

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2113773	(X3) Date Survey Completed 09/18/2020
Name of Provider or Supplier Total Men's Primary Care	Street Address, City, State 180 E Whitestone Blvd Suite # 162, Cedar Park, TX	
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 unannounced onsite investigation of complaint TX22074679 was conducted September 15, 2020. Based on the investigation completed on September 19, 2020, the facility failed to meet the following conditions of the CLIA regulations found at CFR 42 493.1 through 493.1780: 493.1240 Condition: Preanalytic systems 493.1250 Condition: Analytic systems 493.1441 Condition: Laboratories performing high complexity testing; laboratory director. 493.1447 Condition: Laboratories performing high complexity testing; technical supervisor 493.1459 Condition: Laboratories performing high complexity testing; general supervisor 493.1487 Condition: Laboratories performing high complexity testing; testing personnel Complaint TX22074679 was substantiated.
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on review of testing logs and interview, the laboratory failed to retain testing records when the laboratory failed to retain kit manufacturer, kit lot, and expiration date for 32 of 35 boxes of test kits tested. Review of the testing logs showed the kits were identified by codes. Manufacturer, lot, and expiration were not available for review at the time of the survey. The laboratory had 2 open boxes in the laboratory that accounted for 3 testing logs: AAY (AAY1- AAY14) and AIN (AIN1-AIN25 and AIO01-AIN12). The following boxes of test kits were identified without manufacturer, kit lot numbers and expiration, as marked with the following codes: Box Test ID AD AD1-AD25 AG AG1-25 AR AR1-AR20 DM DM1-DM21 DC 12-20 DL DL1-DL20 EV EV1-EV20 EU EU1-EU20 FZ FZ1--FZ20 GA GA1-GA20 IG IG01-IG20 IF IF1-IF20 JN JN1-JN20 KG KG1-KG20 JM JM1-JM20 KF KF1-KF20</p>

KS KS01-KS20 KT KT01-KT20 OG OG1-OG25 SV SV1-SV25 SW SW01-SW25 WJ WJ01-WJ[25] WK WK01-Wk25 ZR ZR01-ZR25 ABA ABA01-ABA25 AAZ AAZ1-AAZ22 XI XI01-XI25 AEH AEH1-AEH25 AFV AFV01-AFV25 AFU AFU01-AFU25 CPA CPA01-CPA25 AEG AEG01-AEG23 Interview with the Vice President of Operations on 9/15/20 at 11:43 AM and again at 2:25 PM was requested COVID-19 test kit manufacturer and kit lot number and expiration dates. Interview with the Vice President of Operations on 9/15/20 at 3:30 PM in the area next to the storage room verified the testing logs were missing dates of collection and some were missing results. Email dated 9/16/20 at 5:53 PM from the Vice President of Operations confirmed what was provided the surveyor is what they have available, and the information they have does not include lot numbers.

D5300

PREANALYTIC SYSTEMS
CFR(s): 493.1240

Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, 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 preanalytic systems and correct identified problems as specified in 493.1249 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:
Based on review of the manufacturer's instructions, policy and procedure, test logs, and interview, the laboratory failed to meet the preanalytic requirements for the Healgen One Step Rapid Test kit for the COVID-19 IgG/ IgM Rapid Test Cassette and the Deangel Biological test kit for the COVID-19 IgG/IgM Rapid test kits. The laboratory used a fingerstick blood specimen for COVID-19 IgG/IgM testing. (See D5311 and D5391)

D5311

SPECIMEN SUBMISSION, HANDLING, AND REFERRAL
CFR(s): 493.1242(a)

The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.

This STANDARD is not met as evidenced by:
Based on review of the manufacturer's instructions, policy and procedure, test logs, and interview, the laboratory failed to follow manufacturer's instructions for specimen collection used for testing the Healgen One Step Rapid Test kit for the COVID-19 IgG/ IgM Rapid Test Cassette and the Deangel Biological test kit for the COVID-19 IgG/IgM Rapid test kits. The laboratory used a fingerstick blood specimen for testing patients for COVID-19. Findings follow: I. Healgen One Step Rapid Test kit for the COVID-19 IgG/ IgM Rapid Test Cassette A. Review of the package insert for the Healgen One Step Rapid Test kit for the COVID-19 IgG/ IgM Rapid Test Cassette under Specimen Collection stated "1. COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) can be performed using either whole blood, serum or

