

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0488872	(X3) Date Survey Completed 02/13/2023
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
D0000	An onsite survey conducted February 13, 2023 found the laboratory in compliance with 42 CFR Part 493, Requirements for Laboratories.
D5213	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1)</p> <p>The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing records and interview with facility personnel, the laboratory failed to evaluate ungraded scores for two of two events in 2022 for the assay cholinesterase. The findings included: 1. Based on review of American Proficiency Institute (API) performance evaluations for the first and second events of 2022, the instructions stated "Laboratories should review the Performance Summary and Comparative Evaluation thoroughly for failures or 'not graded' analytes. Laboratories are responsible for documenting and performing corrective action for failures and must perform a self-evaluation using statistics presented in the Participant Data Summary for samples that have not been graded." For the first event of 2022, the laboratory reported the following: CH-01 - Laboratory reported a value of 2601. API listed the acceptability criteria as 635 to 1523 CH-02 - Laboratory reported a value of 9628. API listed the acceptability criteria as 3495 to 7096 CH-03 - Laboratory reported a value of 24160. API listed the acceptability criteria as 5445 to 16988 CH-04 - Laboratory reported a value of 6229. API listed the acceptability criteria as 2470 to 4998 CH-05 - Laboratory reported a value of 4433. API listed the acceptability criteria as 1291 to 3147 For the second event of 2022, the laboratory reported the following: CH-06 - Laboratory reported a value of 6846. API listed the acceptability criteria as 3005 to 5257 CH-07 - Laboratory reported a value of 907. API listed the acceptability criteria as 0 to 1149 CH-08 - Laboratory reported a value of 4871. API</p>

listed the acceptability criteria as 2140 to 3704 CH-09 - Laboratory reported a value of 3334. API listed the acceptability criteria as 1460 to 2505 CH-10 - Laboratory reported a value of 6559. API listed the acceptability criteria as 2837 to 4921 The laboratory reported that testing for this assay was suspended for the third event of 2022. 2. In an interview at 09:52 hours on 2/13/2022, the Laboratory manager stated the laboratory was aware of the discrepant scores but had not documented a formal evaluation for the two proficiency testing events in 2022.

D5429

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:
Based on review of the chemistry analyzer operator's manual, laboratory maintenance records, and interview with facility personnel, the laboratory failed to perform required monthly maintenance for 3 of 12 months during 2022. The findings included:
1. Based on review of the Dimension clinical chemistry analyzer operator's guide, under Monthly Maintenance, the manual stated the following: "The five monthly maintenance procedures are: Replacing IMT Pump Tubing Cleaning the IMT System Replacing Instrument Air Filters Styletting HM Wash Probes Replacing an HM Pump Head The replacement procedures use tools and commonly replaced parts that are provided in your Accessory Spare Parts kit. After you use a spare part from this kit, be sure to order a new one from Dade Behring Inc. " 2. Based on review of the maintenance logs from January 2022 through December 2022, the laboratory did not record and perform monthly maintenance procedures for the following months: February 2022 March 2022 May 2022 3. In an interview at 15:29 hours on 2/13/2023, the Laboratory Manager stated the maintenance procedures were generally a night shift responsibility and the laboratory had staffing challenges during the affected months.

D5441

CONTROL PROCEDURES
CFR(s): 493.1256(a)(b)(c)(g)

(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on a review of the laboratory's Individualized Quality Control Plan (IQCP), quality control records from 2022, and interview with facility personnel, the laboratory failed to perform both positive and negative quality control for two of

twelve months in 2022. The findings included: 1. Based on review of the facility IQCP titled "Individual Quality Control Plan Template QIAstat-Dx Respiratory Panel", the policy stated: "EXTERNAL CONTROL FREQUENCY External Quality Controls should be run with each new lot number or with a different shipment date of the same lot number. External Quality Controls should be run on the 1st day of each month, unless that day falls on a weekend or holiday. Controls may be run prior to or following the 1st as best suited to lab staffing. External Quality Controls should be run following any major maintenance procedure, upgrade or replacement or a component, if testing personnel suspect damage to the analyzer, or if testing personnel question patient results." 2. Based on a review of monthly quality control records, the laboratory failed to run external quality control materials in November and December of 2022. 3. In an interview at 15:00 hours on 2/13/2023, the laboratory manager searched the instrument digital files and confirmed there was no record of the laboratory performing monthly quality control for November and December of 2022.

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 review of laboratory policy, refrigerator temperature alarm evaluations, and interview with facility personnel, the laboratory failed to perform two of four quarterly alarm checks in 2022. The findings included: 1. Based on review of the policy "BLOOD STORAGE, HANDLING, AND SUPPLIER", the policy stated "4. Perform alarm checks Alarm checks should be performed at least once a quarter. See the alarm manufacturer's booklet for step-by-step instructions. The low temperature of activation should be no colder than 1C and the high temperature of activation should be no higher than 6C. See "Out of Control Plan" for corrective actions to be taken if temperatures of activation are too low or too high and record nature of correction. See "Loss of Monitored Refrigeration" policy and procedure." 2. Based on review of refrigerator alarm check records, two of four quarterly alarm checks were performed on September 17, 2022, and April 27th, 2022. 3. In an interview at 10:53 hours on 2/13 /2022, the Laboratory Manager stated that no other alarm checks had been performed in 2022.

D5783

CORRECTIVE ACTIONS
CFR(s): 493.1282(b)(2)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:

Based on review of quality control records and interview with facility personnel, the laboratory failed to document all corrective actions taken when quality control failed to meet acceptability criteria for three of three quality control failures on the coagulation analyzer in November of 2022. The findings included: 1. Based on review of quality control (QC) records, the laboratory did not document corrective actions taken for the following quality control values that exceeded acceptability criteria: Prottime (PT) QC01 - a value of 11.5 seconds was recorded on 11/16/2022 at 12:38 hours. Acceptable limits in the analyzer software were defined as 9.7 to 10.7 seconds. The control was repeated at 13:20 hours and within limits at 10.1 seconds. No corrective action was documented. D-Dimer QC06 - a value of 1.17 mg/L at 18:53 hours on 11/20/2022 was recorded. Acceptable limits in the analyzer software were defined as 2.48 to 3.72. The control was repeated at 19:13 hours and within acceptable ranges at 2.9 mg/L. No corrective action was documented. Partial thromboplastin time (PTT) QC 1 - a value of 33.1 seconds was recorded on 11/27/2022 at 16:45 hours. Acceptable limits in the analyzer software were defined as 25.2 to 29.6 seconds. The control was repeated at 17:33 hours and within limits at 27.5 seconds. No corrective action was documented. 2. In an interview at 16:45 hours on 2/13/2022 in the laboratory, the Laboratory Manager confirmed the corrective actions were not recorded in laboratory quality control software, analyzer software, or laboratory logs.