

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 21D2113424	<b>(X3) Date Survey Completed</b> 01/22/2019
<b>Name of Provider or Supplier</b> Med-Ped Healthcare Llc	<b>Street Address, City, State</b> 7582 Annapolis Road, Lanham, MD	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5211</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and interview with the technical consultant (TC), the laboratory did not perform a review of all PT results. Findings: 1. The laboratory did not perform an evaluation of the 2018 3rd event Hematology. 2. The PT results were not reviewed and signed by the laboratory director nor the TC. 3. The TC stated that it is his responsibility to evaluate PT results and confirmed that the 2018 3rd event Hematology results was not reviewed.</p>
<b>D5301</b>	<p>TEST REQUEST CFR(s): 493.1241(a)</p> <p>The laboratory must have a written or electronic request for patient testing from an authorized person.</p> <p>This STANDARD is not met as evidenced by: Based on review of patient records, interview with the testing person (TP), and the technical consultant (TC), the laboratory did not have a written nor a electronic test request to perform hematology testing. Findings: 1. The laboratory performs hematology testing and began testing in September 2018. 2. The laboratory did not have written nor electronic physician orders to perform a patient test. 3. The testing person stated they are able to electronically order patient test requests but they have not performed since they began testing in September of last year. 4. The TC confirmed that physicians orders for patient testing was not performed.</p>

**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 review of the written procedure manual, interview with the testing person (TP) and the technical consultant (TC), the laboratory did not have written procedures for labeling hematology specimens. Findings: 1. The laboratory did not have written procedures for labeling hematology specimens once collected for testing. 2. The testing person stated that she hand writes the patient name on the tube. 3. The TP stated they are able to print out a label with patient name, date of birth, date of collection, and unique identifier for the patient samples once the test is ordered but she was not told to do that. 4. The TC confirmed that a written procedure for labeling patient samples for hematology testing was not available.

**D5787**

**TEST RECORDS**

CFR(s): 493.1283(a)

The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).

This STANDARD is not met as evidenced by:

Based on review of the written procedure manual, interview with the testing person (TP) and the technical consultant (TC), the laboratory did not have procedures for identifying the TP performing hematology testing. Findings: 1. The laboratory did not have written procedures for testing personnel to follow when identifying the person who drew the patient samples for testing and the name of the testing person who performed the test. 2. The TC confirmed that written procedures for identifying the person who drew and ran hematology samples was not available.