

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D2087106	(X3) Date Survey Completed 10/14/2022
Name of Provider or Supplier Jill Gibson Md, Llc	Street Address, City, State 106 Highland Park Plaza, Covington, LA	
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 at Jill Gibson MD, LLC, CLIA # 19D2087106, on October 14, 2022. Jill Gibson MD, LLC was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.1250 CONDITION: Analytic systems 42 CFR 493.1403 CONDITION: Laboratories performing moderate complexity testing; Laboratory Director
D5400	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the laboratory failed to ensure the quality of testing within the analytic systems. Findings: 1. The laboratory failed to ensure reagents and supplies did not exceed expiration dates. Refer to D5417. 2. The laboratory failed to ensure complete performance verification studies were performed for testing on the BD Max analyzer. Refer to D5421. 3. The laboratory failed to perform quality control (QC) for the BD Max analyzer every thirty (30) days per policy for two (2) of five (5) random months reviewed. Refer to D5445. 4. The laboratory failed to establish complete procedures to monitor, assess, and correct problems, identified with the analytic system. Refer to D5791.</p>
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on observation by surveyor, review of policies, expired items log, and interview with personnel, the laboratory failed to ensure reagents and supplies did not exceed expiration dates. Findings: 1. Observation by surveyor during the laboratory tour on October 14, 2022 at 9:35 am revealed the following expired items: a) BD Max Instrument Qualification Kit, Lot 9330445, Expiration Date: 2021-05-24, Quantity: three (3) kits b) BD Max Instrument Qualification Kit, Lot 9289655, Expiration Date: 2021-05-17, Quantity: two (2) kits c) BD Max Instrument Qualification Kit, Lot 0247927, Expiration Date: 2033-03-02, Quantity: one (1) kit d) Microbiologics Vaginal Panel Pool 2, Lot 6061-13, Expiration Date: 2021-04-30, Quantity: one (1) pack e) Microbiologics QC sets and Panels, Lot 8209-14, Expiration Date: 2020-11-30, Quantity: two (2) containers f) BD Vacutainer blood collection tubes, Lot 8047611. Expiration Date: 2019-02-28, Quantity: one (1) tube 2. Review of the laboratory's "Material Management" policy revealed "The Laboratory Manager or designee will review the reagent inventory logs at least monthly to determine the need to re-order and the need to remove items from service due to expiration dating." 3. Review of the laboratory's "Expired Item Maintenance Log" revealed the laboratory performs checks weekly. In October 2022 the laboratory performed an expired item check on October 6, 2022 and October 14, 2022. 4. In interview on October 14, 2022 at 9:40 am, the office manager confirmed the identified items were expired.

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 observation by surveyor, review of the laboratory's policies, validation records, test menu, and interview with personnel, the laboratory failed to ensure complete performance verification studies were performed for testing on the BD Max analyzer. Findings: 1. In interview on October 14, 2022 at 9:28 am the office manager stated the laboratory began patient testing on the BD Max analyzer in April 2021. 2. Observation by surveyor during the laboratory tour on October 14, 2022 at 9:35 am revealed the laboratory utilizes the BD Max analyzer for testing of trichomonas, chlamydia, and gonorrhea. 3. Review of the laboratory's "Evaluation of Test Methods" policy revealed "At the time of introduction of a new test system or method, the laboratory is responsible for verifying the performance specification prior to reporting patient test results. The test method evaluation should include a summary of precision and accuracy, linearity for validation of reportable range and patient correlation when applicable. This evaluation should be documented, and all worksheets, instrument

printouts, and related documents shall be retained for the life of the method plus two years for regulatory inspection purposes. All documented data must be reviewed and approved by the lab director prior to initiating patient testing." 4. Review of the laboratory's validation records revealed the laboratory did not include the following: a) Summary to include, but not limited to, how studies were performed b) Laboratory Director's approval/signature 5. In interview on October 14, 2022 at 11:23 am, the office manager confirmed the identified items were not included in the performance verification studies. 6. Review of the laboratory's test menu revealed the laboratory performs 4,500 tests annually on the BD Max analyzer.

