

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0494937	(X3) Date Survey Completed 12/03/2021
Name of Provider or Supplier Care For Women	Street Address, City, State 350 Kingwood Medical Drive, Suite #350, Kingwood, 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	A recertification survey was performed on 12/3/21. The laboratory was found out of compliance with the CLIA regulations. The conditions not met were: D6063 - 42 C.F.R. 493.1421 Condition: Laboratories performing moderate complexity testing; testing personnel; 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.
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's American Proficiency Institute (API) proficiency testing records from 2021 and staff interview, it was revealed that the laboratory failed to have documentation of retaining proficiency testing records for two of three testing events in 2021. Findings include: 1. A review of the laboratory's API proficiency testing records from 2021 revealed the laboratory failed to retain the following records: a) API Microbiology first event: - signed attestation statement - API report form b) API Microbiology second event: - signed attestation statement -</p>

API report form 2. An interview with laboratory director on 12/3/21 at 11:35 a.m. in the office, after review of the records, confirmed the above findings.

D2021

BACTERIOLOGY
CFR(s): 493.823(b)

Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.

This STANDARD is not met as evidenced by:

Based on a review of the American Proficiency Institute (API) proficiency testing records for 2020 and staff interview, it was revealed that the laboratory failed to participate in one of three Microbiology events in 2020 resulting in unsatisfactory performance for the specialty of Bacteriology. Findings include: 1. A review of the laboratory's API proficiency testing records for 2020 revealed the following: API-Microbiology second event 2020- the laboratory failed to participate, resulting in a score of 0% for specialty of Bacteriology and 0% for the analyte Gardnerella vaginalis. 2. An interview with the laboratory director on 12/3/21 at 11:35 a.m. in the office, after review of the records, confirmed the above findings.

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's BD Affirm VPIII Microbial Identification Test quality control records, the laboratory's records, and staff interview, it was revealed that the laboratory failed to have documentation of performing two of four required verification studies for microbial identification testing on a new BD Affirm MicroProbe Processor prior to running patient samples. Findings include: 1. A review of the laboratory's quality control records for the BD Affirm VPIII Microbial Identification Test revealed the following: - May 2021 QC log "Affirm Machine A1 is new- Serial #A573023A" 2. A review of the laboratory's records revealed the laboratory failed to have documentation of performing the following 2 verification studies on the new MicroProbe Processor: - Accuracy - Precision 3. An interview with the laboratory director on 12/3/21 at 11:35 a.m. in the office, after review of the records, confirmed the above findings. Key: QC = Quality Control

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 a review of the laboratory's records and staff interview, it was revealed that the laboratory director failed to ensure verification studies were performed on each test system. (Refer to D5421)

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, it was revealed the laboratory failed to have documentation of the education to qualify one of three testing personnel to perform moderate complexity testing. (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 a review of the laboratory's submitted CMS 209 form, the laboratory's personnel records, and staff interview, it was revealed that the laboratory failed to have documentation of education for one of three testing personnel to qualify them to perform moderate complexity testing. Findings include: 1. A review of the CMS 209 form (signed by the laboratory director on 12/3/21) revealed 3 testing personnel who performed moderate complexity testing. 2. A review of the laboratory's personnel

records revealed the laboratory failed to have documentation of education to qualify testing person #1 to perform moderate complexity testing. 3. An interview with the laboratory director on 12/3/21 at 10:10 a.m. in the office, after review of the records, confirmed the above findings.