Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0489140	05/14/2019
Name of Provider or Supplier	**Street Address, City, State**	
Family Health Center Of Ozona	102 North Ave H, Ozona, 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.
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, review of the laboratory's College of American Pathologists (CAP) proficiency testing records from 2018 and 2019, and staff interview, it was revealed the laboratory failed to test proficiency samples the same number of times as patient samples. The findings were: 1. A review of the laboratory's policy titled "Proficiency Testing Policy" (revised 5/1/15) stated: "Proficiency Testing (PT) samples must be handled in the same manner as patient samples according to the Clinical Laboratory Improvement Act of 1988 (CLIA '88)..." 2. A review of the laboratory's policy titled "Cell-Dyn Emerald Instrument Flags" (approved 1/16/17) stated: "WBC and Differential Flags: Check the specimen for clots or agglutination. Allow the specimen to rock for 10 minutes. Rerun the specimen..." 3.

	A review of the laboratory's College of American Pathologists proficiency testing records from 2018 (events 1, 2, and 3) and 2019 (event 1) revealed the following samples which had flags however the laboratory did not have documentation of repeating them as stated in the policy. They were: a) 2018 event 1 sample: FHI 03 flag: L2 b) 2018 event 2 sample: FHI 08 flag: L3 c) 2018 event 3 sample: FHI 13 flag: L3 d) 2019 event 1 sample: FHI A flag: L2 4. The laboratory was asked to provide documentation of repeating the identified samples as required. No documentation was provided. 5. An interview with the laboratory director on 05/14/2019 at 1020 hours in the office - after her review of the records- confirmed the findings.
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Association of BioAnalysts' (AAB) proficiency testing results, and staff interview, it was revealed the laboratory failed to have documentation of evaluating proficiency testing results not scored by the proficiency testing agency. The findings were: 1. A review of the laboratory's American Association of BioAnalysts' coagulation proficiency testing results from 2018 (events 1, 2, and 3) and 2019 (event 1) revealed the proficiency agency utilized the following flag on results: "# - This method was not graded due to an insufficient number of peer respondents. No appropriate default grouping was available. The listed range should provide a reasonable guide to your performance. However, exercise caution in evaluating your results." 2. Further review of the records identified the following results returned by the proficiency agency as not graded as identified with the flag listed above. They were: a) 2018 event 1 sample: 1 sample: 2 b) 2018 event 2 sample: 1 sample: 3 c) 2018 event 3 sample: 2 sample: 4 d) 2019 event 1 sample: 1 sample: 4 3. The laboratory was asked to provide documentation of evaluating the results which were not graded by the proficiency testing agency. No documentation was provided. 4. An interview with the laboratory director on 05/14 /2019 at 1020 hours in the office - after her review of the records- confirmed the findings.
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 records, and staff interview, it was revealed the laboratory failed to have documentation of ensuring instruments maintained verified

	performance specifications after moving from one location to another. The findings were: 1. A review of the laboratory's records revealed instrumentation was moved into a new facility in April 2018. Instrumentation moved was: Cell-Dyn Emerald COBAS Integra 400 plus Trinity Trini/CLOT PT 2. The laboratory was asked to provide documentation of performing verification studies after the move to ensure the instruments were functioning and able to match the specifications as stated by the manufacturers. No documentation was provided. 3. An interview with the laboratory director on 05/14/2019 at 1020 hours in the office revealed no studies were performed to assess the accuracy and precision of the instruments after the move. This confirmed the findings.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, review of the laboratory's instrument maintenance logs, and staff interview, it was revealed the laboratory failed to have documentation of performing required maintenance. The findings were: 1. A review of the manufacturer's instructions for the Cell Dyn Emerald hematology analyzer revealed the laboratory was to ensure the instruments pistons were lubricated semiannually. 2. A review of the laboratory's Cell Dyn Emerald maintenance logs from January 2017 to December 2018 revealed the laboratory failed to have documentation of lubricating the pistons twice in 2017 and in 2018. 3. A review of the manufacturer's instructions for the COBAS Integra 400 Plus analyzer revealed the following maintenance was required Quarterly and Semi-Annually: a) Quarterly Replace ventilation filters Replace external water reservoir filter b) Semi-Annually Clean external water reservoir Clean fluid waste reservoir Clean internal water reservoir Clean wash station Replace ISE tubing 4. A review of the laboratory's COBAS Integra 400 Plus maintenance logs from January 2018 to April 2019 revealed: a) Quarterly The external water reservoir filter was documented as being changed 07/30/2018, 01/08/2019 and 04/01/2019. Missing documentation for 1/2018, 4/2018, 10/2018 b) Semi-Annual External reservoir was cleaned once in 2018 (03/16 /2018) Clean Fluid waste reservoir - none Clean internal waster reservoir - none Replace ISE tubing - none 5. The laboratory was asked to provide documentation of the missing maintenance being performed. No documentation was provided. 6. An interview with the laboratory director on 05/14/2019 at 1020 hours in the office - after her review of the records- confirmed the findings.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on review of the laboratory's environmental records, and staff interview, it was

	revealed the laboratory failed to have documentation of performing corrective actions when the laboratory's humidity levels were documentation outside the define acceptability levels. The findings were: 1. A review of the laboratory's environmental monitoring records from 2019 revealed the laboratory defined the acceptable room humidity levels to be 20% - 80%. 2. Further review of the records identified the following days were the documented humidity values were outside the laboratory acceptable range: Date Humidity 01/02 19% 01/03 19% 01/04 19% 01/05 17% 01/23 19% 01/24 18% 01/25 17% 01/28 19% 01/29 19% 01/30 19% 02/09 19% 02/19 18% 02/20 17% 02/21 19% 02/24 18% 03/05 17% 03/06 15% 03/16 19% 03/17 19% 03/18 19% 04/12 18% 3. The laboratory was asked to provide documentation of performing corrective actions. No documentation was provided. 4. An interview with the laboratory director on 05/14/2019 at 1020 hours in the office - after her review of the records - confirmed the findings.