Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0918331	07/12/2023
Name of Provider or Supplier	**Street Address, City, State**	
Pediatric Physicians Pc	1172 Vickery Lane, Cordova, TN	

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
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on observation of the laboratory, procedure manual review and staff interview the laboratory failed to establish and follow policies for specimen labeling to include patient name or unique identifier for patient specimens collected for complete blood count (CBC) testing using the Sysmex XP 300 analyzer in 2021, 2022, and 2023. The findings include 1. Observation of the laboratory on 07/12/2023 at 9:00 am revealed the Sysmex XP 300 (Serial C2401) hematology analyzer in use for patient testing of CBC samples. 2. Review of the laboratory procedure manual revealed no policy or procedure for labeling of patient specimens collected for CBC testing. 3. Interview on 07/12/2023 at 9:15 am with testing person one revealed the following: Patient samples for CBC are collected in the patient room and brought to the laboratory for testing. Patient samples for CBC are not labeled with patient name and identifier after collection. 4. Interview on 07/12/2023 at 2:00 with testing person one confirmed the laboratory failed to establish and follow policies for specimen labeling when the laboratory's routine practice did not include labeling of specimens collected for CBC testing with patient name and identifier.
D5405	PROCEDURE MANUAL CFR(s): 493.1251(c)

	Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory. This STANDARD is not met as evidenced by: Based on observation of the laboratory, procedure manual review, patient test review, Department of Health and Human Services Centers for Medicare & Medicaid Services Clinical Laboratory Improvement Amendments (CLIA) Application for Certification (Form CMS-116) review, and staff interview the laboratory failed to ensure the procedure used for the Sysmex XP 300 analyzer used for patient testing of CBC samples included requirements for patient preparation, specimen acceptability or rejection, step-by-step performance of the procedure including interpretation of results, calibration and calibration verification procedures, reportable ranges, control procedures, or corrective action procedures with patient testing beginning 08/20/2021 until the date of the survey on 07/12/2023. The findings include: 1. Observation of the laboratory revealed the Sysmex XP 300 (Serial C2401) in use for CBC patient testing. 2. Review of the laboratory procedure manual revealed the Sysmex XP-300 Automated Hematology Analyzer Quick Guide in use as the procedure for the Sysmex XP 300 did not include the following: Requirements for patient preparation: specimen collection, labeling, storage, preservation, transportation, processing, referral or criteria of specimen acceptance or rejection. Step-by-step performance of the procedure including interpretation of results. Calibration and calibration verification procedures. Reportable range for test results that were verified. Control procedures. Corrective action procedures. 3. Review of patient records revealed the first patient for CBC testing from the Sysmex XP 300 was reported on 08/20/2021 (patient 91306). 4. Review of the annual test volumes as reported on Form CMS- 116 revealed approximately 1200 patient CBC results have been reported using the Sysmex XP 300 analyzer from 08/20/2021 to the date of survey on 07/12/2023 without a complete procedure manual. 5. Interview on 07/12/2023 at 2:00 pm with the laboratory testing person one confirmed the laboratory uses the Sysmex XP-300 Quick Guide as the procedure for the Sysmex XP-300 analyzer for patient CBC testing and further confirmed the Quick Guide did not include requirements for patient preparation, specimen acceptability or rejection, step-by-step performance of the procedure including interpretation of results, calibration and calibration verification procedures, reportable ranges, control procedures, or corrective action procedures .
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 observation of the laboratory, review of the procedure manual , patient test reports, annual test volumes as reported on the Form CMS-116, and staff interview, the laboratory director failed to approve procedures for use of the Sysmex XP 300 CBC instrument prior to patient CBC testing that began on 08/20/2021 until the date of survey (07/12/2023). The findings include: 1. Observation of the laboratory revealed the Sysmex XP 300 (Serial C2401) in use for CBC patient testing. 2. Review of the laboratory procedure manual revealed the procedure in use for the Sysmex XP

