Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D2004958	08/14/2024
Name of Provider or Supplier	**Street Address, City, State**	
Childrens Mercy-Premier Pediatrics, Inc	8675 College Boulevard, Ste 100, Overland Park, KS	

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
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 the review of the procedure for the Medonic M Series hematology analyzer and interview with the technical consultant (TC), the laboratory failed to include the reportable range for six of six analytes as determined by the laboratory. Findings: 1. Review of the Medonic M Series hematology analyzer procedure revealed this procedure did not include the reportable range for red blood cell (RBC), white blood cell (WBC), hemoglobin (HGB), hematocrit (HCT), platelet (PLT) as determined by

	the laboratory for the Medonic M Series hematology analyzer serial number 62350. 2. Interview with the TC on 8/14/24 at 9:15 a.m. confirmed, the laboratory failed to include the reportable range for six of six analytes as determined by the laboratory.
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 the review of the procedure for quality assessment and interview with the TC, the laboratory failed to have a general quality assessment procedure approved, signed, and dated by the current laboratory director (LD). Findings: 1. The surveyor requested procedures for quality (QA). The laboratory provided the "Lab QA Program" procedure. 2. Review of the procedure revealed no approval, signature, or date by the current LD. 3. Interview with the TC on 8/14/24 at 9 a.m. confirmed, the laboratory failed to have a general quality assessment procedure approved, signed, and dated by the current LD.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on the review of performance verification documentation for the Medonic M Series hematology analyzer and interview with the TC, the laboratory failed to verify the RBC, WBC, HGB, HCT, PLT and WBC Diff reference intervals (normal values) were appropriate for the laboratory's patient population prior to reporting patient results. Findings: 1. Review of the performance verification documentation for the Medonic M Series hematology analyzer, serial number 62350, revealed no verification of RBC, WBC, HGB, HCT, PLT and WBC Diff normal values for the laboratory's patient population. Patient testing began on 4/12/24. 2. Test volume from 4/12/24 to date of survey was 656 patient test results. 3. Interview with TC on 8/14/24 at 9:15 a.m. confirmed, the laboratory failed to verify the RBC, WBC, HGB, HCT, PLT and WBC Diff reference intervals (normal values) were appropriate for the laboratory's patient population prior to reporting patient results.
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 the review of the "MEDONIC M SERIES METHOD VALIDATION EVALUATION" verification document and interview with the TC, the laboratory director (LD) failed to ensure that the verification procedure was adequate to determine performance characteristics of the hematology analyzer prior to use for patient testing. Findings: 1. Review of the "MEDONIC M SERIES METHOD VALIDATION EVALUATION" verification document for the hematology analyzer serial number 62350 revealed no approval by the LD or TC. Patient testing began 6/12 /24. 2. Interview with the TC on 8/14/24 at 9:30 a.m. confirmed, the LD failed to ensure that the verification procedure was adequate to determine performance characteristics of the hematology analyzer prior to use for patient testing.