

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1064012	(X3) Date Survey Completed 03/08/2019
Name of Provider or Supplier Fuad Zayed Mdp	Street Address, City, State 3012 E Main Ave Ste F, Alton, 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	A recertification survey was performed on March 8, 2019. The laboratory was found to be NOT IN COMPLIANCE with the CLIA regulations at: CFR 493.1250 Analytic Systems
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 review of the True Metrix Air Self Monitoring Blood Glucose System operator's manual, review of patient records, and interview with facility personnel, the laboratory failed to follow the manufacturer's instructions for use of the analyzer for 3 of 7 patients reviewed from February 26, 2019 to March 8, 2019. The findings included: 1. Based on review of the True Metrix Air Self Monitoring Blood Glucose System (REA4NPD03 Rev. 5) under, "Introduction" it stated, "The TRUE METRIX AIR Self Monitoring Blood Glucose System should not be used for the diagnosis or screening of diabetes or for neonatal use ..." 2. Based on a review of patient records from February 26, 2019 to March 8, 2019 seven (7) patients were identified as having orders for glucose testing by the True Metrix Air Self Monitoring blood glucose monitoring system. The following three (3) patients were identified to have an order for glucose measurement by the True Metrix Air Self Monitoring Blood Glucose System: Date: 03/02/2019 Patient ID: See Patient Alias Report FBS Result: 104 mg /dL No Diagnosis of Diabetes Date: 03/08/2019 Patient ID: See Patient Alias Report RBS Result: 128 mg/dL No Diagnosis of Diabetes Date: 03/08/2019 Patient ID: See Patient Alias Report RBS Result: 94 mg/dL No Diagnosis of Diabetes 3. The laboratory did not follow the manufacturer's instructions to ensure the instrument was not used a screening tool. 4. An interview with the Medical Assistant at the Nurse's</p>

Station on March 8, 2019 at 11:20 hours confirmed the findings. She stated that, "All new patients get a glucose test." 5. An interview with the Technical Consultant on March 8, 2019 at 11:30 hours in the office confirmed the findings. She revealed that testing personnel number two (as listed on Form CMS-209) told her that the glucometer was only used on known diabetics. Key: RBS - random blood sugar FBS - fasting blood sugar mg/dL milligrams per deciliter CMS - Centers for Medicare and Medicaid Services

D5400

ANALYTIC SYSTEMS
CFR(s): 493.1250

Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:
Based on review of laboratory policies, review of manufacturer's instructions, review of patient records, and confirmed in interview of facility personnel, the laboratory failed to monitor and evaluate overall quality of its analytic systems as evidenced by:
1. The laboratory failed to follow its own policy for resolution of abnormal flags on CBC (complete blood count) results. (refer to D5401) 2. The laboratory failed to follow the manufacturer's instructions when performing calibrations on the Medonic M-Series hematology analyzer. (refer to D5437)

D5401

PROCEDURE MANUAL
CFR(s): 493.1251(a)

A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:
Based on review of laboratory policy, review of instrument print outs, review of patient final reports, and confirmed in interview of facility personnel, the laboratory failed to follow its own policy for handling flagged results on patient results. The findings were: 1. Review of the laboratory's policy titled, "Suspect Parameter Flags" approved by the laboratory director on February 16, 2016 stated, "If the provider needs to see the report, the flag results will be blacked out for the doctor not to see those particular results." 2. Review of instrument print outs (Patient Sample Summary Report) from January 2, 2019 to February 28, 2019 revealed the following patient samples had flags on the differential portion of the result: Date: 01-09-2019 Sequence #: 188 LYM * MID * GRAN * LYM% * MID% * GRAN % * Date: 01-11-2019 Sequence #: 231 LYM * MID * GRAN * LYM% * MID% * GRAN % * Date: 01-30-2019 Sequence #: 497 LYM * MID * GRAN * LYM% * MID% * GRAN % * Date: 02-06-2019 Sequence #: 608 LYM * MID * GRAN * LYM% * MID% * GRAN % * Date: 02-19-2019 Sequence #: 755 LYM * MID * GRAN * LYM% * MID% * GRAN % * 3. Review of each of the 5 patients' charts revealed that the results

provided to the provider did not indicate the results had abnormal flags. The flags had been whited out. 4. On March 9, 2019, testing personnel one (as listed on Form CMS-209) provided the surveyor with the instrument printouts for each of the 5 patients' results. Each of the patient's results had flags indicated on the printout. 5. On March 9, 2019 at 12:10 hours in the laboratory, testing personnel two (as listed on Form CMS-209) revealed he had used white out on the flags. When asked if he was trained that way, he stated, "No."

