| # Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number<br>37D0716134 | (X3) Date Survey Completed<br>07/02/2019 |
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| **Name of Provider or Supplier**<br>Utica Park Clinic Elliott | **Street Address, City, State**<br>562 S Elliott, Pryor, OK | |
| 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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| **D0000** | The recertification survey was performed on 07/02/2019. The findings were reviewed with the technical consultant at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited. |
| **D5209** | PERSONNEL COMPETENCY ASSESSMENT POLICIES<br>CFR(s): 493.1235<br><br>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of records, written policy and interview with the technical consultant, the laboratory failed to have a written technical consultant competency policy based on the job responsibilities as listed in Subpart M. Findings include: (1) At the beginning of the survey, the surveyor reviewed personnel records for competency assessments performed during 2017, 2018 and 2019. There was no evidence competencies had been performed for the technical consultant, based on their job responsibilities; (2) The surveyor asked the technical consultant if a written policy to evaluate the technical consultant based on job responsibilities was available. The technical consultant stated a policy to evaluate the technical consultant based on job responsibilities had not been written; and competencies had not been performed. |
| **D5211** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(a)<br><br>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. |

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| | This STANDARD is not met as evidenced by:<br>Based on a review of records and interview with the technical consultant, the laboratory failed to review and evaluate proficiency testing results. Findings include: (1) At the beginning of the survey, the surveyor reviewed 2017, 2018, and 2019 proficiency testing records and identified the following biases (the biases were identified using the SDI (Standard Deviation Index) values assigned by the proficiency program): (a) Third 2017 Hematology Event (i) Hematocrit - 3 of 5 results exhibited a positive bias (aa) HSY-11 - SDI of 2.2 (bb) HSY-13 - SDI of 2.0 (cc) HSY-15 - SDI of 3.1 (b) First 2018 Hematology Event (i) MCV (Mean Corpuscular Volume) - 5 of 5 results exhibited a positive bias (aa) HSY-01 - SDI of 3.0 (bb) HSY-02 - SDI of 2.8 (cc) HSY-03 - SDI of 3.0 (dd) HSY-04 - SDI of 3.0 (ee) HSY-04 - SDI of 2.9 (c) Second 2018 Hematology Event (i) MCV (Mean Corpuscular Volume) - 4 of 5 results exhibited a positive bias (aa) HSY-06 - SDI of 2.5 (bb) HSY-07 - SDI of 2.1 (cc) HSY-08 - SDI of 2.3 (dd) HSY-09 - SDI of 2.3 (d) Third 2018 Hematology Event (i) MCHC (Mean Corpuscular Hemoglobin Concentration) - 3 of 5 results exhibited a negative bias (aa) HSY-11 - SDI of - 2.5 (bb) HSY-12 - SDI of - 2.4 (cc) HSY-15 - SDI of - 2.7 (ii) MCV (Mean Corpuscular Volume) - 5 of 5 results exhibited a positive bias (aa) HSY-11 - SDI of 2.1 (bb) HSY-12 - SDI of 2.1 (cc) HSY-13 - SDI of 2.1 (dd) HSY-14 - SDI of 2.1 (ee) HSY-15 - SDI of 2.1 (e) First 2019 Hematology Event (i) Monocytes - 3 of 5 results exhibited a positive bias (aa) HSY-01 - SDI of 2.0 (bb) HSY-02 - SDI of 2.2 (cc) HSY-04 - SDI of 2.5 (2) The surveyor further reviewed the records and could not locate documentation verifying the biases had been identified and addressed; (3) The surveyor then reviewed the records with the technical consultant, and asked if the biases had been addressed. The technical consultant stated the biases had not been addressed. |
| **D5401** | PROCEDURE MANUAL<br>CFR(s): 493.1251(a)<br><br>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the policy and procedure manual and interview with the technical consultant, the laboratory failed to follow written procedures for CBC (Complete Blood Count) testing. Findings include: (1) At the beginning of the survey, the technical consultant stated to the surveyor: (a) CBC testing was performed on the Medonic M-Series analyzer; (b) The laboratory tested 3 levels (Low, Normal, High) of Boule Con-Diff Quality Control (QC) materials each day of patient testing. (2) Later during the survey, the surveyor reviewed the written procedure titled, "CBC NEW LOT VERIFICATION" which stated, (a) "3. New lot will be run along side of current lot until 2 to 10 runs of each Low, Normal and High control has been ran." (3) The surveyor reviewed records for 9 control lot numbers. There was no evidence the provided ranges were verified before the lot numbers were put into use for 3 of 9 lot numbers as follows: (a) Low control (lot #21902-21), normal control (lot #21902-22), and high control (lot #21902-23) put into use on 03/26/19. (3) The findings were discussed with the technical consultant who stated the manufacturer's ranges had not been verified before the above lot numbers had been put into use. |
| **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 a review of records, manufacturer's instructions, and interview with the technical consultant, the laboratory failed to ensure an analyzer was stored as required by the manufacturer. Findings include: (1) At the beginning of the survey, the technical consultant stated to the surveyor CBC (Complete Blood Count) testing was performed on the Medonic M-Series analyzer; (2) Later during the survey, the surveyor reviewed the manufacturer's environmental requirements for the analyzer. The manufacturer required the relative humidity be maintained within the range of 20-80% (3) The surveyor reviewed laboratory humidity records from November 2017 through May 2018 and identified the following for 6 of 7 months as follows: (a) November 2017 - 4 of 25 humidity readings were documented as "LO" and the surveyor was unable to determine actual humidity (days 1,21,23,27); (b) December 2017 - 17 of 25 humidity readings were documented as "LO" and the surveyor was unable to determine actual humidity (days 6,7,8,9,11,12,13,14,15,16,18,23,26,27,28,29,30); (c) January 2018 - 21 of 26 humidity readings were documented as "LO" and the surveyor was unable to determine actual humidity (days 3,4,5,6,8,9,10,11,12,13,15,16,17,18,19,23,24,25,26,27,29,30 ); (d) February 2018 - 16 of 24 humidity readings were documented as "LO" and the surveyor was unable to determine actual humidity (days 1,2,3,5,6,7,8,9,10,11,12,13,14,17,21,22,26); (e) March 2018 - 12 of 26 humidity readings were documented as "LO" and the surveyor was unable to determine actual humidity (days 6,7,8,9,12,13,14,15,20,21,22,24); (f) April 2018 - 13 of 26 humidity readings were documented as "LO" and the surveyor was unable to determine actual humidity (days 1,4,5,6,7,9,10,11,16,17,19,20,21). (4) The surveyor reviewed the records with the technical consultant who stated the laboratory had not documented the actual humidity results as indicated above. Therefore, the surveyor could not determine the humidity had been maintained according to manufacturer's instructions.