

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0475918	(X3) Date Survey Completed 01/22/2021
Name of Provider or Supplier Prague Regional Memorial Hospital	Street Address, City, State 1322 Klabzuba Avenue, Prague, 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 recertification survey was performed on 01/20,21,22/2021. The findings were reviewed with the laboratory manager and technical consultant #2 at the conclusion of the survey. The laboratory was found out of compliance with the following CLIA regulations: 493.1210; D5016: Routine Chemistry 493.1403; D6000: Laboratory Director
D5016	<p>ROUTINE CHEMISTRY CFR(s): 493.1210</p> <p>If the laboratory provides services in the subspecialty of Routine Chemistry, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1267, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory failed to ensure the requirements were met for the subspecialty of Routine Chemistry for Blood Gas testing. Findings include: (1) The laboratory failed to perform one sample of control material each 8 hours of patient blood gas testing using a combination of control materials that included both low and high values on each day of blood gas testing for 33 of 33 days of patient testing. Refer to D5537.</p>
D5211	<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 a review of records and interview with the laboratory manager and technical</p>

consultant #2, the laboratory failed to review and evaluate proficiency testing results for 4 of 22 events. Findings include: FAILURES (1) On 01/20/2021, the surveyor reviewed 2019 and 2020 proficiency testing records and identified the following failures: (a) Second 2020 Hematology Event (i) Urinalysis- The laboratory failed the results for 1 of 1 samples (UA-01); (2) The surveyor could not locate evidence in the records proving the failures had been addressed; (3) the surveyor reviewed the records with the laboratory manager and technical consultant #2, and asked if corrective action had been taken and documented for the failures. The laboratory manager stated on 01/21/2021 at 02:45 pm corrective action had not been taken. BIASES (1) On 01/21/2021, the surveyor reviewed 2019 and 2020 proficiency testing records. The following biases were identified (biases were identified using the SDI (Standard Deviation Index) values assigned by the proficiency program): (a) Third 2019 Hematology Event (i) MCHC (Mean Corpuscular Hemoglobin Concentration - 4 of 5 results exhibited a negative bias (aa) Sample PNT-12 - SDI of -2.2 (bb) Sample PNT-13 - SDI of -2.2 (cc) Sample PNT-14 - SDI of -2.2 (dd) Sample PNT-15 - SDI of -2.1 (ii) Red Blood Cells - 4 of 5 results exhibited a positive bias (aa) Sample PNT-12 - SDI of 2,7 (bb) Sample PNT-13 - SDI of 3.6 (cc) Sample PNT-14 - SDI of 3.5 (dd) Sample PNT-15 - SDI of 3,8 (b) First 2020 Chemistry Core Event (i) Digoxin - 3 of 5 results exhibited a positive bias (aa) Sample CH-01 - SDI of 2.6 (bb) Sample CH-02 - SDI of 2.1 (cc) Sample CH-03 - SDI of 3.0 (c) First 2020 Chemistry Core Event (i) Potassium - 3 of 5 results exhibited a positive bias (aa) Sample CH-11 - SDI of 2.7 (bb) Sample CH-13 - SDI of 2.1 (cc) Sample CH-14 - SDI of 3.7 (2) The surveyor could not locate evidence in the records proving the biases had been identified and addressed; (3) The records were reviewed with the laboratory manager and technical consultant #2. The laboratory manager stated on 01/20/2021 at 02:40 pm the biases had not been addressed.

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 manager and technical consultant #2, the laboratory failed to verify the accuracy of testing when the proficiency testing program did not evaluate submitted results for 2 of 22 events. Findings include: (1) On 01/20/2021, the surveyor reviewed 2019 and 2020 proficiency testing records and identified the following had not been evaluated by the proficiency testing program: (a) Hematology (i) 2019 First Event - Urine Sediment sample US-02; (b) Coagulation (i) 2019 Third Event - PT (Prothrombin Time) samples: COA-11, COA-12, COA-13, COA-14, COA-15. (2) The surveyor further reviewed the records and could not locate documentation verifying the laboratory had performed a self-evaluation of the non-graded result; (3) The surveyor asked the laboratory manager if the results had been documented as evaluated. The laboratory manager reviewed the records and stated on 01/20/2021 at 01:15 pm the non-graded results had not been documented as reviewed.

