Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 45D0502535	**(X3) Date Survey Completed** 11/11/2019
Name of Provider or Supplier Corpus Family Practice	**Street Address, City, State** 2202 Morgan Ave, Corpus Christi, 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.
D3007	FACILITIES CFR(s): 493.1101(b) The laboratory must have appropriate and sufficient equipment, instruments, reagents, materials, and supplies for the type and volume of testing it performs. This STANDARD is not met as evidenced by: Based on review of the laboratory's testing records, and interview of facility personnel, the laboratory failed to have in-house chemistry reagents for the volume of testing it performs as evidenced by: 1. Review of the laboratory's testing records revealed that the laboratory had not performed testing for Glucose, BUN, Creatinine, Sodium, Potassium, Chloride, and Cholesterol since October 29, 2019. 2. Further review of laboratory records revealed that the laboratory documented "No Reagents" for testing on the NanoEntek FREND analyzer August 19-20, 2019 and July 9-23, 2019. 3. Review of the Form CMS-116 revealed the laboratory documented an annual chemistry test volume of 17,794. 4. An interview with the testing person on November 11, 2019 at 11:25 hours in the laboratory during the initial tour of the

	facility revealed that she was currently not testing patients because she was out of reagent. Key: CMS - Centers for Medicare and Medicaid Services
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: A. Based on surveyor observation, review of manufacturer's instructions, and confirmed in interview of facility personnel, the laboratory failed to follow the manufacturer's instructions for storage of chemistry reagents. The findings were: 1. Surveyor observation made on November 11, 2019 at 11:20 hours during the initial tour of the facility found the following reagent stored at room temperature: Chem/ISE Cleaner (Dual Wedge) Lot: 19059 Expiration Date: 02-28-2020 2. Review of the manufacturer's instructions, located on the outside of the reagent packaging stated the storage temperature for the reagent was, "2-8 degrees Celsius." 3. The findings were confirmed in interview with the testing person on November 11, 2019 at 11:20 hours in the laboratory. She stated that, the manufacturer told her, "To never store them in the refrigerator." Key: ISE - ion selective electrode 42141 B. Based on review of the manufacturer's instructions for the Medonic hematology analyzer, laboratory policy, review of patient test results from July 24, 2019 to September 30, 2019, and staff interview, it was revealed that the laboratory failed to provide documentation of performing corrective actions as required by the manufacturer to ensure CBC (complete blood count) samples with flags were verified prior to release to the provider. The findings were: 1. A review of the manufacturer's instructions for the Medonic hematology analyzer (Serial no. 46107 PN 2031298B R03.14.14) under the section titled "Interpretaion of results" revealed: "The following flags cover abnormalities in the WBC differential and indicate a possible problem with the accuracy of the results: BD - High interference between populations NM - No WBC population found OM - Only one WBC population found TM - Too many WBC populations found 2. A review of the laboratory policy titled, "Policy for handling flagged CBC Differentials" it states "It will be the policy of this laboratory to rerun flagged CBC results. If the second run still shows flags, then the lab will evaluated flagged differentials according the procedures in the unit's operator manual. Sometimes the flags will disapper when the sample is allowed to equilibrate at room temperature for 15 to 20 minutes, or by redrawing th patient. If the flags disappear, then report the result. If the flags persist, then the laboratory will confirm the abnormal differential by sending out to a reference laboratory." 3. A review of patient final results from July 24, 2019 to September 30, 2019 revealed the following patients' whose CBC results had flags: Date Patient Flag 07/24 83984 BD 08/29 84299 OM 08 /29 84300 OM 09/30 84468 BD 4. An interview with the testing personnel number 1 (as listed on Form CMS-209) on 11/11/2019 at 11:45 hours in the office confirmed the findings. The laboratory did not perform any corrective actions for CBC results with flags. Key: WBC - White blood cell CMS - Centers for Medicare and Medicaid Services.
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 instrument calibrations. The findings were: 1. Review of the laboratory's policy titled, "Instrument Operation and Maintenance" approved by the laboratory director on September 5, 2019 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 (Serial no. 46107 PN 2031298 R03.14.14) under, "Calibration" it stated, "Calibration must be performed upon setup of the instrument and then at a minimum of every 6 months." 3. Review of the laboratory's calibration records from January 2017 to December 2018 revealed the laboratory performed calibrations on the following dates: May 08, 2018 November 08, 2018 (6 months later) June 27, 2019 (7 months, 21 days later) The laboratory failed to perform calibrations every 6 months per the manufacturer's instructions. 4. Interview with technical consultant (as listed on Form CMS-209) on November 11, 2019 at 13:50 hours in the laboratory confirmed the findings. Key: CMS - Centers for Medicare and Medicaid Services
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 laboratory policies, review of quality control records from July 2018 to October 2019, and confirmed in interview of facility personnel, the laboratory's quality control plan failed to detect errors over time for the EasyRA chemistry analzyer. The findings were: 1. Review of the "Quality Control" procedure revealed no policy for monitoring quality control (QC) statistics over time for the

