

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D2089523	(X3) Date Survey Completed 01/10/2018
Name of Provider or Supplier Utica Park Clinic-Dermatology	Street Address, City, State 9245 S Mingo Rd #335, Tulsa, 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
D0000	The findings were reviewed with the laboratory director/technical consultant at the conclusion of the survey.
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory director/technical consultant, the laboratory failed to follow the manufacturer's instructions for waived testing. Findings include: (1) At the beginning of the survey, the laboratory director /technical consultant stated to the surveyors the laboratory used the CLINITEK Status + Analyzer to perform macroscopic urinalysis testing; (2) Surveyor #2 reviewed the manufacturer's instructions for the analyzer which required storage from 18-30 degrees Centigrade (C) and 18-80% Relative Humidity; (3) Surveyor #2 reviewed temperature and humidity records from January 2016 through December 2017 and identified the following: (a) Temperature - for 14 of 24 months the documented temperature was less than 18 degrees C (i) March 2016 - Days 19,20,21,25 (ii) April 2016 - Day 2 (iii) June 2016 - Day 28 (iv) July 2016 - Days 5,19 (v) August 2016 - Days 3,24 (vi) September 2016 - Day 17 (vii) October 2016 - Day 18 (viii) November 2016 - Days 24,26 (ix) December 2016 - Days 1,18,19,27,30,31 (x) January 2017 - Day 4 (xi) June 2017 - Day 6 (xii) October 2017 - Day 29 (xiii) November 2017 - Days 19,20,22 (xiv) December 2017 - Days 16,18,23,24,25,26,31 (b) Humidity - for 3 of 24 months the documented humidity was less than 18% (i) January 2016 - Days 18,19 (ii) February 2016 - Days 5,10,12 (iii) January 2017 - Days 5,6,7,8,9 (4) The</p>

surveyors reviewed the findings with the laboratory director/technical consultant, who stated the laboratory failed to follow manufacturer's storage instructions for CLINITEK Status + Analyzer.

D2015

TESTING OF PROFICIENCY TESTING SAMPLES

CFR(s): 493.801(b)(5)(6)

(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.

This STANDARD is not met as evidenced by:

Based on a review of records and interview with the laboratory director/technical consultant, the laboratory failed to ensure proficiency testing attestation statements had been signed by the laboratory director. Findings include: (1) At the beginning of the survey, surveyor #2 reviewed 2016 and 2017 proficiency testing records. The following was identified for 2 of 28 proficiency testing events: (a) 2017 Chemistry Core 3rd Event - The attestation statement had not been signed and dated by the laboratory director; (b) 2017 Hematology 2nd Event - The attestation statement had not been signed and dated by the laboratory director; (2) The surveyors reviewed the records with the laboratory director/technical consultant, who stated the attestation statements, as indicated above, had not been signed and dated by the laboratory director.

D5215

EVALUATION OF PROFICIENCY TESTING PERFORMANCE

CFR(s): 493.1236(b)(2)

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).

This STANDARD is not met as evidenced by:

Based on a review of records and interview with the laboratory director/technical consultant, the laboratory failed to verify the accuracy of testing when the proficiency testing program did not evaluate submitted results. Findings include: (1) At the beginning of the survey, surveyor #2 reviewed 2016 and 2017 proficiency testing records and identified the following had not been evaluated by the proficiency testing program (the proficiency report referred the laboratory to the proficiency data summary, non-graded or see commentary in order to obtain the expected result): (a) Hematology (i) 2016 Hematology 2nd Event (aa) 1 of 5 Monocytes/Mids for sample HEM-06 (ii) 2016 Hematology 3rd Event (aa) 1 of 5 Monocytes/Mids for sample HEM-11 (iii) 2017 Hematology 2nd Event (aa) 2 of 5 Monocytes/Mids for samples

HEM-07 and HEM-10 (2) Surveyor #2 further reviewed the records and could not locate documentation verifying the laboratory had reviewed the data summary, non-graded or see commentary in order to evaluate their results; (3) The surveyors asked the laboratory director/technical consultant if the results had been documented as evaluated. The laboratory director/technical consultant reviewed the records and stated the data summaries, non-graded or see commentary had not been documented as reviewed and therefore, the results had not been evaluated for accuracy.

