Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D2090475	05/19/2021
Name of Provider or Supplier	**Street Address, City, State**	
Business Health Partners	3649 S Beglis Parkway, Sulphur, 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	An initial certification survey was performed at paraoccdocs, Inc - dba Business Health Partners - CLIA # 19D2090475 on May 19, 2021. Business Health Partners 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 42 CFR 493.1409 CONDITION: Laboratories Performing Moderate Complexity Testing; Technical Consultant
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and personnel records as well as interview with the Technical Consultant, the laboratory failed to ensure policies and procedures in place to assess competency for "as needed" employees. Findings: 1. Review of the laboratory's Competency Assessment Polic revealed competency for testing personnel is assessed at the following times: a) after training, b)semi-annually during the first year, c) Annually after the first year. 2. Review of personnel records revealed testing personnel in mobile settings were used as needed when the laboratory had remote contracts; however, the policy did not address the frequency of personnel competency assessment is to be handled. 3. In interview on May 19, 2021 at 12:40 pm, the Technical Consultant confirmed the laboratory policy did not address ongoing competency assessment for as needed employees as they've not exceeded 6 months yet.
D5305	TEST REQUEST

	CFR(s): 493.1241(c) The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to ensure test requisitions included sex of the patient, specimen source and test ordered. Findings: 1. Review of the laboratory's test requisitions revealed the patient name and date of birth, collection date and time as well as order date to be the only information included on requisitions for mobile testing. 2. In interview on May 19, 2021 at 2: 00pm, the Technical Consultant confirmed the requisition for mobile testing did not include sex of patient, specimen source or the test ordered. The Technical Consultant stated they only used these mobile requisitions for one contract and for testing performed and collected at the main site included additional information.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 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. 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 perform complete performance specification studies for the Detectachem analyzer. Refer to D5421. 2. The laboratory failed to establish performance specifications for Zhejiang Orient Gene Biotech COVID-19 IgG/IgM Rapid testing with no FDA authorization. Refer to D5423. 3. The laboratory failed to establish complete procedures to monitor, assess, and correct problems, identified with the analytic system. Refer to D5791
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, review of verification studies, and interview with the Technical Consultant, the laboratory failed to perform complete performance specification studies for the Detectachem analyzer. Findings: 1. Observation by surveyor during laboratory tour on May 19, 2021 at 11:00 am revealed the laboratory utilizes one (1) Detectachem analyzer for SARS-CoV-2 testing in on site. 2. Review of the laboratory's performance verification studies revealed the laboratory had no evalutation by the laboratory of testing performed to ensure verification prior to patient testing. 3. Further review revealed the laboratory did not include any patient testing in the verification of performance specifications. 4. In interview on May 19, 2021 at 3:30 pm, the Technical Consultant confirmed the laboratory did not include any patient samples in the verification studies and that the laboratory director did not sign off on the validation data.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on direct observation during the laboratory tour, the laboratory's patient test records, and interview with the Technical Consultant, the laboratory failed to establish performance specifications for Zhejiang Orient Gene Biotech COVID-19 IgG/IgM Rapid testing with no FDA authorization. Findings: 1. Review of patient testing submitted to Louisiana Department of Health Electronic Laboratory Reporting system revealed the laboratory reported patient results for COVID-19 IgG/IgM rapid serology testing. Review of the laboratory's Test List provided to surveyors revealed no rapid serology test kit listed. 2. Direct observation of the patient testing area on May 19, 2021 at 3:00pm revealed an opened box of Zhejiang Orient Gene Biotech COVID-19 IgG/IgM Rapid Test Cassettes (Whole Blood/Serum/Plasma). Lot number 2005213, Expiration Date 2022-04-30 3. Review of laboratory patient testing logs, quality control logs or maintenance logs documenting testing in the patient testing room revealed no documentation of COVID-19 IgG/IgM rapid serology testing. 4. Review of the Food and Drug Administration (FDA) Emergency Authorization Use (EUA) for serology testing revealed no evaluation or EUA for Zhejiang Orient Gene Biotech