plasma. 2. Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear non-hemolyzed specimens. 3. Testing should be performed immediately after specimen collection...Whole blood collected by venipuncture should be stored at 2-8 degrees C (Celsius)/ 36-48 degrees F (Fahrenheit) if the test is to be run within 2 days of collection...". Under Test Procedures stated, "For Whole Blood Specimen: Hold the 5 ul mini plastic dropper vertically and transfer 1 drop of whole blood (about 10 ul) to the specimen well (S). Then add 2 drops (about 80 ul) of sample buffer to the buffer well (B) immediately. Avoid air bubbles." There is no mention of fingerstick collection of specimens in the package insert. B. Review of the Emergency Use Authorization from the FDA web site for the Healgen Test kit for the COVID-19 IgG/ IgM Rapid Test Cassette Instructions for Use (Cat: GCCOV-402a, Rev 2020-5-2) under Specimen Collection stated, "2. The COVID-19 IgG/ IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) test has not been evaluated with fingerstick specimens. Use of this test with fingerstick blood is not recommended." II. Deangel Biological COVID-19 IgG/IgM Rapid Test A. Review of the package insert for the Deangel Biological test kit (referred by the lab as D&G) for the COVID-19 IgG /IgM Rapid Test Device under Specimen stated, "The test can be used to test Whole Blood/Serum/Plasma specimens. To collect whole blood, serum, or plasma specimens following regular clinical laboratory procedures." Under Test Procedure stated, "allow the test device and specimens to equilibrate to temperature ((15-30 degrees C (Celsius) or 59-86 degrees F (Fahrenheit)) prior to testing. 1. Remove the test device from the sealed pouch. 2. Hold the dropper vertically and transfer 1 drop of specimen to the specimen well (S) for the test device, then add 2 drops of buffer (approximately 70 ul) and start the timer. See the illustration below. " There is no mention of fingerstick collection of specimens in the package insert. The Deangel Biological COVID-19 IgG/IgM Rapid Test kit had not been issued an Emergency Use Authorization (EUA); therefore, the laboratory was using a high complexity laboratory developed test and establishment studies had not been performed. B. Review of the laboratory's policy and procedure titled Z11.89COVID-19 Screening Non-Symptomatic Patients Only dated 6/22/2020 stated on page 5 under "Healgen Updates: Effective immediately: 1. We have procured FDA-authorized test to send to ALL Centers starting today/tomorrow. 2. When talking to Pt's (patients) about tests, please do NOT use the word "Approved" but the word "Authorized". These tests, just like the Cellex tests are FDA-authorized". This is a legal term and we need to all be saying things correctly, please. 3. We will still be using the D&G tests [pictured on page 2 of the policy and procedure and referred in this report as Deangel Biological, and the letters DAG are on the outside of the box], for Pt's who have not been tested yet with us. We are not stopping the use of the D&G tests. 4. Healgen- FDA-authorized tests will be delivered over the next few days at your Centers. New Testing Protocol: We now have a two part testing protocol, that includes two tests over a 14-30 day period. Your first test will be our Phase 1 (D&G), Antibody test that is available at all 26 centers throughout Texas. Once finished and before you leave the Center, we highly suggest scheduling your re-test for 14-30 days out (Insurance Requirement). 2nd Test: Your second test will be 14-30 days (Insurance Requirement) after your first test. This FDA-authorized test will be either Cellex or Healgen, depending on supplies at the specific clinic you're scheduled at. Cellex and Healgen are both FDA-authorized test. Before we needed a Pt to have a Positive result to get the 2nd test- but that is no longer the case. All Pt's will be able to get a 2nd test- but will have to be 14-30 days after the 1st (Insurance Requirement). The Healgen Test will be a finger stick test, just like the D&G Test..." C. Review of testing logs from 4/8 /2020 to 9/15/2020 showed 731 patients were tested. Available test logs showed: 39 patients were tested with the Healgen test kit as identified by "Healgen" on the testing log. 25 patients listed on the June 22, 2020 Testing log labeled BOX-XI Healgen Box.

