Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	25D2147200	12/16/2020
Name of Provider or Supplier	**Street Address, City, State**	
Byrd Family Medical Clinic	705 North State Street, Clarksdale, MS	

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
D2005	ENROLLMENT CFR(s): 493.801(a)(4) Authorize the proficiency testing program to release to HHS all data required to-- (i) Determine the laboratory's compliance with this subpart; and (ii) Make PT results available to the public as required in section 353(f)(3)(F) of the Public Health Service Act. This STANDARD is not met as evidenced by: Based on review of the Centers For Medicare & Medicaid Services (CMS) Casper 155 report and laboratory proficiency test reports available the day of survey and interview with the TP and clinic owner, the laboratory failed to authorize the proficiency testing program to release to HHS, all data and results to determine if the laboratory is compliant with this subpart. Findings include: 1. The CMS Casper 155 report revealed no proficiency scores for this laboratory were released to the CLIA program (HHS) for review for the years 2019 and 2020. 2. Interview with the TP and clinic owner on 12/16/20 at 6:00 pm confirmed they did not ensure scores were released to the HHS for the years 2019 and 2020.
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such

	timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on record review and interview with the clinic owner and testing personnel, the laboratory failed to report SARS-CoV-2 test results as required for 18 of 90 days reviewed from September 2020 through December 2020. Findings Include: 1. SARS-CoV-2 testing documentation (BD Veritor QC and patient reports) was reviewed from September 1, 2020 through December 16, 2020. 2. SARS-CoV-2 test results reporting documentation was reviewed from September 1, 2020 through December 16, 2020. 3. Documentation revealed that SARS-CoV-2 test results were not reported as required for 4 days in November 2020 and 14 days in December 2020. 4. Approximately 103 results were not reported as required during the period of review. 5. The laboratory performed 448 SARS-CoV-2 tests during the period of review. 6. The laboratory testing personnel confirmed the findings on December 16, 2020 at 5:30 pm.
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on review of the laboratory proficiency testing event records from 2019 and 2020 and confirmation with TP (testing personnel) at 5:30 pm the day of survey, the laboratory failed to retain all proficiency records to include but not limited to results, attestation statements and analyzer printouts. Findings include: 1. Observation of 1st, 2nd and 3rd events of the 2019 and 2020 proficiency testing records revealed the laboratory did not retain the following: a. Report sheets /submitted results sheets for 1st of 2019, 2nd and 3rd events of 2020 b. Attestation statement for 1st and 3rd events of 2019; 3rd event of 2020 2. Interview with TP at 5:30 pm on 12/16/20 indicated that previous listed proficiency records were not retained with each completion of the proficiency event.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of laboratory proficiency records, Quick Vue Chlamydia records from installation on 1/16/20 until the day of survey (12/16/20), and interview with the testing personnel at 6:00 pm on the day of survey, the laboratory failed to verify the accuracy of Chlamydia testing at least twice annually since the laboratory began testing patients with the kit. The laboratory must verify the accuracy of testing that is not included in subpart I of this part. Findings Include: 1. Review of the Chlamydia test records from installation of the test kit on 1/16/20 until 12/16/20 revealed no accuracy verification checks on the Quick Vue Chlamydia test. 2. Interview with testing personnel at 6:00 pm on 12/16/20 confirmed the accuracy had not been verified on the Quick Vue Chlamydia test kit by proficiency testing or otherwise.

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 review of the Healgen COVID-19 IgG/IgM Rapid Test Cassette kit records, Quick Vue Chlamydia records, patient testing logs, lack of documentation of verification performance specifications, and interview with staff on 12/16/20 at 3:00 pm, the laboratory failed to ensure that performance specifications were verified before reporting patient test results on the Healgen COVID-19 IgG/IgM Rapid Test Cassette and the Quick Vue Chlamydia test kit. Findings include: A) Healgen COVID-19 IgG/IgM Rapid Test Cassette 1. No documentation of verification of performance specifications for the Healgen COVID-19 IgG/IgM Rapid Test Cassette was available for review on the day of survey 12/16/20. 2. The laboratory began testing and reporting the Healgen COVID-19 IgG/IgM Rapid Test Cassette on 9/1/20. 3. Interview with testing personnel and clinic owner on 12/16/20 at 3:00 pm confirmed that no verification of performance specifications was completed for the Healgen COVID-19 IgG/IgM Rapid Test Cassette. B) Quick Vue Chlamydia test kit 1. No documentation of verification of performance specifications for the Quick Vue Chlamydia test kit was available for review on the day of survey 12/16/20. 2. The laboratory began testing and reporting the Quick Vue Chlamydia test kit on 1/16/20. 3. Interview with testing personnel and clinic owner on 12/16/20 at 3:00 pm confirmed that no verification of performance specifications was completed for the Quick Vue Chlamydia test kit.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of quality control (QC) logs and patient testing logs and interview with testing personnel (TP) and the clinic owner at 3:00 pm on 12/16/2020, the laboratory failed to include a positive and negative control on each day of patient testing for the Healgen COVID-19 IgG/IgM Rapid Test Cassette and the Quidel Quick Vue Chlamydia test kit. A. Based on interview with the testing personnel and clinic owner 12/16/20 at 3:00 pm, the laboratory failed to include a positive and negative control on each day of patient testing for the Healgen COVID-19 IgG/IgM Rapid Test Cassette performed from 11/20 through 12/16/20 for antibodies to SARS-CoV-2. Findings include: 1. Observation of the depleted Healgen Rapid Test Cassette

