Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1035188	05/19/2022
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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on review of laboratory policies, review of the laboratory's American Proficiency Institute (API) proficiency testing records, and confirmed in interview of laboratory personnel, the laboratory failed to retain all proficiency testing records for one of five events reviewed. The findings included: 1. Review of the laboratory's policy titled 'Proficiency Testing' stated, "...All records, reports, and corrective actions must be retained for 2 years." 2. Review of the laboratory's proficiency testing records for Chemistry Core Event for 2020 (event 3), 2021 (events 1, 2, and 3), and 2022 (event 1) found the laboratory failed to retain the instrument records and attestation statement for 2020 (event 3). 3. The laboratory was asked to provide the missing documentation. No records were provided. 4. The findings were confirmed in interview with the technical consultant and testing personnel #1 (as listed on Form CMS 209) on May 19, 2022 at 0952 hours in the conference room. Key: CMS - Centers for Medicare and Medicaid
D3003	FACILITIES

	CFR(s): 493.1101(a)(2) The laboratory must be constructed, arranged, and maintained to ensure contamination of patient specimens, equipment, instruments, reagents, materials, and supplies is minimized. This STANDARD is not met as evidenced by: Based on surveyor observation, review of laboratory policy, review of the Abbott i-STAT instrument operator's manual, and confirmed in interview with laboratory personnel, the laboratory failed to address instrument contamination for potential blood borne pathogens for 1 of 1 Abbot i-STAT analyzers located in the laboratory. The findings included: 1. Surveyor observation made on May 19, 2022 at 09:09 hours in the laboratory found 1 of 1 Abbott i-STAT analyzers contaminated with blood on the outside of the instrument. 2. Review of the laboratory's policy titled 'Instrument Operation and Maintenance' stated, "...Maintenance of each piece of laboratory instrumentation shall be in accordance with the manufacture's [SIC] recommendations..." 3. Review of the Abbott i-STAT operator's manual (Art: 714379-01E) stated, "...Decontaminate the analyzer for Downloader whenever a specimen is spilled onto it or if the item is to be returned to i-STAT for repair..." 4. The findings were confirmed in interview with the technical consultant and testing personnel #1 (as listed on Form CMS 209) on May 19, 2022 at 09:15 hours. Key: CMS - Centers for Medicare and Medicaid Services
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of laboratory policy, review of instrument records, and confirmed in interview of laboratory personnel, the laboratory failed to follow its own policy for performing a new instrument verification study for one of one Abbott i-STAT analyzers when it implemented a new analyzer in November 2021. The findings included: 1. Review of the laboratory's policy titled, 'Validation of a New Test System' stated, "It is the policy of this lab to validate a new test system prior to using it to report patient results." The policy stated the following acceptance criteria: Accuracy: Slope = 1.0 +/- 15% (0.85 - 1.15) R-squared >/= 0.95 Precision: Mean value is within the acceptable range for the Level 1 or normal control mean +/- 2SD and CV is less than 2.0% or as otherwise noted on the worksheet. Reportable Range: Will be determined by the lowest and highest values used during linearity study with acceptable slope and R-squared. Verification of manufacturer's normal values: This will be determined by demonstrating that 5 non-patient results are within the manufacturer's normal values. 2. Review of instrument verification records for the Abbott i-STAT analyzer implemented in November 2021 found the laboratory failed to follow its own policy for evaluation of data to verify the accuracy, precision, reportable range, and patient normal ranges of the analyzer. 3. The laboratory was asked to provide documentation of following its own policy for performing a verification study when implementing a new analyzer. No documentation was

	provided. 4. The findings were confirmed in interview of the technical consultant and testing personnel #1 (as listed on Form CMS 209) at 11:00 hours in the conference room. Key: SD - standard deviation CV - coefficient of variance CMS - Centers for Medicare and Medicaid
D5537	ROUTINE CHEMISTRY CFR(s): 493.1267(b)(d) For blood gas analyses, the laboratory must perform the following: (b) Test one sample of control material each 8 hours of testing using a combination of control materials that include both low and high values on each day of testing. (d) Document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control records, review of patient test results, and confirmed in interview of laboratory personnel, the laboratory failed to perform at least one level of quality control each 8 hours of patient testing for 30 of 30 patient test results reviewed in March 1, 2022 to March 31, 2022. The findings included: Note: The laboratory did not perform an IQCP for the Abbott i-STAT CG4 test cartridge implemented in November 2021 to reduce quality control performance frequency to once every 7 days. Therefore, the laboratory must perform at least one level of quality control every 8 hours of patient testing. 1. Review of laboratory quality control records found the laboratory performs three levels of quality control (ran conservatively) every seven days. Review of quality control records for March 2022 found the laboratory performed quality control testing as follows: March 5, 2022 March 13, 2022 March 20, 2022 March 27, 2022 2. A random sampling of patient test records from March 1, 2022 to March 31, 2022 found the following 30 of 30 patients that were tested when the laboratory failed to perform at least one level of quality control testing each 8 hours of patient testing: Date Last 3 digits of MR# 03-01-2022 995 03-01-2022 936 03-01-2022 956 03-01-2022 946 03-01-2022 960 03-03-2022 967 03-04-2022 988 03-05-2022 967 03-06-2022 967 03-07-2022 946 03-08-2022 944 03-08-2022 000 03-09-2022 901 03-10-2022 062 03-11-2022 917 03-14-2022 946 03-16-2022 067 03-17-2022 132 03-18-2022 134 03-19-2022 067 03-21-2022 967 03-22-2022 059 03-23-2022 489 03-24-2022 016 03-24-2022 917 03-25-2022 067 03-26-2022 067 03-30-2022 917 03-31-2022 056 03-31-2022 261 3. The laboratory was asked to provide documentation of performing at least one level of quality control material each 8 hours of patient testing or an IQCP to reduce the frequency of quality control testing to once every seven days. No documentation was provided. 4. Review of the laboratory's submitted Form CMS 116 stated an annual test volume of 3000 arterial blood gas tests per year. 4. The findings were confirmed in interview with the technical consultant and testing personnel #1 (as listed on Form CMS 209) on May 19, 2022 at 11:04 hours in the conference room. Key: IQCP - Individualized Quality Control Plan CMS - Center for Medicare and Medicaid
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are

	adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on review of laboratory policy, review of instrument verification records, and confirmed in interview of laboratory personnel, the laboratory director failed to ensure the laboratory followed its own policy when implementing a new Abbott i-STAT analyzer. (Refer to D5401)
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control records, review of patient final reports, and confirmed in interview of laboratory personnel, the laboratory director failed to ensure a quality control plan was established and maintained. (Refer to D5537).
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control records, review of patient final reports, and confirmed in interview of laboratory personnel, the technical consultant failed to establish an acceptable quality control plan. (Refer to D5537).