	EasyRA chemistry analyzer. 2. Review of quality control records from July 2018 to October 2019 revealed no documentation of the laboratory monitoring QC statistics at intervals to assess the analytical process for the EasyRA chemistry analyzer. 3. Interview with the testing person on November 11, 2019 at 12:35 hours in the office 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 laboratory policies, review of the laboratory's IQCP (Individualized Quality Control Plan), and confirmed in interview of facility personnel, the laboratory failed to establish a policy for ongoing effectiveness of its IQCP for the NanoEntek FREND analyzer. The findings were: 1. Review of the laboratory's "Quality Assessment" policy revealed no instructions for the ongoing review for effectiveness for its IQCP for the NanoEntek FREND analyzer. 2. Review of the laboratory's IQCP for the NanoEntek FREND analyzer revealed it was signed by the previous laboratory director on March 13, 2017. There was no other documentation of the laboratory monitoring the effectiveness of its IQCP. 3. The findings were confirmed in interview of the technical consultant on November 11, 2019 at 12:05 hours in the office.
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: A. Based on review of laboratory policy, review of manufacturer's instructions, quality control records, and confirmed in interview of facility personnel, the laboratory failed to follow the manufacturer's instructions for establishing its own

	means and ranges for quality control. The findings were: 1. Review of the laboratory's policy titled, "Quantitative Control Validations" approved by the laboratory director on September 5, 2019 stated, " ...If current controls are within range and the new controls are within their range, then the new controls will be acceptable for use for patient testing." 2. Review of the manufacturer's instructions for CLINIQA Liquid QC Immunoassay Control under, "Assignment of Values" it stated, " ...It is considered good laboratory practice for each laboratory to establish its own mean and standard deviations for its test methods. The indicated Mean and Expected Range of the Mean should serve as a guide in assessing the performance of each test method." The laboratory utilizes CLINIQA Liquid QC Immunoassay Controls to verify the accuracy of TSH (Thyroid Stimulating Hormone). 3. Review of the manufacturer's instructions for AUDIT MicroControls under, "Expected Values" it stated, " ...Therefore, a lab must establish its own acceptable target values and ranges." 4. Review of the laboratory's quality control records from January 2018 to October 2019 revealed that for the following lot numbers of CLINIQA Liquid QC Immunoassay Controls the laboratory used the manufacturer's mean and standard deviations: 1706090A 1411070A 1706090A (current lot) 5. Review of the laboratory's quality control records from July 2018 to October 2019 revealed that for the following lot number of AUDIT MicroControls the laboratory used the manufacturer's target values and ranges: 06537 6. Interview with the testing person on November 11, 2019 at 12:28 hours in the office confirmed the findings. She revealed that she goes by the manufacturer's means and ranges. 42141 B. Based on review of the laboratory policy, review of manufacturer's instructions, review of quality control records and confirmed in interview with facility personnel. The findings included: 1. Review of laboratory policy titled, "Quantitative Control Validations" it states, "Policy: It is the policy of this lab to validate quantitative controls prior to placing them into patient testing. Method: New controls shall be run t least once a day for 5 days along with current controls. If current controls are within range and the new controls are with their range, then the new controls will be acceptable for use for patient testing." 2. Review of manufacturer's instructions for Boule Con-Diff Tri-level under, "Summary and Principles," it states, "Boule Con-Diff Hematology Control is prepared from stabilized human blood so that repeated measurements can be made daily to monitor the performance of hematology analyzer systems. Assigned values and expected ranges are determined on systems using specific Boule reagents. Assigned values are confirmed by multiple analysis of the control product." 3. Random Review of Quality Control records from May 2018 (Initial instrumentation verification) through November 11, 2019 (day of survey) revealed there was no documentation the laboratory had performed lot to lot verifications for the following lot numbers of quality control materials prior to patient testing: Tri-level Control Lot# 21902-2k exp. 06/21/19 Lot# 21095-2k exp. 09/20/19 Lot# 21905-3k exp. 09/23/19 Lot# 21908-3k exp. 12/23/19 2. An interview with the primary testing person on November 11, 2019 at 13:30 hours in the office confirmed the findings. The laboratory had not performed lot to lot verifications for new quality control lots. Key: exp. - Expiration CMS - Centers for Medicaid and Medicare Services
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all

	personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, and confirmed in interview of facility personnel, the laboratory director failed to ensure policies were signed by the current laboratory director. The findings were: 1. Review of the laboratory's policy and procedure manual for the NanoEntek FREND analyzer stated, "The manufacturer-provided procedure manual for performing tests on the NanoEntek FREND FT4 and TSH analyzer had been reviewed and will be used by laboratory personnel to perform testing." The laboratory is no longer testing FT4 (Free Thyroxine). 2. The procedure manual was signed and approved by the previous laboratory director on March 13, 2017. 3. The findings were confirmed in interview with the technical consultant on November 11, 2019 at 12:03 hours in the office.
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 personnel records, review of the laboratory's instrument verification records, and confirmed in interview of facility personnel, the technical consultant failed to perform a competency assessment on the primary testing person when a new instrument was implemented. The findings were: 1. Review of the laboratory's personnel records for the primary testing person revealed she received an annual competency assessment January 2018 and January 2019. 2. Review of the laboratory's instrument verification records revealed that the laboratory implemented the Medonic M Series hematology analyzer in May 2018. The laboratroy switched from a Abbot Cell-Dyn to the Medonic (instrument change). Due to the change in instrumentation, the testing person should have received a competency assessment on the Medonic M Series hematology analyzer prior to testing patients in May 2018. 3. An interview with the technical consultant on November 11, 2019 at 11:45 hours in the office confirmed the findings.