D5411

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(a)

Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

This STANDARD is not met as evidenced by:

Based on a review of records, manufacturer's instructions, and interview with the laboratory director/technical consultant, the laboratory failed to follow the manufacturer's instructions for verifying automated differential flags. Findings include: (1) At the beginning of the survey, the laboratory director/technical consultant stated to the surveyors CBC (Complete Blood Count) testing was performed, which included a three part automated differential, using the Boule Medonic M-Series analyzer. The laboratory director/technical consultant also stated the laboratory did not perform manual differential testing in house, but sent them to a reference laboratory when needed; (2) Surveyor #1 reviewed the manufacturer's operator's manual for information regarding flagged results. The instructions stated the following: (a) For BD differential flags, the instructions stated "The calculated populations for LYM, MID, GRAN overlap too much. Often in pathological samples with granulocytosis or lymphocytosis a blood smear is recommended"; (b) For OM differential flags, the instructions stated "There was only one mode in the WBC distribution between the LYM-L and GRAN-H settings. Often in pathological samples with granulocytosis or lymphocytosis a blood smear is recommended". (3) Surveyor #1 then reviewed patient CBC test records and identified 10 records containing differential flags. The manufacturer's instructions had not been followed for 2 of the 10 records as follows: (a) Record #1- OM flags were obtained on 10/23/17 at 12:57 pm. There was no evidence the specimen had been sent to the reference laboratory for a slide review; (b) Record #2 - BD flags were obtained on 11/10/17 at 07:08 pm. There was no evidence the specimen had been sent to the reference laboratory for a slide review. (4) The findings were discussed with the laboratory director/technical consultant who stated the manufacturer's instructions had not been followed.

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 laboratory director/technical consultant, the laboratory failed to ensure equipment was stored as required by the manufacturer. Findings include: (1) At the beginning of the survey, the laboratory director/technical consultant stated to the surveyors CBC (Complete Blood Count) was performed on the Boule Medonic M Series analyzer; (2) Later during the survey, surveyor #2 reviewed the manufacturer's environmental requirements for the analyzer. The manufacturer required the operating environment temperature be maintained within the range of 18 - 32 degrees C (Centigrade); (3) Surveyor #2 then reviewed laboratory's temperature records from January 2016 through December 2017 which verified the documented temperature readings were less than 18 degrees C for 14 of 24 months as follows: (a) March 2016 - Days 19,20,21,25 (b) April 2016 - Day 2 (c) June 2016 - Day 28 (d) July 2016 - Days 5,19 (e) August 2016 - Days 3,24 (f) September 2016 - Day 17 (g) October 2016 - Day 18 (h) November 2016 - Days 24,26 (i) December 2016 - Days 1,18,19,27,30,31 (j) January 2017 - Day 4 (k) June 2017 - Day 6 (l) October 2017 - Day 29 (m) November 2017 - Days 19,20,22 (n) December 2017 - Days 16,18,23,24,25,26,31 (4) The surveyors reviewed the records with the laboratory director/technical consultant who stated the documented temperatures of the laboratory had been maintained below 18 degrees C as indicated above.

D5469

CONTROL PROCEDURES

CFR(s): 493.1256(d)(10)(g)

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-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on a review of records and interview with the laboratory director/technical consultant, the laboratory failed to verify the stated value of control materials before they were put into use. Findings include: (1) At the beginning of the survey, the laboratory director/technical consultant stated the following to the surveyors: (a) CBC (Complete Blood Count) testing was performed using the Boule Medonic M-Series analyzer; (b) Three levels of Boule Con-Diff control materials were analyzed each day of patient testing; (c) The manufacturer's provided ranges were used to determine acceptability of quality control results. (2) Later during the survey, surveyor #1 reviewed records for 15 control lot numbers. There was no evidence the provided ranges were verified before the lot numbers were put into use for 3 of 15 lot numbers as follows: (a) Low control lot #21705-21, Normal control lot #21705-22, and High

control lot #21705-23 put into use on 06/26/17 and used through 09/15/17. (3) The findings were reviewed with the laboratory director/technical consultant, who stated the manufacturer's ranges had not been verified before the above lot numbers had been put into use.

D5807

TEST REPORT
CFR(s): 493.1291(d)

Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:
Based on a review of records, and interview with the laboratory director/technical consultant, the laboratory failed to ensure reference intervals were determined as appropriate for the laboratory's patient population. Findings include: (1) At the beginning of the survey, the laboratory director/technical consultant stated to the surveyors CBC (Complete Blood Count) testing was performed using the Boule Medonic M-Series analyzer; (2) Later during the survey, surveyor #1 reviewed two patient CBC reports - the first report was for an adult female patient with the testing performed on 09/15/17 at 10:07 am; the second report was for an adult male patient with the testing performed on 01/07/18 04:39 pm. Both reports included the same reference intervals for the CBC parameters of RBC (Red Blood Cell), Hemoglobin, and Hematocrit, which were: (a) RBC - 3.50 - 5.50 x10⁶/uL (b) Hemoglobin - 11.5 - 16.5 g/dL (c) Hematocrit - 35 - 55% (3) The surveyors reviewed the findings with the laboratory director/technical consultant who agreed the patient reports did not include gender specific reference ranges. NOTE: Routinely, female reference intervals for the analytes RBC, Hemoglobin, and Hematocrit are lower than male reference intervals.