| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 17D0448520 | 05/17/2018 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Preferred Pediatrics | 13643 S Mur-Len Rd, Olathe, 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 |
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| **D5215** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(b)(2)<br><br>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).<br><br>This STANDARD is not met as evidenced by:<br>Based on review of American Proficiency Institute (API) proficiency testing (PT) records, three events in 2016 and three events in 2017, and confirmed by interview of laboratory director at 1:50 PM on May 17, 2018, the laboratory failed to evaluate ungraded PT scores. The findings include: 1. For API 2016 Hematology / Coagulation second PT testing event, the laboratory received not graded (no consensus) test scores for the following: Sample: QBC-06 White Cell Count QBC-08 Platelet Count and White Cell Count 2. The laboratory did not have documentation of evaluation for the ungraded PT test scores. |
| **D5403** | PROCEDURE MANUAL<br>CFR(s): 493.1251(b)<br><br>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) |

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| | 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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of procedures, review of patient test reports, and confirmed by interview with the Laboratory Director at 4:00 PM on May 17, 2018, it was determined that the laboratory's procedure for Complete Blood Counts (CBCs) did not include normal reference ranges in the procedure for Complete Blood Counts (CBCs). Findings include: Review of the procedure for CBC's did not include any normal or reference ranges for pediatric patients. Review of patient's test reports for two patients revealed that the normal or reference ranges reported were different ranges than the adult ranges available in the procedure. Interview with the Laboratory Director confirmed that the normal range for their patient population was not included in their procedure manual. |
| **D5417** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(d)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based upon direct observation during a tour of the laboratory, review of QBC manufacturer's control assay sheet and interview with testing personnel #4 (refer to the Laboratory Personnel Report (CMS-209)) at 2:25 PM on May 17, 2018, the laboratory failed to ensure that controls in use had not exceeded their expiration date. Findings were: 1. During a tour of the lab, the surveyor observed QBC Hematology Control Samples currently in use did not have an open date or expiration date. 2. Review of the QBC Hematology Control Assay Sheet has open vial stability as 4 days for the current Lot No. Q533, Expiration Date 05-27-2018. 3. Testing personnel #4 stated that control vials were opened every Monday and used all week, which exceeds the manufacturers open vial stability. |