| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 19D2087106 | 02/23/2021 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Jill Gibson Md, Llc | 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 |
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| **D0000** | A Certification survey was performed on February 23, 2021 at Jill Gibson MD, LLC, CLIA ID # 19D2087106. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited. |
| **D2009** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(1)<br><br>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's proficiency test records, policies, and interview with personnel, the laboratory failed to ensure Testing Personnel signed the attestation statement for two (2) of six (6) proficiency testing (PT) events reviewed. Findings: 1. Review of the laboratory's "Quality Assessment Plan" for "Proficiency Testing" revealed "Visual review of staff performing PT, review of all testing, documentation, and final report from PT provider. All testing personnel and Laboratory Director signed attestation sheet?" 2. Review of the laboratory's American Proficiency Institute (API) records for 2019 and 2020 revealed the Testing Personnel did not sign the attestation statement for the following events: 2019 Microbiology 1st Event: Testing Personnel 1 and Testing Personnel 2 did not sign 2020 Microbiology 2nd Event: Testing Personnel 2 did not sign 3. In interview on February 23, 2021 at 11:17 am, the office manager confirmed the Testing Personnel did not sign the identified attestation statements. |
| **D5401** | PROCEDURE MANUAL<br>CFR(s): 493.1251(a)<br><br>A written procedures manual for all tests, assays, and examinations performed by the |

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| | 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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's policies and procedures and interview with personnel, the laboratory failed to have complete policies and procedures. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory did not include a written policy for the following: a) Twice a year instrument comparison of test results for the BD Max and BD Affirm instruments for Parasitology testing; to include but not limited to frequency and acceptability criteria 2. In interview on February 23, 2021 at 10:40 am, the office manager confirmed the laboratory did not have a written policy for instrument comparison of test results for Parasitology testing. |
| **D5413** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(b)<br><br>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation by surveyor, review of patient and maintenance logs, and interview with personnel, the laboratory failed to document the temperatures of the BD MicroProbe Lysis Block temperatures for Microbiology testing on the BD Affirm for five (5) of ten (10) days reviewed. Findings: 1. Observation by surveyor during laboratory tour on February 23, 2021 at 9:45 am revealed the laboratory utilizes the BD Affirm for testing of Trichomonas, Candida, and Gardnerella. 2. Review of the laboratory's "BD MicroProbe Lysis Block-Quality Control Log" for 2019 and 2020 and selection date review of December 7, 2020 through December 11, 2020 and January 25, 2021 through January 29, 2021 revealed temperatures were not documented for the following five days (5) sixteen (16) patients: a) December 9, 2020: b) January 25, 2021: c) January 26, 2021: d) January 27, 2021: e) January 28, 2021: 3. Review of the laboratory's patient test records revealed the following sixteen (16) patients were tested on the identified dates: a) December 9, 2020: Patient 6470 Patient 20677 Patient 26537 b) January 25, 2021: Patient 29684 Patient 2753 Patient 2511 Patient 7403 c) January 26, 2021: Patient 30626 Patient 17404 Patient 20708 d) January 27, 2021: Patient 24157 e) January 28, 2021: Patient 7784 Patient 14701 Patient 11000 Patient 2301 Patient 15672 4. In interview on February 23, 2021 at 11: 40 am, the office manager confirmed the laboratory did not document the MicroProbe Lysis Block temperatures for the identified dates. |
| **D5417** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(d)<br><br>Reagents, solutions, culture media, control materials, calibration materials, and other |

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| | supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.<br><br>This STANDARD is not met as evidenced by:<br>Based on direct observation by surveyor, review of laboratory policies, and interview with personnel, the laboratory failed to ensure laboratory supplies and reagents did not exceed their expiration dates. Findings: 1. Observation by surveyor during laboratory tour on February 23, 2021 at 9:45 am revealed the following expired items: a) Trichloroacetic Acid 50% HealthLink , Lot 8163, Exp 2020-06-12, Quantity: one (1) bottle b) McKesson Consult Diagnostics Liquid Urine Controls Diptube Style, Lot UCD5120003, Exp 2017/11, Quantity: one (1) box 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. In interview on February 23, 2021 at 10:00 am, the office manager confirmed the identified items were expired. |
| **D5481** | CONTROL PROCEDURES<br>CFR(s): 493.1256(f)(g)<br><br>(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation by surveyor, review of patient logs, quality control, and interview with personnel, the laboratory failed to document the results of the internal controls for Microbiology testing on the BD Affirm for five (5) of ten (10) days reviewed. Findings: 1. Observation by surveyor during laboratory tour on February 23, 2021 at 9:45 am revealed the laboratory utilizes the BD Affirm for testing of Trichomonas, Candida, and Gardnerella. 2. Review of the laboratory's "BD Affirm VPIII Microbial Identification Testing Log" for 2019 and 2020 and selection date review of December 7, 2020 through December 11, 2020 and January 25, 2021 through January 29, 2021 revealed patient information and internal controls were not documented for the following sixteen (16) patients: a) December 9, 2020: Patient 6470 Patient 20677 Patient 26537 b) January 25, 2021: Patient 29684 Patient 2753 Patient 2511 Patient 7403 c) January 26, 2021: Patient 30626 Patient 17404 Patient 20708 d) January 27, 2021: Patient 24157 e) January 28, 2021: Patient 7784 Patient 14701 Patient 11000 Patient 2301 Patient 15672 3. In interview on February 23, 2021 at 11:17 am, the office manager stated the laboratory records the patient information, results, and internal controls on the identified log sheet for the BD Affirm. In further interview at 11:40 am, the office manager confirmed the laboratory did not document the internal controls for the identified patients. |
| **D5779** | CORRECTIVE ACTIONS<br>CFR(s): 493.1282(a)<br><br>Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. |