	COVID-19 IgG/IgM. 5. In interview on May 19, 2021 at 3:15pm, the Technical Consultant stated she was unaware the personnel was performing this COVID-19 rapid serology test. The Technical Consultant further confirmed there the test kit was not reviewed for FDA EUA status, no establishment studies or quality control had been performed to her knowledge. Further interview on May 19, 2021 at 3:30 with the owner confirmed the laboratory had brought in antibody testing for self-pay options. 6. Review of April 2021-May 19 patient test records revealed 14 Zhejiang Orient Gene Biotech COVID-19 IgG/IgM Rapid serology tests had been performed.
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 review of quality control records and laboratory procedures as well as 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 procedure for SARS-CoV-2 testing revealed positive and negative controls are to be processed with each plate of patient samples. 2. Review of MD-BIO BCC19 Test Kit for SARS-CoV-2 test logs revealed the following two (2) of five (5) patient test runs reviewed did not contain positive and negative quality control samples with each plate: a) January 7, 2021 - 0958 run: no negative control sample documented: 32 patient samples in run b) January 20, 2021 - 1700 run: no negative control, no positive control documented: 50 patient samples in run 3. Review of quality assessment logs and procedures revealed the laboratory had no specific marker for review of patient test runs performed remotely or by alternate testing personnel to ensure quality control was performed and documents. 4. Interview with the Technical Consultant on May 19, 2021 at 3:30pm confirmed the identified runs did not have quality control documented as required by the laboratory's policy. The Technical Consultant further confirmed quality assessment did not identify incomplete quality control.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of patient final reports and interview with personnel, the laboratory failed to include the laboratory's address, reference range, specimen source, disclaimer

	that testing has not been FDA approved or fact sheet required by EUA on patient final reports for SARS-CoV-2 testing. Findings: 1. Review of random selection of patient reports revealed the laboratory had multiple formats for final reports: testing performed at remote sites, COVID-19 IgG/IgM Rapid Test, self-pay, and routine testing). 2. The final report used for testing performed at remote sites reviewed May 19, 2021 at 3pm did not include the address where testing is performed, reference ranges, specimen source, or disclaimer that the testing performed is under EUA and not approved by FDA along with the fact sheet required. 3. The final report used for COVID-19 IgG/IgM Rapid Testing reviewed May 19, 2021 at 4pm did not include the complete address of the laboratory, sample source, or disclaimer that the testing performed is under EUA and not approved by FDA along with the fact sheet required. 4. The final report used for self-pay patients reviewed on May 19, 2021 at 3:30pm did not include the complete address of the laboratory. 5. In interview on May 19, 2021 at 4pm, the Technical Consultant stated the laboratory was updated the final report to be more consistent and only use one format. The Technical Consultant confirmed information was not included on various final reports previously used.
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 during laboratory tour, 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 6013. 2. The Laboratory Director failed to ensure that a quality assessment (QA) program was maintained to assure the quality of laboratory services provided. Refer to D6021. 3. The Laboratory Director failed to ensure patient final reports included required pertinent information. Refer to D6026. 4. The Laboratory Director failed to ensure procedures in place to assess competency for "as needed" employees. Refer to D6031. 5. The Laboratory Director failed to delegate, in writing, the responsibilities of the Technical Consultant. D6032
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 observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure performance specification studies were complete. Refer to D5421 & D5423.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was maintained to assure the quality of laboratory services provided. Refer to D5791.
D6026	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(8) 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)(8) Ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: Based on review of the laboratory's test menu, patient final test reports, and interview with personnel, the Laboratory Director failed to ensure patient final reports included required pertinent information. Refer to D5805.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure procedures in place to assess competency for "as needed" employees. Refer to D5209.
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 review of personnel records and interview with personnel, the Laboratory Director failed to delegate, in writing, the responsibilities of the Technical Consultant. Findings: 1. Review of personnel records for the Technical Consultant revealed the owner of the laboratory signed the delegation tasks and responsibilities of Clinical Consultant. 2. In interview on May 19, 2021 at 12:40 pm, the Technical Consultant confirmed the competency and delegation was signed by the owner and not the laboratory director.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on record review and interview with personnel, the Technical Consultant failed to provide technical oversight of the laboratory for moderate complexity testing. Findings: 1. The Technical Consultants failed to provide technical and scientific oversight to the laboratory. Refer to D6036. 2. The Technical Consultant failed to ensure performance specification verification studies were complete. Refer to D6040. 3. the Technical Consultant failed to ensure corrective actions were taken and documented when deviations from the laboratory's policies occurred. Refer to D6044
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. This STANDARD is not met as evidenced by: Based on observation by surveyor, record review and interview with personnel, the Technical Consultant failed to provide technical and scientific oversight to the laboratory. 1. The laboratory failed to ensure test requisitions included sex of the patient, specimen source and test ordered. D5305 2. The laboratory failed to ensure patient final reports included required pertinent information. Refer to D5805

D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Technical Consultant failed to ensure performance specification verification studies were complete. Refer to D5421.
D6044	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(6) (b) The technical consultant is responsible for-- (b)(6) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Consultant failed to ensure corrective actions were taken and documented when deviations from the laboratory's policies occurred. Refer to D5793