Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1035188	02/27/2018
Name of Provider or Supplier	**Street Address, City, State**	
Chg Hospital Mcallen Llc	301 W Expressway 83, 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.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of laboratory polices, surveyor observations, and confirmed in staff interview, it was revealed that the laboratory failed to have documentation that their policies and procedures reflected current laboratory practice for performance of quality control procedures. The findings were: 1. A review of the policy titled, "Control Policy" approved by the laboratory director on 02/29/2012 stated, "For quantitative testing, two levels of control shall be run for every procedure on each day of use or for every eight (8) hours of operation ..." 2. According to the department manager on 02/27/2018 at 0945 hours in the conference room, the laboratory's practice is to run 3 levels of external quality control weekly and with a new shipment according to its IQCP (Individualized Quality Control Plan). 3. The laboratory was

	asked to provide documentation of an updated policy that reflected its current laboratory practice. No documentation was provided. 4. An interview with the department manager on 02/27/2018 at 1215 hours in the conference room confirmed the findings. He agreed the policy needed to be updated.
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 record review and interview with facility personnel, the laboratory failed to follow its own quality control plan that it developed when implementing an Individualized Quality Control Plan (IQCP) for: The findings were: 1. Review of the Quality Control Plan for the laboratory's developed IQCP for i-STAT indicated that the laboratory, "Would perform 3 levels of external quality control testing weekly and with each new shipment." 2. Review of quality control records for the Abbott i-STAT August 1, 2017 to January 31, 2018 revealed quality control was performed as follows: 08/07/2017 08/14/2017 08/21/2017 08/28/2017 09/06/2017 (2 days late) 09 /07/2017 09/18/2017 (4 days late) 09/25/2017 10/02/2017 10/09/2017 10/16/2017 10 /23/2017 10/30/2017 11/07/2017 (1 day late) 11/13/2017 11/20/2017 11/27/2017 12/04 /2017 12/06/2017 12/11/2017 12/18/2017 12/30/2017 (5 days late) 3. A random review of patient records for the time period of September 7, 2017 to September 18, 2017 revealed the laboratory performed 12 patient tests when quality control was not performed. 4. The laboratory was asked to provide documentation of following its IQCP study to perform testing weekly. No documentation was provided. 5. An interview with the laboratory manager on 02/27/2018 at 1215 hours in the conference room confirmed the findings.