

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2183405	(X3) Date Survey Completed 05/13/2021
Name of Provider or Supplier Synergy Wellness	Street Address, City, State 7105 Bailey Creek Circle, Suite B, Huntsville, AL	
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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a lack of proficiency testing or accuracy verification documentation for the Zhejiang COVID Ig (Immunoglobulin) G /IgM Rapid test kit, and an interview with the Laboratory Director, the surveyor determined the laboratory failed to enroll in an approved proficiency testing program or implemented a mechanism to verify the accuracy of the procedure at least twice a year. This affected one of one moderate-complexity tests performed at this facility since April 2020. The findings include: 1. An initial certification survey was conducted on 5/12/2013. During the entrance tour of the laboratory at 8:30 AM, the surveyor determined the only moderate-complexity test performed at this facility was the Zhejiang COVID IgG/IgM Rapid test kit for the detection of antibodies to COVID-19. The surveyor requested validation, quality control, proficiency testing, quality assurance, and personnel records, however the employees most familiar with laboratory testing were not at the clinic on 5/12/2021. The surveyor provided a list of required documentation and scheduled the survey for the following day. 2. On 5/13/2021 at 8:30 AM, the surveyor returned to complete the survey. The Laboratory Director was also present and explained the facility had wanted to help with the COVID-19 crisis in 2020. The clinic had begun patient testing in April 2020 without knowing all the CLIA requirements, so the laboratory did not have most of the documentation the surveyor was requesting. The Director confirmed the laboratory was not performing proficiency testing, and had not implemented a mechanism to verify the accuracy of the procedure at least semi-annually. .</p>
D5400	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</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.

This CONDITION is not met as evidenced by:

Based on a lack of validation, quality control, quality assurance, and proficiency testing or accuracy verification records for the Zhejiang COVID Ig (Immunoglobulin) G /IgM Rapid test kit, and an interview with the Laboratory Director, the surveyor determined the laboratory failed to implement an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the quality of the analytic systems. This affected one of one moderate-complexity tests performed at this facility since April 2020. The findings include: 1. Refer to D5217, D5421, D5449, and 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 a lack of validation documentation for the Zhejiang COVID Ig (Immunoglobulin) G /IgM Rapid test kit, and an interview with the Laboratory Director, the surveyor determined the laboratory failed to ensure the manufacturer's performance specifications for accuracy and precision were verified and documented. This affected one of one moderate-complexity tests performed at this facility since April 2020. The findings include: 1. An initial certification survey was conducted on 5 /12/2013. During the entrance tour of the laboratory at 8:30 AM, the surveyor determined the only moderate-complexity test performed at this facility was the Zhejiang COVID IgG/IgM Rapid test kit for the detection of antibodies to COVID-19. The surveyor requested validation, quality control, quality assurance, proficiency testing, and personnel records, however the employees most familiar with laboratory testing were not at the clinic on 5/12/2021. The surveyor provided a list of required documentation and scheduled the survey for the following day. 2. On 5/13/2021 at 8: 30 AM, the surveyor returned to complete the survey. The Laboratory Director was also present and explained the facility had wanted to help with the COVID-19 crisis in 2020. The clinic had begun patient testing in April 2020 without knowing all the CLIA requirements, so the laboratory did not have most of the documentation the surveyor was requesting. 3. As the interview continued, the surveyor asked if the laboratory had validated the COVID antibody kit. The Director stated they were not always able to receive kits from the same manufacturer, however each new kit was "validated" with serum from three positive patients and a negative patient. The

surveyor asked if the laboratory had documented this for any of the test kits including the current Zhejiang COVID IgG/IgM Rapid test kit. The Director answered, "No, we didn't do that". The Director confirmed there was no documentation of studies confirming the accuracy and precision of the test kit as stated in the manufacturer's performance specifications. .