	300 analyzer had not been approved by the laboratory director. 3. Review of patient test records revealed the patient testing on the Sysmex XP300 began on 08/20/2021 (patient 91306). 4. Review of the Form CMS-116 revealed an estimated annual test volume of 620, resulting in approximately 1200 patient CBC results reported from 08 /20/2021 to the date of the survey on 07/12/2023 without laboratory director approval of the procedure. 4. Interview on 07/12/2023 at 2:00 pm with testing person one confirmed the laboratory director failed to approve the procedure for the Sysmex XP 300 CBC instrument prior to patient testing which began on 08/20/2021.
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 observation of the laboratory, review of the manufacturer's operating manuals, environmental records, patient test records, annual test volumes reported on the Form CMS-116, and staff interview, the laboratory failed to monitor room humidity for the Sysmex XP 300 CBC analyzer with approximately 1200 patients reported during the period the humidity was not being monitored in 2021, 2022, and 2023 . The findings include: 1. Observation on 07/12/2023 at 9:00 am revealed the Sysmex XP 300 (Serial C2401) in use for patient CBC testing. 2. Review of the Sysmex XP 300 manufacturer operator's manual revealed an operating relative humidity of 30-85%. 3. Review of the laboratory environmental records for the months of 08/2021, 03/2022, 10/2022, 02/2023, and 06/2023 revealed no documentation monitoring of room humidity where the Sysmex XP 300 analyzer was in use for patient testing. 4. Review of patient test records revealed the first patient was reported on the Sysmex XP 300 on 08/20/2021 (patient 91306). 5. Review of the Form CMS-116 annual test volume estimates revealed approximately 1200 patient CBC results reported using the Sysmex XP 300 analyzer from 08/20/2021 to the date of the survey (07/12/2023). 6. Interview on 07/12/2023 at 9:15 am with testing person one confirmed the laboratory did not monitor room humidity for the use of the Sysmex XP 300 in 2021, 2022, and 2023.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g)

	The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observation of the laboratory, quality control (QC) record review, and staff interview, the laboratory failed to have a procedure in place to monitor the accuracy and precision of QC for the Sysmex XP 300 instrument used for CBC patient testing in 2021, 2022, and 2023. The findings include: 1. Observation of the laboratory revealed the Sysmex XP 300 (Serial C2401) in use for CBC patient testing. 2. Review of the laboratory QC records revealed the laboratory did not print Levy Jennings (LJ) charts to monitor accuracy and precision over time. Records indicate the Sysmex XP 300 in use from 08/20/2021 through the date of the survey (07/12/2023) for patient CBC testing. 3. Interview on 07/12/2023 at 2:00 pm with testing person one confirmed the laboratory did not evaluate accuracy and precision of QC data over periods of time in 2021, 2022, and 2023.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of quality control (QC) records, patient test records, and staff interview the laboratory failed to retain statistical parameters of QC for the Sysmex XP 300 analyzer used for CBC patient testing. The findings include: 1. Observation of the laboratory revealed the Sysmex XP 300 (Serial C2401) in use for CBC patient testing. 2. Review of laboratory QC records revealed no documentation of statistical parameters (mean or standard deviation) of QC for 12 of 15 lot numbers reviewed that were used for CBC patient testing in 2022 and 2023 as follows: 30800710, 30800711, 30800712 Expiration date 06/28/2023 23610710, 23610711, 23610712 Expiration date 04/05/2023 21930710, 21930711, 21930712 Expiration date 10/19/2022 20250710, 20250711, 20250712 Expiration date 05/04 /2022 3. Review of patient test records revealed the first patient was reported on the Sysmex XP300 on 08/20/2021 (patient 91306). 4. Interview on 07/12/2023 at 2:00 pm with testing person one confirmed the laboratory did not retain statistical parameter data for the Sysmex XP 300 QC for 2022 or 2023.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of verification of performance (VoP) data, patient test records, Form CMS-116 annual test volume, and staff interview, the laboratory director failed to document review of the VoP data for the Sysmex XP 300 used for CBC patient testing in use from 08/2021. The findings include: 1. Observation of the laboratory revealed the Sysmex XP 300 (Serial C2401) analyzer in use for CBC patient testing. 2. Review of the VoP data performed on 08/19/2021 for the Sysmex XP 300 revealed no evidence the data had been reviewed and approved by the laboratory director. Subsequent normal range verification study was not reviewed or approved by the laboratory director. . 3. Review of patient test records revealed the first patient was reported on the Sysmex XP 300 on 08/20/2021 (patient 91306). 4. Review of the Form CMS-116 revealed an estimated annual test volume of 620, resulting in approximately 1200 patient CBC results reported from 08/20/2021 to the date of the survey on 07/12/2023 without laboratory director approval of VoP. 5. Interview on 07/12/2023 at 2:00 pm with testing person one confirmed the laboratory director failed to review the performance verification studies for the Sysmex XP 300 used for CBC patient testing.
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) 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)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system; This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of calibration records, patient records, annual test volumes, and staff interview, the laboratory director failed to review calibration records for the Sysmex XP 300 CBC instrument to ensure acceptable levels of performance were maintained. Calibration records from 2021, 2022, and 2023 (four of four calibrations reviewed) were not reviewed by the laboratory director. The findings include: 1. Observation of the laboratory revealed the Sysmex XP 300 (Serial C2401) analyzer in use for CBC patient testing. 2. Review of the following Sysmex XP 300 calibration records revealed no documentation of review by the laboratory director: 08/19/2021 01/28/2022 06/29/2022 07/10/2023 3. Patient test review revealed the patient 91306 reported 08/20/2021 was the first patient reported using the Sysmex XP 300 CBC analyzer. 4. Review of the laboratory annual test volume estimates revealed approximately 1200 patient CBC results reported using the Sysmex XP 300 analyzer from 08/20/2021 to the date of the survey (07/12/2023). 5. Interview on 07/12/2023 at 2:00 pm with testing person one confirmed the laboratory director failed to ensure acceptable levels of analytic performance was

