qualified Accountant Specializing in Computer Sciences."The personnel records did not include a credential evaluation by a nationally recognized organization to determine equivalency of the education to education obtained in the United States. During the exit interview at approximately 3pm, the office manager confirmed the certification of translation accuracy on file for

	TP#3 would be considered the high school diploma in the country where it was obtained.