D5439

CALIBRATION AND CALIBRATION VERIFICATION

CFR(s): 493.1255(b)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:

Based on a review of records and interview with the laboratory manager and technical consultant #2, the laboratory failed to perform calibration verification procedures at least once every 6 months. Findings include: (1) On 01/21/2021 at 09:45 am, the laboratory manager stated to the surveyor Ammonia, Alcohol, and CO2 testing were performed using the Beckman Coulter AU 480 analyzer; (2) The surveyor reviewed calibration verification records for the analyzer from January 2019 through December 2020 (since routine calibration procedures were performed using less than three calibrators for the above analytes, calibration verification procedures, using three or more levels of calibration materials, were required every 6 months). There was no evidence calibration verification procedures had been performed prior to 10/09/2019; (3) The surveyor reviewed the records with the laboratory manager and technical consultant #2. Both stated on 01/22/2021 at 02:05 pm, calibration verification had not been performed every 6 months for Ammonia, Alcohol, and CO2 as stated above.

D5449

CONTROL PROCEDURES

CFR(s): 493.1256(d)(3)(ii)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (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 manager and technical consultant #2, the laboratory failed to perform a negative and positive control material 1 of 5 days of patient qualitative serum pregnancy testing. Findings include: (1) On 01/21/2021 at 09:45 am, the laboratory manager stated the following to the surveyor: (a)

The laboratory performed qualitative serum pregnancy testing using the OSOM HCG Combo test kit; (b) Positive and negative serum quality control (QC) materials were performed each day of patient testing. (2) The surveyor reviewed QC and patient testing records between 03/10/2020 through 09/22/2020. The review showed that negative and positive QC materials had not been performed 1 of 5 days of patient testing reviewed. The specific day was 03/13/2020; (3) The surveyor reviewed the records with the laboratory manager and technical consultant #2, who stated on 01/20/2021 at 04:15 pm, negative and positive QC materials had not been performed on 03/13/2020.

D5537

ROUTINE CHEMISTRY
CFR(s): 493.1267(b)(d)

