Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1035188	01/09/2024
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	The laboratory was found out of compliance with the CLIA regulations. The condition not met was: D6063 - 42 C.F.R. 493.1421 Condition: testing personnel
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's iSTAT CG4+ quality control records from July 2022 to December 2023 and staff interview, the laboratory failed to have documentation of monitoring quality control values over time for 18 of 18 months. The findings include: 1. A review of the laboratory's iSTAT CG4+ quality control records from July 2022 to December 2023 determined the laboratory performed quality control testing monthly and with each new lot or shipment of cassettes. 2. Further review of the quality control records determined the laboratory graphed a single point for each of the three levels of quality control material tested. The laboratory graphed the monthly quality control, but did not graph the quality control tested with each new lot or shipment. Graphing a single point does not allow the

	assessment of quality control results to identify any shifts or trends. 3. The technical consultant confirmed the findings in an interview conducted on 01/09/2024 at 1020 hours in the conference room.
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 room temperature records from November 2023 and staff interview, the laboratory failed to have documentation of performing corrective actions when the documented room temperature was outside the laboratory's acceptable range on 4 of 30 days. The findings include: 1. A review of the laboratory's room temperature records from November 2023 determined the laboratory's acceptable room temperature range was identified as 64 - 86F. 2. Further review of the records determined the laboratory documented temperatures outside the acceptable range on 4 of 30 days in November 2023. They were: Date Temperature 11 /21 61F 11/22 61F 11/23 61F 11/27 62F 3. The laboratory was asked to provide documentation of performing corrective actions for the identified dates. No documentation was provided. 4. The technical consultant confirmed the findings in an interview conducted 01/09/2023 at 1014 hours in the conference room.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel records and staff interview, the laboratory failed to have documentation of the technical consultant performing 23 of 23 competency assessments in 2023. The finding include: 1. A review of the laboratory's personnel records determined 23 of 23 competency assessments performed in 2023 determined the assessments were performed by testing personnel number 1 (as listed on Form CMS 209) and then signed by the technical consultant. Assessments were completed in a different ink than the ink used for the technical consultants signature. 2. Examples are: Testing personnel number 5 performed: 08/15 /2023 signed by TC: 09/01/2023 Testing personnel number 6 performed: 08/16/2023 signed by TC: 08/31/2023 Testing personnel number 7 performed: 08/16/2023 signed by TC: 08/31/2023 Testing personnel number 10 performed: 08/16/2023 signed by TC: 08/31/2023 Testing personnel number 11 performed: 08/16/2023 signed by TC: 08/31/2023 Testing personnel number 12 performed: 08/15/2023 signed by TC: 08/31 /2023 Testing personnel number 15 performed: 08/16/2023 signed by TC: 08/31/2023 Testing personnel number 16 performed: 08/15/2023 signed by TC: 08/31/2023 3. A review of the personnel records for testing personnel number 1 determined he did not meet the qualifications to be a technical consultant. 4. Testing personnel number 1 confirmed the findings in an interview conducted on 01/09/2023 at 1000 hours in the

	conference room. He stated he performed all the competency assessments and the technical consultant signed them on his next visit. This confirmed the findings. Key TC - technical consultant
D6053	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 at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel records and staff interview, it was determined the laboratory failed to have documentation of the technical consultant performing competency assessments twice within the first year for 1 of 11 testing personnel. The findings include: 1. A review of the laboratory's personnel records determined the technical consultant failed to perform semiannual competency assessments within the first year for 1 of 11 testing personnel. 2. Testing personnel number 1 (as listed on Form CMS 209 was trained in December 2021, and thus required two competency assessments by December 2022. A review of his personnel records determined competency assessments were performed in August 2022 and August 2023. 3. The laboratory was asked to provide documentation of a second competency assessment being performed by December 2022. No documentation was provided. 4. The technical consultant confirmed the findings in an interview conducted 01/09/2024 at 1000 hours in the conference room.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on review of the laboratory's personnel records and staff interview, the laboratory failed to have documentation of education to qualify 1 of 23 testing personnel (refer to D6065).
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a

	high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel records and staff interview, the laboratory failed to have documentation of education to qualify 1 of 23 testing personnel. The finding include: 1. A review of the laboratory's personnel records determined the laboratory failed to have documentation of education for testing personnel number 19 (as listed on Form CMS 209). 2. The laboratory was asked to provide documentation of a diploma or GED (general educational development) to qualify testing personnel number 19. No documentation was provided. 3. The technical consultant confirmed the findings in an interview conducted on 01/09/2024 at 1015 in the conference room.