Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2000387	10/22/2019
Name of Provider or Supplier	**Street Address, City, State**	
Texas Internal Medicine And Diagnostic Center	4502 N Laurent St, Victoria, 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	Noted deficiencies and plans of correction were discussed with the laboratory representative at the entrance and exit conferences. The facility representative was given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) 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. This STANDARD is not met as evidenced by: Based on direct observation, review of manufacturer's instructions, laboratory policy, review of patient records, and staff interview, it was revealed the laboratory failed to follow the manufacturer's instructions for performance of quality control on Siemens Multistix 10SG. The findings were: 1. Surveyor observation October 22, 2019 at 10: 001 hours in the laboratory revealed one vial of Siemens Multistix 10SG (lot number 907103, expiration date: 2021-01-31) with 77 test strips left in the vial. 2. A review of the manufacturer's instructions for Siemens Multistix 10SG under, "Quality Control" it stated, "Test known negative and positive specimens or controls whenever a new bottle is first opened." 3. A review of the laboratory's policy "Clinitek Status +" under

	"Quality Control" it stated, "Positive and negative control solutions should be tested each time a new bottle of Multistix are opened. This provides a check to ensure the test strips are reacting properly and the instrument is ready the strips properly. Testing controls also helps detect errors caused by incorrect user technique. Follow package insert for complete information." 4. A review of the patient test records from October 17-21, 2019 revealed the following patients were tested when no documentation that quality control had been performed on the vial of Siemens Multistix 10SG. 10/17 /2019 Patient #1 DOB 08/18/74 10/17/2019 Patient #2 DOB 11/08/68 10/17/2019 Patient #3 DOB 07/03/46 10/172019 Patient #4 DOB unknown 10/17/2019 Patient #5 DOB 10/08/46 10/17/2019 Patient #6 DOB 11/12/39 10/17/2019 Patient #7 DOB 02 /12/52 10/17/2019 Patient #8 DOB 04/18/52 10/17/2019 Patient #9 DOB 02/22/62 10 /17/2019 Patient #10 DOB 12/11/44 10/17/2019 Patient #11 DOB 02/05/46 10/17 /2019 Patient #12 DOB 03/11/40 10/17/2019 Patient #13 DOB 06/09/38 10/17/2019 Patient #14 DOB 06/13/50 10/17/2019 Patient #15 DOB 10/15/71 10/17/2019 Patient #16 DOB 02/17/46 10/21/2019 Patient #17 DOB 10/16/57 10/21/2019 Patient #18 DOB 08/0535 10/21/2019 Patient #19 DOB 11/15/48 10/21/2019 Patient #20 DOB 09 /23/28 10/21/2019 Patient #21 DOB 02/14/44 10/21/2019 Patient #22 DOB 09/08/59 10//21/2019 Patient #23 DOB 03/27/79 10/21/2019 Patient #24 DOB 11/02/45 5. An interview with the laboratory director in the break room 10/22/2019 at 10:01 hours confirmed the findings. Key DOB- date of birth
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on review of laboratory policy, review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records, and confirmed in interview of facility personnel, the laboratory failed to test proficiency testing samples the same manner as patient samples. The findings were: 1. Review of the laboratory's policy titled, "Texas Internal Medicine Laboratory Proficiency Surveys" signed and dated by the laboratory director on 06/29/2018, it stated, "All proficiency testing samples will be analyzed in the same manner and some number of times that is performed on patients. Sample will not be repeated unless a patient would be routinely repeated as well. Nonlinear results will be treated as a patient nonlinear result is treated." 2. Based on review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records for 2018 event 2 and 3, revealed the laboratory did not follow its own policy to analyze PT samples in the same manner as patient samples. The laboratory did not repeat critical hemoglobin values as evidence by: 2018 Hematology/coagulation (event 2) Sample ID: 08 Hemoglobin = 5.6 (g/dl) 2018 Hematology/coagulation (event 3) Sample ID: 15 Hemoglobin = 5.5 (g/dl) 3. Review of laboratory panic values revealed the following: Hemoglobin Less than 6.6 gm/dl Greater than 20 gm/dl (adult) 4. The findings were confirmed in interview with Laboratory Director on 10/22/2019 at 11: 10 hours in the break room. He agreed the PT samples were not repeated as they