D5437

CALIBRATION AND CALIBRATION VERIFICATION
CFR(s): 493.1255(a)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

This STANDARD is not met as evidenced by:

Based on review of laboratory policy, review of instrument calibration records, and confirmed in interview of facility personnel, the laboratory failed to follow the manufacturer's instructions for performance of instrument calibrations. The findings were: 1. Review of the laboratory's policy titled, "Instrument Operation and Maintenance" approved by the laboratory director on November 1, 2013, stated, "This laboratory will follow procedures as the manufacturer describes for testing, reporting, calibrating, controls specialty protocols, and for performing/documenting remedial action." 2. Review of the manufacturer's instructions for the Medonic M-Series hematology analyzer (May 2009, Article No. 1504248) under, "7.1 Preparations before Calibration" it stated, "Prior to calibration print Calibration Log." 3. Review of the laboratory's calibration records from January 2017 to December 2018 revealed the laboratory performed calibrations on the following dates: March 27, 2017 June 27, 2017 September 28, 2017 December 28, 2017 March 29, 2018 June 25, 2018 September 24, 2018 December 20, 2018 4. For each of the 8 of 8 calibrations performed, the laboratory failed to follow the manufacturer's instructions to print the "Calibration Log" prior to performing calibrations. 5. Interview with testing personnel one (as listed on Form CMS-209) on March 8, 2019 at 10:50 hours in the laboratory confirmed the findings. Key: CMS - Centers for Medicare and Medicaid Services

D5793

ANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1289(b)(c)

(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:
Based on review of laboratory policies, review of manufacturer's instructions, review of patient results, and confirmed in interview of facility personnel, the laboratory's quality assurance program failed to identify and correct errors in its analytic systems as evidenced by: 1. The laboratory failed to follow the manufacturer's instructions when performing instrument calibrations. (refer to D5437) 2. The laboratory failed to follow its own policy for resolution of abnormal flags on CBC results. (refer to D5401)

D5813

TEST REPORT
CFR(s): 493.1291(g)

The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values.

This STANDARD is not met as evidenced by:
Based on laboratory policy, review of patient final reports, review of laboratory logs, and confirmed in interview of facility personnel, the laboratory failed to immediately alert panic or critical values to healthcare providers. The findings were: 1. Review of the laboratory's policy titled, "Reporting Panic Values" approved by the laboratory director on April 19, 2008, stated, "It is the policy of this laboratory to document the reporting of panic values." The policy went on to state, "Document 1) Who was Notified Dr. Zayed, 2) When was the person notified, 3) By whom was the person notified." The laboratory listed the following critical values as part of its policy: WBC 2000 - 20,000 HGB 7.5 - 18 HCT 25 - 55 PLTS 50,000 - 800,000 2. Review of patient results from January 2, 2019 to February 28, 2019 revealed the laboratory should have identified and reported 2 critical values. 3. The following patient result met the laboratory's defined critical criteria: Date: 01/03/2019 Sequence #: 104 Critical Value: HCT = 55.0 4. Review of the laboratory's "Critical Value Log" revealed the laboratory failed to follow its own policy to document who was notified, when was the person notified, and by whom was the person notified for 1 of 2 critical patient values. The patient and the critical results were not documented on the logsheet. 5. Review of the patient final report retrieved from the electronic patient chart did not contain evidence that the laboratory documented who was notified, when the person was notified, and by whom was the person notified for 1 of 2 critical patient values. 6. Interview with the technical consultant on March 8, 2019 at 10:50 hours in the office confirmed the findings. She agreed the information was not available in the patient chart or on the Critical Value Log. Key: WBC - white blood cell HGB- hemoglobin HCT - hematocrit PLTS - platelets

D6014

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(3)(iii)

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)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results.

This STANDARD is not met as evidenced by:

Based on review of laboratory policy, review of manufacturer's instructions, review of patient records, and confirmed in interview of facility personnel, the laboratory director failed to ensure testing personnel were performing patient testing as required. (refer to D5401)