Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0503393	03/11/2019
Name of Provider or Supplier	**Street Address, City, State**	
Nolana Family Med Center	204 Nolana Loop, Mcallen, 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.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on review of the laboratory's centrifuge function checks, review of the laboratory's policies, staff interview, it was revealed the laboratory failed to have documentation of defining the acceptable limits for speed checks on the centrifuge used to spin urine samples. The findings were: 1. A review of the laboratory's speed

	and timer check log from October 2015 to March 2019 revealed the laboratory performed function checks on the speed of the urine centrifuge a total of 7 times. The documented speeds were: 12/2015 1316 rpm 08/2016 1930 rpm 08/2017 2070 rpm 03 /2018 1896 rpm 08/2018 1865 rpm 03/2019 1582 rpm The log did not define the acceptable ranges for the speed of the urine centrifuge. 2. A review of the laboratory's policy titled "Procedure for Micro urinalysis" revealed the laboratory's acceptable speed for urine specimens was 1500 rpm. 3. The laboratory was asked to provide documentation of establishing the acceptable range of speed for functions checks on the urine centrifuge. No documentation was provided. 4. An interview with testing personnel number 2 (as listed on Form CMS 209) on 03/11/2019 at 1100 hours in the laboratory revealed the laboratory did not define what the acceptable ranges for the function checks were. This confirmed the findings. Key rpm - revolutions per minute