	would a patient. Key: g/dL - grams per deciliter CMS - Centers for Medicare and Medicaid Services
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on review of laboratory records and confirmed in interview of facility personnel, the laboratory failed provide documentation of retaining quality control records for the ALFA WASSERMAN Ace Alera chemistry analyzer from January 2018 through May 2018. The findings were: 1. Attempted review of quality control records from January 2018 to September 2019 revealed that no records were available for review for the previous ALFA WASSERMAN Ace Alera chemistry analyzer from January 2018 to May 2018. 2. The ALFA WASSERMAN Ace Alera chemistry analyzer is no longer in use by the laboratory or onsite and therefore no records could be retrieved from the analyzer. 3. An interview with the technical consultant on October 22, 2019 revealed the January to May 2018 timeframe was about the time he was hired as the technical consultant and the records could not be located.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on surveyor's direct observation, review of the laboratory policy, and confirmed in interview with facility staff, the laboratory failed to follow its own policy for specimen labeling. The findings were: 1. Surveyor observation in the laboratory, on October 22, 2019 at 10:21 hours during the initial tour of the laboratory found 1 patient urine sample labeled with: Patient's first and last name only 2. Review of the laboratory policy "Specimen Collection and Processing Manual" under "Criteria for Specimens Received into the Lab" it stated "It is the responsibility of each technologist to verify that the specimen matches the patient. Specimens will be clearly tabled with the following information, in accordance with CLIA regulations #493, 110." Full name of patient Date and time of collection Second form of identification such as date of birth or medical record number Initials of person collecting specimen Sources of specimen (required for cultures) 3. The laboratory failed to follow its own policy to ensure specimens are labeled with date and time of collection, second form of identification such as date of birth or medical record number, and initials of person collections specimen. 4. An interview with testing person #1 (as listed on CMS form-209) in the laboratory on 10/22/2019 at 09:30 hours confirmed the laboratory failed to follow its own policy to ensure each patient sample is labeled with two identifiers.

	Key CLIA - Clinical Laboratory Improvement Amendments CMS - Centers for Medicare and Medicaid Services
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on surveyor observation, review of manufacturer's instructions, and confirmed in interview of facility personnel, the laboratory failed to monitor revised expiration dates for Alfa Wassermann quality control reagents. The findings were: 1. Surveyor observation made on October 22, 2019 at 09:30 hours in the laboratory during the initial tour of the facility found 1 vial each of ALFA WASSERMANN quality control level 1 and 2. The QC (quality control) reagents were labeled with an open date of 10-22-2019. The QC reagents were stored in the refrigerator. 2. Review of the manufacturer's instructions package insert for ALFA WASSERMANN Chemistry Control under, "Storage and Stability" it stated: "Reconstituted at 2-8 degrees Celsius (when stored tightly capped): -ALP: 3 days -ALT and AST: 5 days -All other analytes: 7 days 3. The QC reagents were opened the day of the survey and therefore, were not expired. 4. An interview with the primary testing person on October 22, 2019 at 11:20 hours confirmed the findings. When asked how long the QC reagents were good for in the refrigerator, she responded, "7 days." Note: The laboratory refrigerates its QC and performs ALP (Alkaline Phosphatase) testing, and therefore QC reagents are stable for 3 days.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the laboratory's verification studies and confirmed in interview of facility personnel, the laboratory failed to ensure verification studies were complete prior to testing patients when it implemented a new FDA-cleared chemistry analyzer. The findings were: 1. Review of laboratory records revealed that laboratory implemented an FDA-cleared Ace Axcel chemistry analyzer in January 2019. 2. Review of the instrument verification records for the Ace Axcel revealed that the laboratory failed to provide documentation of: a. Completing accuracy assessments (no final statistical analysis) b. Verifying patient normal range 3. An interview with the technical consultant on October 22, 2019 at 10:15 hours in the break room confirmed the findings. He revealed that he evaluated the assessment based on a slope of 1, but confirmed there isn't a policy stating such. He went on to say that the

	laboratory is using the manufacturer's patient normal ranges but they haven't been verified yet.