Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1106041	(X3) Date Survey Completed 11/15/2022
Name of Provider or Supplier Womens Hospital At Renaissance	**Street Address, City, State** 5502 S Mccoll Road, Edinburg, 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: Laboratories performing moderate complexity testing; testing personnel Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility representatives were given an opportunity to provide evidence of compliance with noted deficiencies and no such evidence was provided prior to survey exit.
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions for the Accu-chek Inform II glucometer, review of the laboratory's records and staff interview, it was revealed the facility failed to have documentation of cleaning the meter between patients as required. The findings include: 1. A review of the manufacturer's instructions for the Accu-check Inform II glucometer [08424705601 (06) 2021-11 USA] revealed: "If dedicating blood glucose meters to a single patient is not possible, the meters must be properly cleaned and disinfected after every use following the guidelines provided in this manual (see section "Maintenance and Care")." 2. A review of the laboratory's records revealed the facility did not have documentation of cleaning and disinfecting its glucometer after each use. The laboratory was asked to provide documentation of cleaning and disinfecting. No documentation was provided. 3. An interview with the Point of Care Manager on 11/15/2022 at 1515 hours in the conference room revealed

	the laboratory used the glucometer for multiple patients and did not have documentation of the cleaning and disinfection after each use as required. This confirmed the findings.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of the laboratory's instrumentation, review of the laboratory's calibration verification records from 2020, 2021, and 2022 for the GEM 4000 blood gas analyzers, and staff interview, it was revealed the laboratory failed to have documentation of performing 4 of 5 calibration verifications. The findings include: 1. A review of the laboratory's instrumentation revealed the laboratory utilized 2 GEM 4000 blood gas analyzers for patient testing. Serial number: 16059863 Serial number: 16059866 2. A review of the laboratory's calibration verification records from 2020, 2021 and 2022 revealed the facility failed to have documentation of performing calibration verification for 4 of 5 six month periods. The laboratory did not perform calibration verification in December 2020, April 2021, December 2021 and April 2022. The following analytes required calibration verification: Calcium Chloride Glucose Hematocrit Potassium Lactic Acid Sodium pCO2 pH pO2 total Hemoglobin 3. The laboratory was asked to provide documentation of performing the missing calibration verifications on the two blood gas analyzers. No documentation was provided. 4. An interview with the Point of Care Manager on 11/15/2022 at 1225 hours in the conference room revealed calibration verifications had not been performed since April 2020 for both analyzers. This confirmed the findings.
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 GEM 4000 blood gas analyzers' quality control records from 2021 and 2022, review of the laboratory's quality control plan, and staff interview, it was revealed the laboratory failed to have documentation of monitoring quality control values over time. The findings include: 1. A review of the laboratory's GEM 4000 blood gas analyzer's quality control records from 2021 and 2022 revealed the laboratory performed quality control testing utilizing 2 levels of quality control material with each new cartridge loaded onto the analyzers. Quality control testing was performed on the following analytes: Calcium Chloride Glucose Hematocrit Potassium Lactic Acid Sodium pCO2 pH pO2 total Hemoglobin 2. A review of the laboratory's quality control plan revealed the facility did not have a procedure for monitoring quality control values over time. 3. The laboratory was asked to provide documentation of monitoring control values over time. No documentation was provided. 4. An interview with the Point of Care Manager on 11/15/2022 at 1411 hours in the conference room revealed the laboratory did not monitor quality control values over time as required. This confirmed the findings.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on the review of the laboratory's job description for testing personnel and staff interview, it was revealed the laboratory director failed to specify the duties for laboratory testing for 24 of 24 testing personnel. The findings include: 1. A review of the laboratory's job descriptions revealed the laboratory had descriptions for respiratory techs who performed blood gas analysis and nurses who performed rupture of membrane testing. The job descriptions for both failed to include the laboratory testing each was responsible for. 2. The laboratory was asked to provide documentation of job descriptions which included laboratory testing. No documentation was provided. 3. An interview with the Point of Care Manager on 11 /15/2022 at 1330 hours in the conference room - after her review of the records- confirmed the findings.

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 submitted Form CMS 209, review of personnel records, and staff interview, it was revealed the laboratory failed to have documentation of education to qualify 2 of 24 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 submitted Form CMS 209, review of personnel records, and staff interview, it was revealed the laboratory failed to have documentation of education to qualify 2 of 24 testing personnel. The findings include: 1. A review of the laboratory's submitted Form CMS 209 revealed the facility identified 24 testing personnel who performed moderate complexity testing. 2. A review of the laboratory's personnel records revealed the facility failed to have documentation of education to qualify 2 of 24 testing personnel. They were (as on Form CMS 209): Testing personnel #23 - diploma from the Philippines - no documentation of foreign credentialing Testing personnel #24 - Associates degree - no documentation of what degree was awarded 3. The laboratory was asked to provide documentation of education to qualify the identified personnel. No documentation was provided.