Test ID XI01 through XI25 14 patients listed on the July 6, 2020 Testing Log labeled Healgen-AAY included Test ID AAY1 through AAY14 59 patients were tested with the Deangel Biological (D&G) as identified by D&G on the test logs or Box "AIN" on the log sheet. On 9/15/20 at 0930 in the laboratory it was observed by the surveyor the Deangel Biological (D&G) test kit had a sticky note with the letters AIN attached to the box. Included were: 22 patients listed on the July 1, 2020 testing log labeled AAZ D&G included Test ID AAZ1 through AAZ22 25 patients listed on the July 29, 2020 testing log labeled Antibody included Test ID AIN1 through AIN25 D. Interview with the Assistant Manager on 9/15/20 at 10:00 am in the laboratory when asked how do you determine which test is used for the COVID-19 Antibody test, she stated they used the older brand first. Interview with testing personnel #4 listed on the CMS form 209 on 9/15/20 at 10:07 am in the laboratory acknowledged if the patient had not been tested prior, they use the D&G (observed by surveyor as the Deangel Biological) kit. If they had been tested before, they use the Healgen test. If they request an antigen test, they use the Sophia test. Interview with the Assistant Manager on 9/15/20 at 10:09 am in the laboratory said they do not have written procedures for the COVID-19 testing. Interview with testing personnel #4 listed on the CMS form 209 on 9/15/20 at 10:45 am in the laboratory confirmed there was a procedure and was able to provide a procedure for the COVID-19 testing on google documents on-line and provided a copy to the surveyor. Interview with testing personnel 4 listed on the CMS form 209 confirmed she started working at the facility in July, and on 9/15/20 at 09:30 AM and 2:34 PM in the laboratory acknowledged she collected a fingerstick specimen for the antibody tests. Key: CMS is the Centers for Medicare and Medicaid

D5391

PREANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1249(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 preanalytic systems specified at 493.1241 through 493.1242.

This STANDARD is not met as evidenced by:
Based on review of the laboratory policies and procedures and interview of facility personnel found the laboratory failed to have a written policy to monitor, assess and correct problems in the pre-analytic laboratory systems. The laboratory failed to ensure that testing personnel were using the appropriate specimen type when using the Healgen and Deangel IgG/IgM COVID 19 test methods. (See D5311)

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 upon observations, review of manufacturers instructions for use, laboratory policies and procedures, patient test records and interview of facility personnel the

laboratory failed to meet the analytic requirements. The laboratory failed to ensure that test kits were maintained at the appropriate temperature as specified in the manufacturers instructions for use. (See D5413) The laboratory failed to validate the test systems for accuracy, precision, specificity, sensitivity and other performance specifications as required when using an alternate specimen (fingerstick blood specimens). (See D5423) The laboratory failed to test negative and positive control specimens at least once each day when using the Healgen and Deangel IgG/IgM COVID 19 test methods. (See D5449)

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

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.

This STANDARD is not met as evidenced by:

Based on review of manufacturer's instructions, test logs, and interview, the laboratory failed to have a means to monitor and document room temperature and humidity in the laboratory for two of two years reviewed. Findings follow. I. Healgen One Step Rapid Test kit for the COVID-19 IgG/ IgM Rapid Test Cassette A. Review of the package insert found: 1. Under Test Procedure stated "Allow test cassette, specimen buffer and/or controls to equilibrate to room temperature ((15-30 degrees C (Celsius)) prior to testing." 2. Under Storage and Stability stated "the kit can be stored at room temperature or refrigerated ((2-30 degrees C (Celsius)/36-86 Degrees F (Fahrenheit))". B. Review of the Emergency Use Authorization from the FDA website for Instructions for Use, Cat: GCCOV-402a, Rev 2020-5-2, 1. Under Warnings and Precautions stated, "3. This test should be performed at 15 to 30 degrees C (Celsius)." 2. Under Warnings and Precautions stated, "9. Humidity and temperature can adversely affect results (especially with an RH over 80%). 3. Under Test Procedure stated, "Allow test cassette, specimen buffer and/or controls to equilibrate to room temperature ((15-30 degrees C (Celsius)) prior to testing." II. Deangel Biological test kit for the COVID-19 IgG/IgM Rapid Test Device review of the package insert 1. Under Test Procedure stated, "allow the test device and specimens to equilibrate to temperature ((15-30 degrees C (Celsius) or 59-86 degrees F (Fahrenheit)) prior to testing." 2. Under Storage and Stability stated "store as packaged in the sealed pouch at the temperature ((4-30 degrees C (Celsius) or 40-86 degrees F (Fahrenheit))." C. The laboratory's temperature charts for the past 2 years were requested at 09:55 AM but not provided. D. Review of testing logs showed 731 patients were tested. Available test logs showed 39 patients were tested with the Healgen test kit as identified by "Healgen" on the test sheet. Available test logs showed 37 patients were tested with the Deangel Biological (D&G) as identified by D&G on the test logs or Box "AIN" on the log sheet. On 9/15/20 at 0930 in the laboratory it was observed by the surveyor the Deangel Biological (D&G) test kit had a sticky note with the letters AIN attached to the box. E. Interview with testing personnel #4 listed on the CMS form 209 on 9/15/20 at 2:48 in the laboratory confirmed there were no temperature

