Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0678186	12/08/2020
Name of Provider or Supplier	**Street Address, City, State**	
Luis F Arango Md	104 S Bryan, Mission, 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.
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records from 2019 and 2020, review of laboratory policies, review of the laboratory's Form CMS 209, and staff interview, it was revealed the laboratory failed to ensure that proficiency testing was performed by all personnel who performed testing. The findings were: 1. A review of the laboratory's American Proficiency Institute (API) proficiency testing records from 2019 and 2020 revealed testing personnel number one as listed on Form CMS 209 performed the analysis of proficiency testing samples for 3 of 3 testing events in 2019. The events documented as performed by testing personnel number one were: 2019 Hematology Event 1 2019

	Hematology Event 2 2019 Hematology Event 3 2. Review of the laboratory's policy titled, "Proficiency Testing" approved by the laboratory director on May 20, 2012 revealed the following: "Every testing personnel will participate on proficiency testing by rotation of testing events or by splitting each event among them." 3. A review of the laboratory's Form CMS 209 revealed the laboratory listed two testing personnel. Testing personnel number 2 performed testing in 2019. 4. An interview with testing personnel number one as listed on Form CMS 209 on December 8, 2020 at 09:19 hours in the break room confirmed that he was the only one who performed hematology PT testing in 2019. He stated the other testing person performed patient testing, but did not participate in proficiency testing. Key: CMS - Centers for Medicare and Medicaid Services
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records from 2019 and 2020 and staff interview, it was revealed the laboratory failed to have documentation of the laboratory director and testing personnel signature on 2 of 6 attestation statements. The findings were: 1. A review of the laboratory's American Proficiency Testing (API) proficiency testing records from 2019 (events 1, 2, and 3) and 2020 (events 1, 2, and 3) revealed the laboratory failed have documentation of the laboratory director and testing personnel signing 2 of 6 attestation statements: 2020 Chemistry (event 2) 2020 Chemistry (event 3) 2. The laboratory was asked to provide documentation of the laboratory director and testing personnel signing the attestation statements. No documentation was provided. 3. An interview with testing personnel number one (as listed on Form CMS 209) at 09:19 hours in the break room confirmed the findings. Key: CMS - Centers for Medicare and Medicaid Services
D5305	TEST REQUEST CFR(s): 493.1241(c) The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable.

	This STANDARD is not met as evidenced by: Based on direct observation, review of laboratory records, review of patient results, and confirmed in interview of facility personnel, the laboratory failed to ensure that test requisitions included specimen collection time for 11 of 11 specimens located in the laboratory refrigerator. The findings were: 1. Direct observation made in the laboratory on December 8, 2020 found 11 of 11 specimens labeled with two unique patient identifiers. The specimens were not labeled with the time of collection. 2. Review of requisitions for the 11 of 11 specimens revealed no documentation of collection time. 3. Review of the specimen collection log for the 11 of 11 specimens revealed the time of collection was not documented. 4. Review of patient final reports for the 11 of 11 specimens revealed each specimen was collected on 12-07-2020 and no time of collection was documented: Accession #81985 Accession #81986 Accession #81987 Accession #81988 Accession #81989 Accession #81990 Accession #81991 Accession #81992 Accession #81993 Accession #81994 Accession #81995 5. An interview with testing personnel one (as listed on Form CMS 209) at 10:30 hours in the break room revealed the laboratory did not consistently document specimen collection time. When asked about the specimen collection time on the patient final reports, he revealed that the time is not necessarily the actual time of collection, it could be the time the tests are entered in the system. He revealed that some collectors put the time on the tube, some put it on the laboratory log, and some put it on the requisition. He confirmed that the laboratory could not be sure of the time of collection for the 11 samples. Key: CMS - Centers for Medicare and Medicaid Services
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 direct observation, review of laboratory policy, review of instrument records, and confirmed in interview of facility personnel, the laboratory failed to follow its own policy for performing yearly centrifuge checks. The findings were: 1. Direct observation made in the laboratory during the initial tour of the laboratory on December 8, 2020 at 08:30 hours revealed that laboratory uses a fixed angle centrifuge provided by a reference laboratory. 2. Review of laboratory policy titled, "Centrifuge Operation and Maintenance" approved by the laboratory director on January 16, 2013 it stated, "If the reference laboratory furnishes the centrifuge, make sure that paperwork or certificates of these checks are left in the laboratory. Document the actual RPMs and times obtained by the reference lab in the centrifuge log." 3. The laboratory was asked to provide documentation of following its own policy to ensure documentation of centrifuge checks done by the reference laboratory. No documentation was provided. 4. An interview with testing personnel one (as listed on Form CMS 209) on December 8, 2020 at 13:00 hours confirmed the findings. He revealed the centrifuge in use was from a previous reference laboratory no longer used by the facility and that he did not have centrifuge check records to review. Key: RPMs - rotations per minute CMS - Centers for Medicare and Medicaid Services
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:
Based on direct observation, review of laboratory policy, review of manufacturer's instructions, review of laboratory environmental records, review of patient final reports, and confirmed in interview of facility personnel, the laboratory failed to monitor refrigerator temperature for 2 of 2 patient testing days from December 1, 2020 to December 8, 2020. The findings were: 1. Direct observation during the initial tour of the laboratory on December 8, 2020 (the day of the survey) at 09:05 hours found 14 patient (serum) samples. a. Testing Personnel was asked when the samples were collected and when they would be tested. He stated the samples were collected the previous day and would be tested on December 8, 2020 (the day of the survey). 2. Review of laboratory policy titled, "Policy for Laboratory Temperatures" approved by the laboratory director on April 20, 2016 stated, "It is the policy of this laboratory to take and document laboratory and refrigerator temperatures prior to patient testing." 3. Review of the manufacturer's instructions for Vital Diagnostics Envoy 500 Total Bilirubin Reagent Kit (Document Number: FTEVY-BITV-v1, 07/2013) under "Specimens" it stated, " ...Bilirubin in serum and cell free plasma is table for 3 days at 2 to 8 degrees Celsius or for three months when stored in the dark at -70 degrees Celsius." 4. Review of laboratory refrigerator records revealed that as of December 8, 2020 (the day of the survey), the laboratory failed to provide documentation of monitoring the refrigerator temperature where specimens were stored from December 1, 2020 to December 8, 2020. 5. Random review of patient final reports from December 4, 2020 and December 8, 2020 found the following patient samples for Total Bilirubin were tested when refrigerated temperature storage could not be confirmed: Accession #81962 Collected on: 12-02-2020 Performed on: 12-04-2020 Total Bilirubin Result: 0.2 mg/dL Accession #81963 Collected on: 12-02-2020 Performed on: 12-04-2020 Total Bilirubin Result: 0.2 mg/dL Accession #81964 Collected on: 12-02-2020 Performed on: 12-04-2020 Total Bilirubin Result: 0.3 mg /dL Accession #81965 Collected on: 12-02-2020 Performed on: 12-04-2020 Total Bilirubin Result: 0.3 mg/dL Accession #81968 Collected on: 12-03-2020 Performed on: 12-04-2020 Total Bilirubin Result: 0.4 mg/dL Accession #81969 Collected on: 12-03-2020 Performed on: 12-04-2020 Total Bilirubin Result: 0.3 mg/dL Accession #81970 Collected on: 12-03-2020 Performed on: 12-04-2020 Total Bilirubin Result: 0.4 mg/dL Accession #81972 Collected on: 12-03-2020 Performed on: 12-04-2020 Total Bilirubin Result: 0.7 mg/dL Accession #81973 Collected on: 12-03-2020 Performed on: 12-04-2020 Total Bilirubin Result: 0.2 mg/dL Accession #81974 Collected on: 12-03-2020 Performed on: 12-04-2020 Total Bilirubin Result: 0.5 mg /dL Accession #81975 Collected on: 12-03-2020 Performed on: 12-04-2020 Total Bilirubin Result: 0.5 mg/dL Accession #81985 Collected on: 12-07-2020 Performed on: 12-08-2020 Total Bilirubin Result: 0.7 mg/dL Accession #81986 Collected on: 12-07-2020 Performed on: 12-08-2020 Total Bilirubin Result: 0.3 mg/dL Accession #81987 Collected on: 12-07-2020 Performed on: 12-08-2020 Total Bilirubin Result: 0.5 mg/dL Accession #81988 Collected on: 12-07-2020 Performed on: 12-08-2020

