Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0991702	03/07/2018
Name of Provider or Supplier	**Street Address, City, State**	
Jose S Cisneros Md	1001 Calle Milagros, Brownsville, 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. 493.51 Notification requirements for laboratories issued a certificate of compliance Laboratories issued a certificate of compliance must meet the following conditions: (a) Notify HHS or its designee within 30 days of any change in - (1) Ownership; (2) Name; (3) Location; (4) Director; or (5) Technical supervisor (b) Notify HHS no later than 6 months after performing any test or examination within a specialty or subspecialty area that is not included on the laboratory's certificate of compliance, so that compliance with requirements can be determined. Based on review of the laboratory's test menu, review of the laboratory's 116 and staff interview, it was revealed the laboratory failed to notify HHS within 6 months after adding the subspecialty of endocrinology. The findings were: 1. A review of the laboratory's test menu revealed the laboratory started testing under the subspecialty of endocrinology in April 2017. 2. A review of the laboratory's 116 revealed the subspecialty of endocrinology was not included as part of the laboratory's certificate of compliance. 3. The laboratory was asked to provide documentation of the notifying HHS of the addition endocrinology. No documentation was provided. 4. An interview with the technical consultant on 03/07 /2018 at 1000 hours in the office revealed he assumed the laboratory had notified HHS, but he was unable to provide documentation. This confirmed the findings.
D5445	CONTROL PROCEDURES

	CFR(s): 493.1256(d)(1)(2)(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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's Individualized Quality Control Plan (IQCP) for Thyroid Stimulating Hormone performed on the Frend system, review of the laboratory's quality control records, and staff interview, it was revealed the laboratory failed to: A) have documentation of quality control testing to support the frequency of quality control testing, and B) have documentation of following the laboratory's IQCP. The findings were: A) Supporting evidence 1. A review of the laboratory's Individualized Quality Control Plan (IQCP) for Thyroid Stimulating Hormone performed on the Frend system (approved by the laboratory director on 04/01/2017) revealed the laboratory established the required quality control testing frequency for the test at least every 30 days. 2. Further review of the laboratory's IQCP revealed the laboratory failed to have documentation performing quality control testing each day for 30 days to support its plan. 3. The laboratory was asked to provide documentation of performing quality control for 30 days to support its IQCP. No documentation was provided. 4. An interview with the technical consultant on 03/07/2018 at 1110 hours in the office - after his review of the records- confirmed the findings. B) Following the laboratory's IQCP 1. A review of the laboratory's Individualized Quality Control Plan (IQCP) for Thyroid Stimulating Hormone performed on the Frend system (approved by the laboratory director on 04/01/2017) revealed the laboratory established the required quality control testing frequency for the test at least every 30 days. 2. A review of the laboratory's quality control records from September 2017 to March 2018 revealed the laboratory performed quality control testing on the following days: 09/09 /2017 10/07/2017 (28 days later) 12/05/2017 (59 days later) 02/08/2018 (67 days later) 03/06/2018 (26 days later) 3. The laboratory was asked to provide documentation of performing quality control testing at least every 30 as required by its IQCP. No documentation was provided. 4. An interview with the technical consultant on 03/07/2018 at 1110 hours in the office - after his review of the records- confirmed the findings.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by:

	Based on review of the laboratory's policies, review of the laboratory's quality control records, and staff interview, it was revealed the laboratory director failed to ensure a quality control program was followed. The findings were: 1. A review of the laboratory's Quality Control corrective action policy (approved by the laboratory director on 04/29/2002) revealed: "It is the policy of this laboratory to do the following when controls are not within range: 1. Ensure that controls are not expired then remix and rerun control sample; if controls fail then, 2. Open a new vial of controls and run; if controls fail then, 3. Verify that control ranges are correct and that the correct level of control is evaluated- then, 4. Ensure that all specimens and reagents are at the right temperature, then, 5. Evaluate maintenance schedule, ensure that all of manufacturer's recommendations are followed and that maintenance procedures are being done as required. 6. Evaluate calibration; if necessary re-calibrate unit and run controls; if controls fail then, 7. Call technical support for help. 8. Ensure that all remedial action steps are documented. 2. A review of the laboratory's quality control records from June 2017 revealed the following days where laboratory failed to have documentation of following the laboratory's policy: Date Control Test times tested 06/02 Normal HCT 5 06/15 Normal HCT 6 06/15 High HCT 5 06/16 Normal HCT 8 06/16 High HCT 6 06/21 Normal HCT 5 06/23 Normal HCT 10 06/23 High HCT 5 06/26 Normal HCT 16 06/26 High HCT 6 3. The laboratory was asked to provide documentation of following its policy for quality control failures. No documentation was provided. 4. An interview with the technical consultant on 03/07/2018 at 1240 hours in the office revealed the laboratory personnel would rerun quality control samples until the results were acceptable. He stated they did not follow the laboratory's policy. This confirmed the findings.
D6055	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing whenever test methodology or instrumentation changes. The individual's performance must be reevaluated to include the use of the new test methodology or instrumentation prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory's test menu, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of the technical consultant performing competency assessments on 3 of 3 testing personnel prior to performing patient testing. The findings were: 1. A review of the laboratory's test menu revealed the laboratory started performing thyroid stimulating hormone testing utilizing the Frend system in April 2017. 2. A review of the laboratory's personnel records revealed the following three personnel performed testing on the Frend system. They were (as listed on Form CMS 209): Testing personnel number 1 Testing personnel number 3 Testing personnel number 4 3. Further review of the laboratory's personnel records revealed the laboratory failed to have documentation of the technical consultant performing competency assessments on each of the identified testing personnel performing testing utilizing the Frend system prior to patient samples being tested. 4. The laboratory was asked to provide documentation of competency assessments being performed prior to patient testing. No documentation was provided. 5. An interview with the technical consultant on 03 /07/2018 at 0955 hours in the office revealed competency assessments had not been performed. This confirmed the findings.

D6066	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel records, and staff interview it was revealed the laboratory failed to have documentation of training 1 of 3 personnel who performed testing on the Frend system. The findings were: 1. A review of the laboratory's personnel records revealed 3 personnel were identified as performing thyroid stimulating hormone testing on the Frend system. They are (as listed on Form CMS 209) Testing personnel number 1 Testing personnel number 3 Testing personnel number 4 2. Further review of the laboratory's personnel records revealed the laboratory failed to have documentation of testing personnel number 3 being trained to perform testing on the Frend system. 3. The laboratory was asked to provide documentation of training for testing personnel number 3. No documentation was provided. 4. An interview with the technical consultant on 03/07/2018 at 950 hours in the office - after his review of the records- confirmed the findings.