charts or a means to monitor the temperature of the laboratory and has not been doing that for the room temperature or refrigerator temperature. Key: CMS is the Centers for Medicare and Medicaid

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 review of the manufacturer's instructions, policy and procedure, testing logs, and interview, the laboratory had a modified procedure for performing the Healgen One Step Rapid Test kit for the COVID-19 IgG/ IgM Rapid Test Cassette and the Deangel Biological test kit for the COVID-19 IgG/IgM Rapid Test Device for which they had not established performance specifications for accuracy, precision, analytical sensitivity, specificity, normal values or any other performance characteristics for 2 of 2 modified COVID-19 test methods. Findings follow: I. Healgen One Step Rapid Test kit for the COVID-19 IgG/ IgM Rapid Test Cassette A. Review of the package insert for the Healgen One Step Rapid Test kit for the COVID-19 IgG/ IgM Rapid Test Cassette under Specimen Collection stated "1. COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) can be performed using either whole blood, serum or plasma. 2. Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear non-hemolyzed specimens. 3. Testing should be performed immediately after specimen collection...Whole blood collected by venipuncture should be stored at 2-8 degrees C (Celsius)/ 36-48 degrees F (Fahrenheit) if the test is to be run within 2 days of collection...". Under Test Procedures stated, "For Whole Blood Specimen: Hold the 5 ul mini plastic dropper vertically and transfer 1 drop of whole blood (about 10 ul) to the specimen well (S). Then add 2 drops (about 80 ul) of sample buffer to the buffer well (B) immediately. Avoid air bubbles." There is no mention of fingerstick collection of specimens in the package insert. B. Review of the Emergency Use Authorization from the FDA website for the Healgen Test kit for the COVID-19 IgG/ IgM Rapid Test Cassette Instructions for Use, Cat: GCCOV-402a, Rev 2020-5-2, under Specimen Collection stated, "2. The COVID-19 IgG/ IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) test has not been evaluated with fingerstick specimens. Use of this test with fingerstick blood is not recommended." II. Review of the package insert for the Deangel Biological test kit (referred by the lab as D&G) for the COVID-19 IgG/IgM Rapid Test Device under Specimen stated, "The test can be used to test Whole Blood/Serum/Plasma specimens. To collect whole blood, serum, or plasma specimens following regular clinical laboratory procedures." Under Test Procedure stated, "allow the test device and specimens to equilibrate to temperature ((15-30 degrees C (Celsius) or 59-86 degrees F (Fahrenheit)) prior to testing. 1. Remove the test device from the sealed pouch. 2. Hold the dropper vertically and transfer 1 drop of specimen to the specimen well (S) for the test device,