	box revealed 17 tests had been used from a box of 25 tests. On the day of survey, 12 /16/20, there was no quality control (QC) material (positive or negative) available for use. 2. Interview with the testing personnel and clinic owner on 12/16/20 at 3:00 pm confirmed that no QC had been performed on the test as none was provided by the manufacturer in the kit. 3. Interview with the testing personnel and clinic owner on 12 /16/20 at 3:00 pm confirmed that TP was not performing two levels of QC each day of patient testing with the Healgen COVID-19 IgG/IgM Rapid Test Cassette. B. Based on the review of the QC and patient log for the Quidel Quick Vue Chlamydia test kit from 1/16/20 through the day of survey, lack of documentation of an Individualized Quality Control Plan (IQCP), and interview with TP on 12/16/20 at 3:00 pm, the laboratory failed to include a positive and negative control on each day of patient testing. Findings include: 1. Review of the QC and patient log for the Quidel Quick Vue Chlamydia test performed from 1/16/20 through 12/16/20 revealed that two levels of QC (positive or negative) were not performed on each day of patient testing. 2. On five days that patients were tested and reported, no QC was done. This included: 1/16/20 when 13 patients were tested 3/20/20 when 11 patients were tested 5/27/20 when 13 patients were tested 9/02/20 when 9 patients were tested 12/3/20 when 1 patient was tested 3. Interview with TP on 12/16/20 at 3:00 pm confirmed that two levels of QC were not tested on each day of use. The QC was only tested with each new lot number of the Quidel Quick Vue Chlamydia test kit.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on review of approximately 20 patient test reports for SARS COV-2 antigen and antibody tests that were performed at the laboratory, test reports from the laboratory's EMR (electronic medical records) system, and interview with staff on the day of survey at 4:30 pm, the laboratory failed to report the patient tests for SARS CoV-2 with the correct testing method. Findings include: 1. On review of approximately 20 patient SARS Cov-2O patient results in the clinic EMR system on the day of survey, it was observed that the SARS COV-2 tests results were reported as "COVID-19 RNA (SARS-COV-2), QL, RRT-PCR in the EMR and printed and given to patients when patients needed a copy of their results. The laboratory is not testing SARS COV-2 in this RNA/PCR method. They are using the BD Veritor and the Healgen as their testing methods for SARS COV -2. According to the EMR 693 antigen and antibody patient tests have been reported since 9/1/20. 2. Interview with the laboratory TP at 4:30 pm, confirmed "COVID-19 RNA (SARS-COV-2), QL, RRT-PCR" is the method chosen in the EMR when patients' results are manually entered into the clinic EMR to report SARS COV-2 tests results. According to the EMR report accessed by the laboratory TP, 693 antigen and antibody patient test results have been reported since 9/1/20.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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. This STANDARD is not met as evidenced by: Based on review of the personnel testing records on 12/16/20 (day of survey), review of Quality Control (QC) and Proficiency Testing (PT) records, and the lack of education and training documentation, the laboratory director had not ensured that the employee listed on the CMS (Centers for Medicare and Medicaid Services) 209 personnel form as testing personnel (TP) had the appropriate education and training to perform moderate complexity testing prior to testing patient samples. Findings Include: 1. Review of the personnel records available the day of survey provided no documentation of education or training for the TP as listed on the CMS 209 form. 2. The TP started testing patient samples in September 2019 according to QC (quality control) and proficiency testing records. 3. There was no documentation on the day of survey 12/16/20 to indicate that the laboratory director had ensured testing personnel had the proper education or training required to perform testing prior to testing patient samples.
D6049	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iii) The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. This STANDARD is not met as evidenced by: Based on review of the BD Affirm VP and Quidel Quick Vue Chlamydia quality control records, procedure manuals, maintenance records, and testing records from 1 /16/20 through 12/16/20, the Technical Consultant (TC) had not documented as reviewed all quality control records and preventative manintenance records as required. Findings Include: 1. Review of the BD Affirm VP quality control (QC), patient result and heat block logs from 1/16/20 through 12/3/20 revealed the Affirm VP QC (positive and negative control results) for Trichomonas, Candida and Gardnerella were not documented as reviewed from installation of both testing systems on 1/16/20 by the technical consultant. 2. Review of the Quidel Quick Vue Chlamydia quality control records, procedure manuals, and testing records revealed that quality control records had not been documented as reviewed by the technical consultant.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) 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.

	This STANDARD is not met as evidenced by: Based on review of laboratory personnel records from the last survey on 1/8/19 through the current survey on 12/16/20, the Centers of Medicare and Medicaid Services (CMS) 209 personnel form, and interview with testing personnel (TP) and clinic owner at 5:00 pm on the day of survey, the technical consultant (TC) failed to evaluate and document the performance of the TP responsible for performing moderate testing at least semiannually during the first year of employment. Findings include: 1. There was no 6 month evaluation/competency documented by the TC available for review on the laboratory TP for the period from September 2019 through September 2020. 2. The TP began performing moderate complexity testing in September 2019. 3. Interview with the TP and clinic owner at 5:00 pm on the day of survey confirmed that the semi-annual evaluation/ competency was not performed on the TP during the first year of testing.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on review of laboratory personnel records from the last survey on 1/8/19 through the current survey on 12/16/20, the Centers of Medicare and Medicaid Services (CMS) 209 personnel form, and interview with testing personnel (TP) and clinic owner at 5:00 pm on the day of survey, the technical consultant (TC) failed to evaluate and document the performance of the TP responsible for performing moderate testing at least annually. Findings include: 1. No annual evaluation or competency for the TP was available for review on 12/16/2020. 2. Interview with the TP and clinic owner confirmed that no annual evaluation/competency for TP had been performed by the technical consultant.