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| | This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's policies, corrective action documents, and interview with personnel, the laboratory failed to follow their established corrective action policies regarding review and documentation. Findings: 1. Review of the laboratory's "Quality Assessment Plan" under the "Corrective Action" section revealed "All data, corrective action and follow-up will be communicated to the Laboratory Director or Technical Consultant and will become part of the Quality Assessment records." 2. Review of corrective action records for the following dates in July 2020 and January 2021 revealed the laboratory's Testing Personnel completed "Corrective Action Request" forms; however, there was no documentation of the Laboratory Director's review: July 30, 2020 January 31, 2021 3. In interview on February 23, 2021 at 10:40 am, the office manager confirmed the identified corrective action forms did not include documentation of the Laboratory Director's review. |
| **D5793** | ANALYTIC SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1289(b)(c)<br><br>(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation by surveyor, record review, and interview with personnel, the laboratory's quality assessment monitors failed to correct issues identified with the analytic system. Findings: 1. Review of the laboratory's "Quality Assessment Plan" revealed the following processes are monitored: a) General b) Pre-Analytic Phase c) Analytic Phase d) Post-Analytic Phase 2. Observation by surveyor during laboratory tour, review of the laboratory's policies, quality control and patient records revealed the laboratory's monitors did not identify the following issues: a) The laboratory failed to have complete policies and procedures. Refer to D5401. b) The laboratory failed to document the temperatures of the BD MicroProbe Lysis Block temperatures for Microbiology testing on the BD Affirm for five (5) of ten (10) days reviewed. Refer to D5413. c) The laboratory failed to ensure laboratory supplies and reagents did not exceed their expiration dates. Refer to D5417. d) The laboratory failed to document the results of the internal controls for Microbiology testing on the BD Affirm for five (5) of ten (10) days reviewed. Refer to D5481. e) The laboratory failed to follow their established corrective action policies regarding review and documentation. Refer to D5779. |
| **D6014** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(3)(iii)<br><br>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. |

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| | This STANDARD is not met as evidenced by:<br>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. Findings: 1. The laboratory failed to document the temperatures of the BD MicroProbe Lysis Block temperatures for Microbiology testing on the BD Affirm for five (5) of ten (10) days reviewed. Refer to D5413. 2. The laboratory failed to ensure laboratory supplies and reagents did not exceed their expiration dates. Refer to D5417. |
| **D6016** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(4)(i)<br><br>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)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview with personnel, the Laboratory Director failed to ensure proficiency samples are tested as required. Refer to D2009. |
| **D6020** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(5)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>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 D5481. |
| **D6024** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(7)<br><br>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)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, |

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| | This STANDARD is not met as evidenced by:<br>Based on record review and interview with personnel, the Laboratory Director failed to ensure corrective actions were taken and documented when deviations from laboratory's policies occurred. Refer to D5779. |
| **D6029** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(11)<br><br>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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's policies, review of personnel training records, and interview with personnel, the Laboratory Director failed to ensure two (2) of two (2) Testing Personnel had appropriate training documentation for the BD Max instrument prior to patient testing. Findings: 1. Review of the laboratory's "Staff Orientation, Training and Competency" policy revealed "Ultimately, the Lab Director (LD) is responsible for ensuring that all testing personnel are competent and maintain their competency in order to perform and report accurate and reliable test results." 2. Review of personnel records revealed Testing Personnel 1 and Testing Personnel 2 received training for the BD Max instrument through BD Diagnostics and were issued a training certificate. Further review of the BD Max training certificates revealed no documentation of the Laboratory Director's approval/signature for patient testing. 3. In interview on February 23, 2021 at 10:40 am, the office manager confirmed the Laboratory Director did not sign off on the initial BD Max training for Testing Personnel 1 and Testing Personnel 2. |
| **D6030** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(12)<br><br>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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures for assessing personnel competency were maintained. Refer to D6053. |

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| **D6031** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(13)<br><br>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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview with personnel, the Laboratory Director failed to ensure an approved policy and procedure manual was available to all personnel. Refer to D5401. |
| **D6053** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(9)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's policies, personnel records, and interview with personnel, the Technical Consultant failed to perform a competency assessment at least semi-annually during the first year for one (1) of two (2) testing personnel reviewed. Findings: 1. Review of the laboratory's "Staff Orientation, Training and Competency" policy revealed "After initial competency assessment at the completion of orientation and training, competency assessment will occur at 6 months, 12 months, and annually thereafter. Ultimately, the Lab Director (LD) is responsible for ensuring that all testing personnel are competent and maintain their competency in order to perform and report accurate and reliable test results. The Technical Consultant (TC) for moderate complexity testing is responsible for performing and documenting competency assessments." 2. Review of personnel records for Testing Personnel 1, hired January 2018, revealed the laboratory did not have documentation of a semi-annual competency assessment due July 2018. 3. In interview on February 23, 2021 at 10:40 am, the office manager stated the laboratory did not have the semi-annual competency assessment for Testing Personnel 1. |