	maintained when the laboratory director did not review calibration data for the Sysmex XP 300 CBC instrument in 2021, 2022, and 2023.
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 review of laboratory records, personnel training records, and staff interview, the technical consultant failed to review training documents for one of one testing personnel (TP) for the new Sysmex XP 300 CBC instrument for patient testing in use from 08/20/2021. The findings include: 1. Review of the laboratory records for the Sysmex XP 300 (Serial C2401) in use for CBC patient testing (new instrument since the last survey 01/22/2020). 2. Review of the laboratory personnel training records for the Sysmex XP 300 CBC instrument revealed training documents completed on 08/19 /2021 for TP one (one of one) lacking the signature of the technical consultant. 3. Interview on 07/12/2023 at 2:00 pm with TP one confirmed the technical consultant failed to review training documents for the Sysmex XP 300 CBC instrument prior to patient testing which began on 08/20/2021.
D6055	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 whenever test methodology or instrumentation changes. The individual's performance must be reevaluated to include the use of the new test methodology or instrumentation prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on observation of the laboratory, personnel record review, patient test record review, and staff interview the technical consultant failed to evaluate and document testing personnel (TP) performance of CBC patient testing using the Sysmex XP 300 analyzer prior to patient testing. The findings include: 1. Observation of the laboratory revealed the Sysmex XP 300 (Serial C2401) (new since the last survey date 01/22 /202) in use for CBC patient testing. 2. Review of TP records revealed the technical consultant failed to re-evaluate the competency of TP one (one of one TP) for use of the Sysmex XP 300 CBC instrument prior to patient testing. 3. Review of patient test records revealed the first patient performed o the Sysmex XP300 was reported on 08 /20/2021 (patient 91306). 4. Interview on 07/12/2023 at 2:00 pm with testing person one confirmed the technical consultant failed to re-evaluate the competency of TP one for used of the Sysmex XP 300 CBC instrument prior to patient testing which began on 08/20/2021.