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 a lack of quality control (QC) documentation for the Zhejiang COVID Ig (Immunoglobulin) G /IgM Rapid test kit, and an interview with the Laboratory Director, the laboratory failed to perform and document QC every day of patient testing. This affected one of one moderate-complexity tests performed at this facility since April 2020. The findings include: 1. An initial certification survey was conducted on 5/12/2013. During the entrance tour of the laboratory at 8:30 AM, the surveyor determined the only moderate-complexity test performed at this facility was the Zhejiang COVID IgG/IgM Rapid test kit for the detection of antibodies to COVID-19. The surveyor requested validation, quality control, proficiency testing, and personnel records, however the employees most familiar with laboratory testing were not at the clinic on 5/12/2021. The surveyor provided a list of required documentation and scheduled the survey for the following day. 2. On 5/13/2021 at 8:30 AM, the surveyor returned to complete the survey. The Laboratory Director was also present and explained the facility had wanted to help with the COVID-19 crisis in 2020. The clinic had begun patient testing in April 2020 without knowing all the CLIA requirements, so the laboratory did not have most of the documentation the surveyor was requesting. 3. As the interview continued, the surveyor asked how often the laboratory had performed external positive and negative QC on the COVID Antibody kits. The Director stated they were not always able to receive kits from the same manufacturer and quality controls were not available when they first began testing, so no QC was run. The surveyor then requested the manufacturer's package insert from the current Zhejiang COVID IgG/IgM Rapid test kit. The surveyor and Laboratory Director reviewed the instructions in the insert under "QUALITY CONTROL" which revealed, "...it is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance." the surveyor then asked if the laboratory had run any external QC as per the manufacturer's instructions on the current COVID antibody kit; the Director answered, "No". .

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 a lack of quality assurance documentation for the Zhejiang COVID Ig (Immunoglobulin) G /IgM Rapid test kit, and an interview with the Laboratory Director, the surveyor determined the laboratory failed to implement an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems. This affected one of one moderate-complexity tests performed at this facility since April 2020. The findings include: 1. An initial certification survey was conducted on 5/12/2013. During the entrance tour of the laboratory at 8:30 AM, the surveyor determined the only moderate-complexity test performed at this facility was the Zhejiang COVID IgG/IgM Rapid test kit for the detection of antibodies to COVID-19. The surveyor requested validation, quality control, quality assurance, proficiency testing, and personnel records, however the employees most familiar with laboratory testing were not at the clinic on 5/12/2021. The surveyor provided a list of required documentation and scheduled the survey for the following day. 2. On 5/13 /2021 at 8:30 AM, the surveyor returned to complete the survey. The Laboratory Director was also present and explained the facility had wanted to help with the COVID-19 crisis in 2020. The clinic had begun patient testing in April 2020 without knowing all the CLIA requirements, so the laboratory did not have most of the documentation the surveyor was requesting. 3. As the interview continued, the surveyor asked if the laboratory had implemented and documented a quality assurance program to monitor, assess, and when indicated, correct problems noted with the COVID Antibody testing. The Director confirmed they had not. .

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 a review of laboratory testing, a lack of validation, quality control, quality assurance, proficiency testing, and personnel records, and interviews with the Laboratory Director and Testing Personnel #3, the surveyor determined the Laboratory Director failed to fulfill his responsibilities as the Laboratory Director. The findings are: 1. Refer to D6004, D6013, D6015, D6020, D6021, and D6029. .

D6004

LABORATORY DIRECTOR RESPONSIBILITIES
 CFR(s): 493.1407(a)(b)

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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

	<p>This STANDARD is not met as evidenced by: Based on a review of personnel listed on Form CMS-209 (Laboratory Personnel Report), a review of personnel files, and an interview with the Laboratory Director, the surveyor determined the Laboratory Director failed to ensure the position of the Technical Consultant was filled with a qualified individual to provide technical and scientific oversight since the laboratory began performing moderate complexity patient testing in April 2020. The findings include: 1. Refer to D6036. .</p>
<p>D6013</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii)</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)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;</p> <p>This STANDARD is not met as evidenced by: Based on a lack of validation documentation for the Zhejiang COVID Ig (Immunoglobulin) G /IgM Rapid test kit, and an interview with the Laboratory Director, the surveyor determined the Laboratory Director failed to ensure the manufacturer's performance specifications for accuracy and precision were verified and documented. This affected one of one moderate-complexity tests performed at this facility since April 2020. The findings include: 1. Refer to D5421. .</p>
<p>D6015</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)</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)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.</p> <p>This STANDARD is not met as evidenced by: Based on a lack of proficiency testing or accuracy verification documentation for the Zhejiang COVID Ig (Immunoglobulin) G /IgM Rapid test kit, and an interview with the Laboratory Director, the surveyor determined the Laboratory Director failed to ensure the laboratory was enrolled in an approved proficiency testing program or implemented a mechanism to verify the accuracy of the procedure at least twice a year. This affected one of one moderate-complexity tests performed at this facility since April 2020. The findings include: 1. Refer to D5217. .</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</p>

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.

This STANDARD is not met as evidenced by:
Based on a lack of quality control (QC) documentation for the Zhejiang COVID Ig (Immunoglobulin) G /IgM Rapid test kit, and an interview with the Laboratory Director, the surveyor determined the Laboratory Director failed to ensure QC was performed and documented every day of patient testing. This affected one of one moderate-complexity tests performed at this facility since April 2020. The findings include: 1. Refer to D5449. .

