

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0472727	(X3) Date Survey Completed 10/04/2018
Name of Provider or Supplier Mercy Hospital Watonga, Inc	Street Address, City, State 500 N Clarence Nash Blvd, Watonga, 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 10/2/18 - 10/4/18. The laboratory was found out of compliance with the following CLIA regulation: 493.1409: D6033: Condition: Technical Consultant, Moderate Complexity The findings were reviewed with the laboratory manager and the director of nursing services at the conclusion of the survey.
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, the laboratory failed to thoroughly review and evaluate proficiency testing results. Findings include: (1) On the first day of the survey, the surveyor reviewed the 2017 and 2018 proficiency testing records. The following biases (the biases were identified using the SDI (Standard Deviation Index) values assigned by the proficiency testing program) were identified: (a) Second 2017 Chemistry Core Event (i) Alcohol: 5 of 5 results exhibited a Negative bias (aa) ALC-06: SDI -2.3 (bb) ALC-07: SDI -3.0 (cc) ALC-08: SDI -3.2 (dd) ALC-09: SDI -4.4 (ee) ALC-10: SDI -2.4 (ii) Digoxin: 4 of 5 results exhibited a Negative bias (aa) CH-06: SDI -4.0 (bb) CH-08: SDI -0.1 (cc) CH-09: SDI -3.7 (dd) CH-10: SDI -3.5 (iii) Dilantin: 4 of 5 results exhibited a Negative bias (aa) CH-06: SDI -3.5 (bb) CH-08: SDI -0.7 (cc) CH-09: SDI -3.7 (dd) CH-10: SDI -3.6 (iv) Total Cholesterol: 5 of 5 results exhibited a Negative bias (aa) CH-06: SDI -2.5 (bb) CH-07: SDI -4.6 (cc) CH-08: SDI -4.7 (dd) CH-09: SDI -3.0 (ee) CH-10: SDI -1.9 (b) Second 2017 Hematology Event (i) Red Blood Cell: 4 of 5 results exhibited a Positive bias (aa) XE-07: SDI 3.7 (bb) XE-08: SDI 3.6 (cc) XE-09: SDI 0.7 (dd) XE-10: SDI 3.5 (2) Documentation showed that although the biases had been identified, they had not been thoroughly investigated to determine the cause or if a</p>

systematic failure had occurred; (3) The surveyor reviewed the findings with the laboratory manager who stated to the surveyor the biases had not been thoroughly investigated to determine the cause and to ensure a systematic failure had not occurred.

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, the laboratory failed to evaluate the accuracy of testing when a proficiency testing result had not been graded by the proficiency program. Findings include: (1) On the first day of the survey, the surveyor reviewed the 2017 and 2018 proficiency testing records and identified the laboratory did not address a result not graded by the proficiency testing program for Urobilinogen testing: (a) Second 2017 Event (i) Sample UA-03 had not been evaluated by the proficiency testing program due to non-consensus among the peers. The laboratory reported, "2.0/3.0 mg/ml." Under "Expected Result" it stated, "See Data Summary." There was no evidence the laboratory reviewed the data summary to evaluate their result. (2) The surveyor reviewed the records with the laboratory manager, who stated to the surveyor the non-graded proficiency testing result had not been evaluated.

D6033

TECHNICAL CONSULTANT-MODERATE COMPLEXITY

CFR(s): 493.1409

The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

This CONDITION is not met as evidenced by:

Based on a review of records, and interview with the laboratory manager, individuals performing the duties of a technical consultant failed to meet the qualification requirement of a technical consultant as defined in 493.1411. Findings include: (1) The technical consultant failed to ensure individuals who performed the duties and responsibilities of the technical consultant, met the qualifications. Refer to D6035.

D6035

TECHNICAL CONSULTANT QUALIFICATIONS

CFR(s): 493.1411

(a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of

Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service.

This STANDARD is not met as evidenced by:

Based on a review of records, and interview with the laboratory manager, the technical consultant failed to ensure individuals who performed the duties of a technical consultant met the educational qualifications as defined in 493.1411. Findings include: (1) On the first day of the survey, the laboratory manager stated to the surveyor the laboratory performed moderate complexity testing, which included the following: (a) CBC (Complete Blood Count) testing (e.g., WBC-White Blood Count, RBC-Red Blood Count, Hemoglobin, Hematocrit, Platelet Count, etc.) using the Sysmex XS-1000i analyzer (b) Chemistry (e.g., Alcohol, Digoxin, Glucose, Potassium, Triglycerides, Uric Acid, etc.) using the Roche Cobas c311 analyzer (c) Microscopic urinalysis (d) Wet prep examinations (e) PT/INR (Prothrombin Time /International Normalized Ratio) testing using the Stago STA Satellite analyzer (f) Arterial Blood Gas (pH, pO₂, pCO₂) testing using the OPTI CCA-TS analyzer (2) The surveyor reviewed the Laboratory Personnel Report (Form CMS-209) completed by the laboratory prior to the survey. The form indicated the laboratory director was designated as the technical consultant for the moderate complexity testing performed by the laboratory; (3) The surveyor then reviewed personnel records and identified individuals who did not meet the required educational requirements of a technical consultant performed testing person competency assessments. The findings follow: (a) Laboratory Manager - Obtained an Associates of Applied Science degree in Medical Laboratory Technology: (i) Performed the 2017 annual competency assessment (on 06/07/17) for Testing Person #1 (ii) Performed the 2017 annual competency assessment (on 08/15/17) and the 2018 annual competency assessment (on 04/16/18) for Testing Person #2 (iii) Performed the 2017 annual competency assessment (on 06/20/17) and the 2018 annual competency assessment (on 08/16/18) for Testing Person #3 (b) Testing person #1 - Obtained an Associates of Applied Science degree in Medical

Laboratory Technology: (i) Performed the semi-annual competency assessment (on 08/17/18) for Testing Person #4 (ii) Performed the semi-annual competency assessment (on 12/27/17) for Testing Person #5 (c) Testing person #2 - Obtained an Associates of Applied Science degree in Medical Laboratory Technology: (i) Performed the 2017 annual competency assessment (on 06/01/17) and the 2018 annual competency assessment (on 06/04/18) for the laboratory manager (d) Testing person #5 - Obtained an Associates of Applied Science degree in Medical Laboratory Technology: (i) Performed the 2018 annual competency assessment (on 06/01/18) for Testing Person #1 (4) The surveyor reviewed the findings with the laboratory manager who stated to the surveyor, the laboratory failed to ensure individuals who performed competency assessments, met the educational requirements of a technical consultant.