	Total Bilirubin Result: 0.5 mg/dL Accession #81989 Collected on: 12-07-2020 Performed on: 12-08-2020 Total Bilirubin Result: 0.7 mg/dL Accession #81990 Collected on: 12-07-2020 Performed on: 12-08-2020 Total Bilirubin Result: 0.4 mg /dL Accession #81991 Collected on: 12-07-2020 Performed on: 12-08-2020 Total Bilirubin Result: 0.3 mg/dL Accession #81992 Collected on: 12-07-2020 Performed on: 12-08-2020 Total Bilirubin Result: 0.5 mg/dL Accession #81993 Collected on: 12-07-2020 Performed on: 12-08-2020 Total Bilirubin Result: 0.5 mg/dL Accession #81994 Collected on: 12-07-2020 Performed on: 12-08-2020 Total Bilirubin Result: 0.4 mg/dL 6. The laboratory was asked to provide documentation of monitoring the temperature of the refrigerator where patient samples were stored prior to testing. No documentation was provided. 7. Interview with testing personnel one (as listed on Form CMS 209) on December 8, 2020 at 11:09 hours in the break room confirmed the findings. When asked for the refrigerator records for December 2020, he stated he had not stared a log for December yet. Key: Mg/dL - milligrams per deciliter CMS - Centers for Medicare and Medicaid Services
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the package insert for ELITechGroup Serum Control Kit for the Envoy 500 chemistry controls, quality control records from November 2019 to December 2020, and staff interview, it was revealed the laboratory failed to establish its own acceptable means and ranges for quality control testing. The findings were: 1. A review of the ELITechGroup Serum Control Kit for the Envoy 500 chemistry controls (FVEY-CONV-v8, 06/209) under the section titled "Assigned Values and Ranges" revealed, "For routine use it is recommended that each laboratory establishes its own means and acceptable ranges and use the published ranges as a guide." 2. A review of chemistry quality records from November 2019 to December 2020 revealed the following lots were placed into use: Lot 8067, expiration date: 01-2020 Lot 9061, expiration date: 07-2020 Lot 9114, expiration date: 10-2021 The laboratory was asked to provide documentation of establishing its own acceptable means and ranges for each lot placed into use. No documentation was provided. 3. An interview with testing personnel number one (as listed on Form CMS 209) on December 8, 2020 at 11:45 hours in the break room revealed the laboratory would use the mean and ranges provided by the manufacturer and would not establish its own means and ranges. This confirmed the findings. Key: CMS - Centers for Medicare and Medicaid Services