

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0488872	(X3) Date Survey Completed 12/06/2018
Name of Provider or Supplier Ballinger Memorial Hospital/Laboratory	Street Address, City, State 608 Avenue B, Ballinger, TX	
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
D2098	<p>ENDOCRINOLOGY CFR(s): 493.843(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's American Proficiency Institute (API) endocrinology proficiency testing results and interview of facility personnel found that the laboratory failed to attain a satisfactory score for the analyte of TSH (thyroid stimulating hormone) in the 2018 1st testing event. The findings included: 1. A review of the laboratory's API proficiency testing results from the 1st Chemistry testing event of 2018 found that the facility failed to attain a satisfactory score. The laboratory submitted unacceptable responses for 4 of 5 specimens resulting an unsatisfactory score of 20% for TSH. Further review of the laboratory's corrective actions found that the laboratory determined the cause of the failures to be an issue with the calibration of the TSH, but did not evaluate patient results tested using the same lot number of TSH reagent. 2. An interview with the technical consultant conducted on December 6, 2018 at 10:07 AM confirmed the findings.</p>
D2099	<p>ENDOCRINOLOGY CFR(s): 493.843(b)</p> <p>Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's American Proficiency Institute (API) endocrinology proficiency testing results and interview of facility personnel found</p>

that the laboratory failed to attain an overall testing event score for Endocrinology in the 2018 1st testing event, resulting in unsatisfactory performance. The findings included: 1. A review of the laboratory's API proficiency testing results from the 1st Chemistry testing event of 2018 found that the facility received an overall score of 60% for the specialty of Endocrinology. The laboratory submitted unacceptable responses for 4 of 5 specimens resulting an unsatisfactory score of 20% for TSH. Further review of the laboratory's corrective actions found that the laboratory determined the cause of the failures to be an issue with the calibration of the TSH, but did not evaluate patient results tested using the same lot number of TSH reagent. 2. An interview with the technical consultant conducted on December 6, 2018 at 10:07 AM confirmed the findings.

D2123

HEMATOLOGY
CFR(s): 493.851(c)

Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.

This STANDARD is not met as evidenced by:
Based on review of proficiency testing records for 2017 and 2018, and interview of facility personnel, the laboratory failed to participate in 1 of 6 proficiency testing events for the specialty of hematology. The findings include: 1. A review of the American Proficiency Institute (API) proficiency testing records found the laboratory failed to submit the results in the time frame specified by the program for the 2017 Hematology 2nd testing event. a. Review of the 2017 Hematology 2nd event proficiency testing instructions found that the Proficiency online and postmark due date as Friday, July 28, 2018 11:59 PM b. Review of the 2017 Hematology 2nd event Performance Summary found no scores for the analytes Erythrocytes, Hematocrit, Hemoglobin, Leukocyte Count, MCH, MCHC, MCV, Platelet count, RDW, and White Blood Cell Differential, Prottime (PT) and Partial Thromboplastin Time (PTT). 2. Interview of the Technical Consultant conducted on July 18, 2018 at 09:29 AM confirmed that the laboratory failed to test specimens and submit results to the proficiency testing agency before the submission deadline. She went on to explain that the laboratory failed to order the appropriate proficiency testing product for testing on their new Hematology analyzer which replaced the Cell Dyn in April 2018, and was unable to get the appropriate samples.

D3021

REQUIREMENTS FOR TRANSFUSION SERVICES
CFR(s): 493.1103(c)(1)

Blood and blood products storage and distribution. If a facility stores or maintains blood or blood products for transfusion outside of a monitored refrigerator, the facility must ensure the storage conditions, including temperature, are appropriate to prevent deterioration of the blood or blood product.

This STANDARD is not met as evidenced by:
 Based on review of laboratory policies and procedures, surveyor observations, and interview with facility personnel, the laboratory failed to ensure the audible alarm system on the blood product refrigerator was configured such that hospital personnel would be notified of a blood product storage issue after laboratory normal operation hours for 16 of 16 months the new blood product refrigerator has been in service. Facilities that provide transfusion services (not certified for the specialty of Immunohematology) and perform non-waived testing are held to the requirements for the storage and distribution of blood and blood products. The findings included: 1. Based on review of the laboratory's policy "LOSS OF MONITORED REFRIGERATION", reviewed by the Laboratory Director and General Supervisor on 12/21/2015, the policy states the following: "The Blood Bank refrigerator is equipped with a temperature alarm system that has a very audible sound activated when the refrigerator temperature falls outside the acceptable range" And; "If the alarm should sound when a technologist is not available in the laboratory, nursing personnel will notify the technologist on call, who will then take appropriate steps to correct the problems." 2. At 14:00 hours on 12/06/2018 in the laboratory, the General Supervisor demonstrated an alarm check on the Helmer blood product refrigerator and the audible alarm sounded in the laboratory at 1.5 Celsius and 5.5 Celsius respectively. 3. In an interview at 14:04 hours on 12/06/2018 in the laboratory, the General Supervisor stated that laboratory scientists took call after normal hours. When asked if the hospital had an audible alarm outside of the laboratory to notify hospital staff if there was an issue with blood product storage, the General Supervisor stated the laboratory had purchased an alarm, but it had not yet been installed. The Helmer blood product refrigerator has been in use to store blood products since July 2017.

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:
 Observations, review of package inserts, patient test records, and interview of facility personnel found that the laboratory failed to test a negative and positive serum quality control material each day of patient testing for Serum Acetone when using the AimTab Ketone Tablets. Findings included: 1. Observations made during the tour the facility found that the laboratory was currently using AimTab Ketone tablets lot 70671 expiration 2018-12-31 for testing patient specimens. 2. Review of the package insert for the AimTab Ketone Tablets found under the heading quality control - "Performance can be confirmed by using commercially available positive and negative control materials. Contact Germaine Laboratories for a list of acceptable control materials. Each organization should establish its own guidelines for adequate standards of performance and should question handling and testing procedures if the standards are not met." 3. Review of patient test records found that the laboratory had tested 19 patient specimens for serum Acetone since January 1, 2018 without testing a negative and positive serum control. 4. Interview of the technical consultant conducted on December 6, 2018 at 2:13 PM confirmed that the laboratory does not

test serum controls each day of patient testing when using the AimTab Ketone Tablets. She went on to say that they only ran urine quality controls to ensure performance of the Ketone tablets.