Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0983597	02/13/2019
Name of Provider or Supplier	**Street Address, City, State**	
Focus Total Health - New Braunfels	598 N Union Avenue Suite 300, New Braunfels, 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.
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 policies, review of the laboratory's verification studies performed on the Tosoh AIA-900 analyzer, and staff interview, it was revealed the laboratory failed to have documentation of verifying patient reference ranges. The findings were: 1. A review of the laboratory's policy titled "Reference Range Verification" (effective date May 22, 2015) revealed: "Generally somewhere around 5

	- 10 patient samples can be utilized for testing and verifying the manufacturer's published reference ranges." 2. A review of the laboratory's verification studies performed on the Tosoh AIA-900 analyzer revealed the laboratory stated the following patient reference ranges were to be used to interpret patient test results: A) Estradiol 2 Female 25 - 433 pg/mL Male 25 - 47 pg/mL B) Testosterone Female 0.10 - 75.0 ng/mL Male 175 - 781 ng/mL 3. The laboratory was asked to provide documentation of verifying the identified patient reference ranges. No documentation was provided. 4. An interview with the practice manager on 02/13/2019 at 11:30 hours in the office - after her review of the records - 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 submitted Form CMS 209, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of training for 1 of 4 personnel performing testing on the Tosoh AIA-900 analyzer. The findings were: 1. A review of the laboratory's submitted Form CMS 209 (signed by the laboratory director on 02/08/2019) revealed the laboratory identified 4 personnel who performed testing on the Tosho AIA-900 analyzer. 2. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of testing personnel number 3 (as listed on Form CMS 209) being trained on the Tosho AIA-900 analyzer. 3. The laboratory was asked to provide documentation of training for testing personnel number 3. No documentation was provided. 4. An interview with the practice manager on 02/13/2019 at 11:30 hours in the office - after her review of the records- confirmed the findings.