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 a lack of quality assurance documentation for the Zhejiang COVID Ig (Immunoglobulin) G /IgM Rapid test kit, and an interview with the Laboratory Director, the surveyor determined the Laboratory Director failed to ensure an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic system was implemented and documented. This affected one of one moderate-complexity tests performed at this facility since April 2020. The findings include: 1. Refer to D5791. .

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 a lack of educational records for nine of nine Testing Personnel (TP), a lack of training documentation for nine of nine TP until the day of the survey, and interviews with the Laboratory Director and TP #3, the surveyor determined the Laboratory Director failed to ensure testing personnel had appropriate educational

records, and documentation of training to perform moderate complexity testing, prior to testing patients' specimens. The findings include: 1. An initial certification survey was conducted on 5/12/2013. During the entrance tour at 8:30 AM, the surveyor determined the only moderate-complexity test performed at this facility was the Zhejiang COVID Ig (Immunoglobulin) G/IgM Rapid test kit for the detection of antibodies to COVID-19. The surveyor requested validation, quality control, proficiency testing, and personnel records, however the employees most familiar with laboratory testing were not at the clinic on 5/12/2021. The surveyor provided a list of required documentation and scheduled the survey for the following day. 2. On 5/13/2021 at 8:30 AM, the surveyor returned to complete the survey. The Laboratory Director was also present and explained the facility had wanted to help with the COVID-19 crisis in 2020. The clinic had begun patient testing in April 2020 without knowing all the CLIA requirements, so the laboratory did not have most of the documentation the surveyor was requesting. 3. During a review of the personnel files and an interview on 5/13/2021 at 9:25 AM, TP #3 explained she had trained all the TP to perform the COVID antibody test when they were hired, however this was not documented until the date of the survey; the surveyor reviewed training forms for seven of nine TP, all signed and dated 5/13/2021. There was no documentation of training for TP #2 or #3. The surveyor then requested the TP's educational documentation (a High School diploma or a degree in a Chemical, Physical or Biological Science); TP #3 confirmed they did not have this documentation for nine of nine TP. .

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 a review of personnel listed on Form CMS-209 (Laboratory Personnel Report), a review of personnel files, and an interview with the Laboratory Director, the surveyor determined the laboratory failed to fill the position of the Technical Consultant (TC) with a qualified individual since the laboratory began performing moderate complexity patient testing in April 2020. The findings include: 1. During a review of personnel listed on the Form CMS-209, the surveyor noted the Laboratory Director was also listed as the TC. 2. During an interview on 5/13/2021 at 8:30 AM, the surveyor explained CLIA requirements for all laboratories performing moderate-complexity testing, including the requirement to employ a qualified individual to perform the Technical Consultant's scientific oversight responsibilities. The surveyor then reviewed the Laboratory Director's educational documentation and experience. The Laboratory Director confirmed he had no documentation of one year of "hands-on" laboratory testing experience, which are the minimal requirements to qualify a physician as the TC. The Director was also unable to provide the name of another qualified individual to fill the position on the date of the survey. 3. Refer to D6036. .

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 a review of personnel listed on Form CMS-209 (Laboratory Personnel Report), a review of personnel files, and an interview with the Laboratory Director, the surveyor determined the laboratory failed to fill the position of the Technical Consultant (TC) with a qualified individual to provide technical and scientific oversight since the laboratory began performing moderate complexity patient testing in April 2020. The findings include: 1. During a review of personnel listed on the Form CMS-209, the surveyor noted the Laboratory Director was also listed as the TC, however the surveyor was unable to qualify the Director or another designated individual as the TC. (Refer to D6033.) 2. A review of laboratory testing revealed the only moderate-complexity test performed at this facility was the Zhejiang COVID IgG /IgM Rapid test kit for the detection of antibodies to COVID-19; the laboratory had also used COVID antibody kits from other manufacturers (whatever was available), however the laboratory was able to specify which kits were used. 3. During an interview on 5/13/2021 at 8:30 AM, the Laboratory Director explained the facility had wanted to help with the COVID-19 crisis in 2020. The clinic had begun patient testing in April 2020 without knowing all the CLIA requirements. Due to a lack of technical and scientific oversight, the laboratory had failed to: A) Implement and document a mechanism to verify the accuracy of the procedure at least twice a year (Refer to D5417.) B) Verify the manufacturer's performance specifications for accuracy and precision (Refer to D5421.) C) Perform and document qualitative quality controls before patient testing (Refer to D5449.) SURVEYOR ID# 32558 Licensure and Certification Surveyor