

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0960104	(X3) Date Survey Completed 02/12/2020
Name of Provider or Supplier Pediatric Associates Of Dearborn	Street Address, City, State 2331 Monroe St, Dearborn, MI	
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
D5024	<p>HEMATOLOGY CFR(s): 493.1215</p> <p>If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: . Based on record review and interview, the laboratory failed to meet the requirements for the specialty in Hematology as specified in 493.1230 through 493.1256, 493.1269, and 493.1281 through 493.1299. Findings include: 1. The laboratory failed to ensure control procedures were followed according to laboratory-established requirements. Refer to D5445.</p>
D5445	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: . Based on observation, record review and interview with Testing Personnel #1 (TP1), the laboratory failed to ensure control procedures were followed according to</p>

laboratory-established requirements for 35 testing days out of 2 years reviewed. Findings include: 1. An observation made by the surveyor on 2/12/2020 at 9:08 am revealed a Beckman Coulter AcT Diff hematology analyzer present in the laboratory. 2. A review of the laboratory's established "QC procedures" revealed a section stating, "Each day of testing: Test three levels of 4C cell controls (low, normal, and high) prior to testing patient samples on each day of testing according to the instructions in the AcT Diff Operator's Guide. Those who perform patient tests must perform QC." "Compare control results to the expected results. (located on the Coulter 4C PLUS cell control package insert). All control results must be in expected ranges before patient test results are reported." 3. A review of the laboratory's quality control records for the Beckman Coulter AcT Diff hematology analyzer revealed the following days had only two levels of controls ran: a. 2/8/19 normal control was not performed. b. 2/15/19 high control was not performed. c. 2/22/19 normal control was not performed. d. 3/13/19 high control was not performed. e. 3/14/19 normal control was not performed. f. 3/20/19 low control was not performed. g. 3/23/19 low control was not performed. h. 6/26/19 low control was not performed. 3. A review of the laboratory's quality control records for the Beckman Coulter AcT Diff hematology analyzer revealed one control out of range for the following testing days: a. 2/12/19 White Blood Cell count (WBC), Red Blood Cell Count (RBC), and Hemoglobin (HGB) were out of range for the low control. b. 2/13/19 WBC was out of range for the normal control. c. 2/25/19 Platelet count (PLT) was out of range for the low control. d. 3/6/19 RBC was out of range for the high control. e. 4/13/19 PLT was out of range for the high control. f. 5/4/19 Mean Corpuscular Hemoglobin (MCH) and Mean Corpuscular Hemoglobin Concentration (MCHC) were out of range for the normal control. g. 5/6/19 MCHC was out of range for the low control. h. 5/7/19 MCH and MCHC were out of range for the low control. i. 5/8/19 RBC was out of range for the high control. j. 5/23/19 MCH and MCHC were out of range for the low control. k. 6/7/19 MCHC was out of range for the low control. l. 6/8/19 PLT was out of range for the high control. m. 6/24/19 HGB, MCH, and MCHC were out of range for the low control. n. 6/25/19 RBC was out of range for the high control. o. 6/27/19 RBC was out of range for the normal control. p. 6/28/19 RBC was out of range for the high control. q. 7/8/19 RBC, HGB, Hematocrit (HCT), PLT, WBC, absolute lymphocyte count, and absolute granulocyte count were out of range on the high control. r. 7/9/19 HGB was out of range for the low control, RBC was out of range for the normal control. s. 7/10/19 PLT and WBC were out of range for the low control. t. 7/12/19 PLT was out of range for the low control. u. 7/15/19 HGB, MCH, and MCHC were out of control for the low control. 4. A review of the laboratory's quality control records for the Beckman Coulter AcT Diff hematology analyzer revealed at least two levels of control out of range for the following testing days: a. 2/27/19 PLT was out of range for both low and high controls. b. 3/11/19 RBC was out of range for both the normal and high controls. c. 4/10/19 RBC and WBC were out of range for both the normal and high controls. d. 5/6/19 RBC was out of range for the normal and high controls, MCH was out of range for low and normal controls. e. 5/8/19 MCH and MCHC were out of control for both the low and normal controls. f. 5/9/19 HGB was out of control for both normal and high controls, MCHC was out of control for all three levels of control, and MCH was out of control for both the low and normal controls. g. 5/23/19 HGB was out of range for both low and normal controls. h. 7/9/19 MCH and MCHC were out of range for both the low and normal controls. i. 7/10/19 HGB, MCH, and MCHC were out of range for all three levels of control. j. 7/12/19 HGB, MCH, and MCHC were out of range for all three levels of control. 5. A review of the laboratory's "Lab Testing Log (CBC)" revealed patient testing was reported on the dates listed above. 6. An interview on 2/12/2020 at 11:57 am with TP1 confirmed all levels of control were required to be in range before reporting patient results.

D6033

TECHNICAL CONSULTANT-MODERATE COMPLEXITY

CFR(s): 493.1409

The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

This CONDITION is not met as evidenced by:

. Based on record review and interview, the Testing Personnel #1 (TP1) and Testing Personnel #5 (TP5) do not meet the Technical Consultant qualification requirements at 493.1411. Findings include: 1. The laboratory failed to have a qualified Technical Consultant evaluate the competency of testing personnel performing hematology testing. Refer to D6046.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

. Based on record review and interview with Testing Personnel #1 (TP1), the laboratory failed to have a qualified Technical Consultant evaluate the competency of testing personnel performing hematology testing for 5 (Testing Personnel #1-5) of 5 testing personnel listed on the CMS-209 form. Findings include: 1. A review of the laboratory's personnel competency assessments revealed TP1 and Testing Personnel #5 (TP5) were performing and evaluating the competency assessments for Testing Personnel #1-5 listed on the CMS-209 form for 2018 and 2019. 2. The surveyor requested credentials for TP1 and TP5 to determine if they met the requirements to be Technical Consultants on 2/12/2020 at 10:45 am and they were not made available. 3. An interview on 2/20/2020 at 10:45 am with TP1 confirmed TP1 and TP5 were not qualified to perform duties as Technical Consultants.