Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2058578	10/24/2019
Name of Provider or Supplier	**Street Address, City, State**	
Focus Total Health - San Antonio	1202 E Sonterra Blvd, Suite 102, San Antonio, 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.
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's proficiency testing records from 2018 and 2019, and staff interview it was revealed the laboratory failed to have documentation of the laboratory director and testing personnel signing 2 of 4 attestation statements. The findings were: 1. A review of the laboratory's American Proficiency Institute's proficiency testing records from 2018 (events 1 and 2) and 2019 (events 1 and 2) revealed the laboratory director and testing personnel failed to sign 2 of 4 attestation statements. They were: 2019 event 1 2019 event 2 2. The laboratory was asked to provide documentation of the signed attestation statements. No documentation was provided. 3. An interview with the practice

	manager on 10/24/2019 at 1110 hours in the laboratory - after her review of the records - 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 policies, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of the competency assessments being performed on 2 of 2 testing personnel for the Tosoh AIA 900 analyzer prior to performing patient testing. The findings were: 1. Based on the review of the laboratory's test menu, the laboratory installed a Tosoh AIA 900 analyzer in October 2017. 2. A review of the laboratory's policy titled "Laboratory Procedure Quality Assessment Plan" (Effective date: May 22, 2015) revealed: "any time a new technical procedure is introduced into the laboratory, a detailed Skills Competency Checklist accompanies the new procedure, which must be completed for every testing personnel performing that procedure." 3. A review of the laboratory's personnel records revealed competency assessments were performed on the following dates: a) Testing personnel #1 02/09/2017 02/09/2018 02/08/2019 b) Testing personnel #2 09/12/2017 09/12 /2018 09/12/2019 4. The laboratory was asked to provide documentation of competency assessment being perform in October 2017 on both testing personnel prior to patient testing being performed. No documentation was provided. 5. An interview with the practice manager on 10/24/2019 at 1115 hours in the office - after her review of the records- revealed competence assessments had not been performed prior to patient testing. This confirmed the findings.