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 observation by surveyor, review of the laboratory's policies, control records, patient logs, and interview with personnel, the laboratory failed to perform quality control (QC) for the BD Max analyzer every thirty (30) days per policy for two (2) of five (5) random months reviewed. Findings: 1. Observation by surveyor during the laboratory tour on October 14, 2022 at 9:35 am revealed the laboratory utilizes the BD Max analyzer for testing of trichomonas, chlamydia, and gonorrhea. 2. Review of the laboratory's "BD Max CT/GC/TV" policy under the "Quality Control" section revealed "Every Positive and Negative Controls will be ran with every new lot, every new shipment and every thirty days." 3. Review of random selection of patient test reports and corresponding QC records revealed the laboratory did not perform external QC every thirty (30) days for the following two (2) months: December 2021: QC due December 11, 2021; however, was not performed until December 16, 2021 August 2022: QC due August 6, 2022; however, was not performed until August 15, 2022 4. Further review of patient test logs revealed the laboratory reported the following patients without performance of external QC per policy: December 13, 2021: Patient 8679, Patient 11562, and Patient 28216; Total of twenty three (23) patient test results reported August 9, 2022: Patient 37495, Patient 6470, and Patient 15897; Total of twenty four (24) patient test results reported 5. In interview on October 14, 2022 at 11:30 am, the office manager stated he was unsure why the laboratory's QC performance exceeded thirty (30) days for the identified patients and months. The office manager confirmed the laboratory did not perform the external QC for the BD Max per laboratory's policy.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT
 CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The

laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on observation by surveyor, review of records, and interview with personnel, the laboratory failed to establish complete procedures to monitor, assess, and correct problems, identified with the analytic system. Findings: 1. Review of the laboratory's "Quality Assessment Plan" revealed a monthly checklist that included the following monitors: Proficiency Testing Specimen Handling, Collection, Labeling, LJ and data tables Quality Control Records Temperature Logs Quality Assessment Plan Corrective action logs Monthly, Quarterly meetings, and Complaints Additional new /relevant items 2. Further review of the laboratory's "Quality Assessment Plan" and monthly checklist revealed the laboratory did not include monitoring of BD Max testing. 3. Observation by surveyor, review of laboratory records, and interview with personnel revealed the laboratory did not identify the following issues: a) The laboratory failed to ensure reagents and supplies did not exceed expiration dates. Refer to D5417. b) The laboratory failed to ensure complete performance verification studies were performed for testing on the BD Max analyzer. Refer to D5421. c) The laboratory failed to perform quality control (QC) for the BD Max analyzer every thirty (30) days per policy for two (2) of five (5) random months reviewed. Refer to D5445.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR

CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:

Based on observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to provide overall management and direction for the laboratory. Findings: 1. The Laboratory Director failed to ensure performance verification studies were complete. Refer to D6013. 2. The Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Refer to D6014. 3. The Laboratory Director failed to ensure that a quality control program was maintained to assure quality laboratory services were provided. Refer to D6020. 4. The Laboratory Director failed to ensure that a complete quality assessment (QA) program was established to assure the quality of laboratory services provided. Refer to D6021.

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;

	<p>This STANDARD is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure performance verification studies were complete. Refer to D5421.</p>
<p>D6014</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii)</p> <p>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)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results.</p> <p>This STANDARD is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Refer to D5417.</p>
<p>D6020</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure that a quality control program was maintained to assure quality laboratory services were provided. Refer to D5445.</p>
<p>D6021</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>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 quality assessment programs are established and maintained to assure the quality of laboratory services provided.</p> <p>This STANDARD is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure that a complete quality assessment (QA) program was established to assure the quality of laboratory services provided. Refer to D5791.</p>