For blood gas analyses, the laboratory must perform the following: (b) Test one sample of control material each 8 hours of testing using a combination of control materials that include both low and high values on each day of testing. (d) Document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Based on a review of records and interview with the laboratory manager, the laboratory failed to perform one sample of control material each 8 hours of patient testing using a combination of control materials that include both low and high values on each day of blood gas testing for 33 of 33 days. Findings include: (1) On 01/21/2021 at 10:00 am, the laboratory manager stated the following to the surveyor: (a) Blood Gas (pH, pCO₂, pO₂) testing was performed using the G3+ on the iSTAT (serial number 397663) analyzer; (2) The surveyor reviewed QC and patient testing records from January 2019 through November 2020. The review showed that one sample of control material had not been performed each 8 hours of patient testing using a combination of control materials that include both low and high values on each day of patient testing for 33 of 33 days of patient testing reviewed as follows (QC had not been performed on the days of patient testing): (a) Patient #1 - Testing performed on 01/29/2019 (b) Patient #2 - Testing performed on 01/31/2019 (c) Patient #3 - Testing performed on 03/03/2019 (d) Patient #4 - Testing performed on 04/20/2019 (e) Patient #5 - Testing performed on 05/03/2019 (f) Patient #6 - Testing performed on 05/08/2019 (g) Patient #7 - Testing performed on 06/24/2019 (h) Patient #8 - Testing performed on 07/04/2019 (i) Patient #9 - Testing performed on 07/12/2019 (j) Patient #10 - Testing performed on 08/30/2019 (k) Patient #11 - Testing performed on 09/20/2019 (l) Patient #12 - Testing performed on 10/28/2019 (m) Patient #13 - Testing performed on 11/01/2019 (n) Patient #14 - Testing performed on 11/27/2019 (o) Patient #15 - Testing performed on 12/19/2019 (p) Patient #16 - Testing performed on 01/03/2020 (q) Patient #17 - Testing performed on 01/24/2020 (r) Patient #18 - Testing performed on 01/29/2020 (s) Patient #19 - Testing performed on 02/23/2020 (t) Patient #20 - Testing performed on 03/02/2020 (u) Patient #21 - Testing performed on 04/07/2020 (v) Patient #22 - Testing performed on 04/17/2020 (w) Patient #23 - Testing performed on 05/14/2020 (x) Patient #24 - Testing performed on 06/16/2020 (y) Patient #25 - Testing performed on 06/27/2020 (z) Patient #26 - Testing performed on 07/03/2020 (aa) Patient #27 - Testing performed on 07/27/2020 (bb) Patient #28 - Testing performed on 08/05/2020 (cc) Patient #29 - Testing performed on 09/03/2020 (dd) Patient #30 - Testing performed on 09/28/2020 (ee) Patient #31 - Testing performed on 10/11/2020 (ff) Patient #32 - Testing performed on 10/16/2020 (gg) Patient #33 - Testing performed on 11/30/2020 (3) The surveyor reviewed the records with the laboratory manager who stated on 01/22/2021

at 03:00 pm, one sample of control material had not been performed each 8 hours of patient testing using a combination of control materials that include both low and high values on each day of patient testing as indicated above.

D5555

IMMUNOHEMATOLOGY

CFR(s): 493.1271(c)(f)

(c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Based on a review of records and interview with the laboratory manager and technical consultant #2, the laboratory failed to ensure units of blood were stored under appropriate conditions that included an adequate temperature alarm system that is regularly inspected for 1 of 8 alarm checks; and failed to ensure units of blood were stored under appropriate conditions for 3 of 31 charts. Findings include: ALARM CHECKS (1) On 01/20/2021 at 10:00 am, the laboratory manager stated to the surveyor that units of packed red blood cells were stored in the blood bank refrigerator. The units were to be used for patient transfusions; (2) On 01/21/2021, the surveyor reviewed the quarterly refrigerator alarm records for 2019 and 2020. The records indicated the alarm checks had not been performed quarterly. They had not been performed between 02/20/2019 and 05/14/2020; (3) The surveyor reviewed the records with the laboratory manager and technical consultant #2. The laboratory manager stated on 01/21/2021 at 02:20 pm, the alarm checks had not been performed quarterly as required. THERMOGRAPH CHARTS (1) On 01/20/2021 at 10:00 am, the surveyor observed the thermograph temperature recorder for the blood bank refrigerator. The refrigerator had a recorder connected to it for continuously recording the temperature on thermograph charts (Note: units of packed cells must be stored at 1-6 degrees Centigrade). Each chart monitored the temperature for a 7 day period; (2) On 01/21/2021, the surveyor reviewed 31 refrigerator charts dated from 06/06/2020 through 01/11/2021. The review indicated that 3 of 31 charts had not been changed by the 7th days of usage as follows: (a) Chart #17 - The chart was put into use on 09/26/2020 and removed on 10/10/2020 (14 days); (b) Chart #25 - The chart was put into use on 11/28/2020 and removed on 12/06/2020 (8 days); (c) Chart #29 - The chart was put into use on 12/20/2020 and removed on 12/28/2020 (8 days). (3) The surveyor reviewed the charts with the laboratory manager and technical consultant #2. The laboratory manager stated on 01/21/2021 at 01:35 pm the charts had not been within 7 days as indicated above.

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 manager and technical consultant #2, the laboratory failed to make appropriate reference ranges available for hematology testing for 2 of 2 patient reports and coagulation testing for 1 of 1 patient report. Findings include: HEMATOLOGY (1) On 01/20/2021 at 09:30 am, the laboratory manager stated to the surveyor the laboratory performed CBC (Complete Blood Count) testing using the Beckman Coulter DxH 520 analyzer; (2) On 01/22/2021, the surveyor reviewed two patient CBC reports - the first report was for an adult female patient with the testing performed on 01/14/2021; the second report was for an adult male patient with the testing performed on 01/14/2021. Both reports included the same reference intervals for the CBC parameters of RBC (Red Blood Cell), Hemoglobin, and Hematocrit which were: (a) RBC - 3.80 - 5.50 $10^6/\text{ul}$ (b) Hemoglobin - 12.0 - 18.0 g/dL (c) Hematocrit - 36.0 - 54.0 % (3) The surveyor reviewed the findings with laboratory manager and the technical consultant #2. The laboratory manager stated on 01/22/2021 at 01:35 pm 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. COAGULATION (1) On 01/20/2021 at 10:05 am, the laboratory manager and technical consultant #2 stated to the surveyor the ACL Elite analyzer was used to perform PT (ProthrombinTime) testing; (2) On 01/22/2021, the surveyor reviewed the implementation records for the current lot number of reagent and identified the following: (a) PT reagent - Hemosil lot # N0797382 had been put into use on 05/01/2020; (b) The laboratory had established a PT normal reference interval of 12.05 - 16.05 seconds. (3) The surveyor then reviewed a patient PT report dated 01/13/2021 with a normal reference range of 10.9 - 17.9 seconds; (4) The surveyor reviewed the findings with the laboratory manager and technical consultant #2. On 01/22/2021 at 12:35 pm the laboratory manager stated that although the laboratory had established a PT normal reference interval with a PT reagent lot change, the laboratory had not implemented the change into the laboratory's computer information system as indicated above.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR
CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:
Based on a review of records and interview with the laboratory manager and technical consultant #2, the laboratory director failed to provide overall management and direction for moderate complexity testing. Findings include: (1) The laboratory director failed to attest that, at the time of testing, proficiency testing samples were tested in the same manner as patient specimens as required under Subpart H for 2 of 22 events. Refer to D6016; (2) The laboratory director failed to ensure a quality control program was maintained to ensure the quality of laboratory services. Refer to D6020.

D6016

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(i)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform

test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:
Based on a review of records and interview with the laboratory manager and technical consultant #2, the laboratory director failed to attest that, at the time of testing, proficiency testing samples were tested in the same manner as patient specimens as required under Subpart H for 2 of 22 events. Findings include: (1) On 01/20/2021, the surveyor reviewed 2019 and 2020 proficiency testing records. It was identified for 2 of 22 events, the attestation statements had been signed approximately 2-3 months after the samples had been tested (not within a timeframe for the director to attest that, at the time of testing, the proficiency samples had been tested as required) as follows: (a) Microbiology first event of 2019 - The samples had been tested on 03/01/2019 and the attestation statement had not been signed by the laboratory director until 04/30/2019; (b) Chemistry core First event of 2019 - The samples had been tested on 05/02/2019 and the attestation statement had not been signed by the laboratory director until 06/21/2019. (2) The surveyor reviewed the findings with the laboratory manager and technical consultant #2 and explained that attestation statements must be signed within a timeframe to definitively attest to the fact that proficiency samples were tested in the same manner as patient specimens.

D6020

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(5)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:
Based on a review of records and interview with the laboratory manager, the laboratory director failed to ensure a quality control program was maintained to ensure the quality of laboratory services. Findings include: (1) The laboratory director failed to ensure one sample of control material had been performed each 8 hours of patient blood gas testing using a combination of control materials that include both low and high values on each day of blood gas testing for 33 of 33 days of patient testing. Refer to D5537.