then add 2 drops of buffer (approximately 70 ul) and start the timer. See the illustration below. " There is no mention of fingerstick collection of specimens in the package insert. The Deangel Biological COVID-19 IgG/IgM Rapid Test kit had not been issued an Emergency Use Authorization (EUA); therefore, the laboratory was using a high complexity laboratory developed test and establishment studies had not been completed. III. Review of the laboratory's policy and procedure titled Z11. 89COVID-19 Screening Non-Symptomatic Patients Only dated 6/22/2020 on page 2 under Drawing Sample stated "1. Ask the patient to stand in order to get a better blood sample from finger. 2. Swab patient's middle or index finger with alcohol... 3. Use a single-use lancet on the patient's finger. 4. If the test has two wells, the blood goes in the TOP well. 5. Use Capillary tool to squeeze the patient's finger to drop blood directly into the appropriate cartridge well. The well should turn completely red. The more blood you can get the more accurate the test will be. DO NOT mix blood samples from two different fingers. This will invalidate the test." On page 5, stated under "Healgen Updates: Effective immediately:... The Healgen Test will be a finger stick test, just like the D&G Test..." IV. Review of testing logs from 4/8/2020 to 9/15/2020 showed 731 patients were tested. V. Interview with testing personnel #4 listed on the CMS form 209 acknowledged she started in July, and on 9/15/20 at 09:30 AM and 2:34 PM in the laboratory acknowledged she collected a fingerstick specimen for the antibody tests. There were no establishment studies of performance specifications available for review. Interview with the Vice President of Operations in the doctor's office on 9/15/20 at 3:17 pm confirmed there were no verification of performance specifications for review at the time of the survey.

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 the manufacturer's instructions, policy and procedure, observations, test logs, review of quality control, and interview, the laboratory failed to perform quality control each day of patient testing for the Healgen One Step Rapid Test kit for the COVID-19 IgG/ IgM Rapid Test Cassette and the Hangzhou Deangel Biological COVID-19 IgG/IgM Rapid Test Device for COVID-19 testing. Findings follow: I. Healgen One Step Rapid Test kit for the COVID-19 IgG/ IgM Rapid Test Cassette: A. Review of the package insert for the Healgen One Step Rapid Test kit for the COVID-19 IgG/ IgM Rapid Test Cassette under Quality Control stated, "a procedural control is included in the test. A redline appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique B. Review of the Emergency Use Authorization from the FDA website for the Healgen Test kit for the COVID-19 IgG/ IgM Rapid Test Cassette Instructions for Use, Cat: GCCOV-402a, Rev 2020-5-2, under Quality Control stated, "Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance." II. Review of the package insert for the Hangzhou Deangel Biological COVID-19 IgG/IgM Rapid Test Device (referred by the lab as D&G) found under Quality Control , "Control standards are not

supplied with this kit. However, 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." III. Review of the laboratory's policy and procedure titled Z11. 89COVID-19 Screening Non-Symptomatic Patients Only dated 6/22/2020 did not include instructions for testing quality controls. IV. Observations made during the tour the facility found that the laboratory was currently using the Healgen One Step Rapid Test kit for the COVID-19 IgG/ IgM Rapid Test Cassette lot 200-4159 expiration 202204 and the Hangzhou Deangel Biological COVID-19 IgG/IgM Rapid Test Device lot nCOV 200302 expiration 2022-02 1. Review of patient test logs provided found no documentation for the date of testing of each patient specimen . Further review of testing logs from 4/8/2020 to 9/15/2020 found 731 patients were tested. Available test logs showed: a. 39 patients were tested with the Healgen test kit as identified by "Healgen" on the testing log. 25 patients listed on the June 22, 2020 Testing log labeled BOX-XI Healgen Box. Test ID XI01 through XI25 14 patients listed on the July 6, 2020 Testing Log labeled Healgen-AAY included Test ID AAY1 through AAY14 b. 59 patients were tested with the Deangel Biological (D&G) as identified by D&G on the test logs or Box "AIN" on the log sheet. On 9/15/20 at 0930 in the laboratory it was observed by the surveyor the Deangel Biological (D&G) test kit had a sticky note with the letters AIN attached to the box. Included were: 22 patients listed on the July 1, 2020 testing log labeled AAZ D&G included Test ID AAZ1 through AAZ22 25 patients listed on the July 29, 2020 testing log labeled Antibody included Test ID AIN1 through AIN25 . Available test logs found 39 patients were tested with the Healgen test kit as identified by "Healgen" on the test sheet. Available test logs showed 59 patients were tested with the Hangzhou Deangel Biological (D&G) as identified by D&G on the test logs or Box "AIN" on the log sheet. On 9/15/20 at 0930 in the laboratory it was observed by the surveyor the Hangzhou Deangel Biological (D&G) test kit had a sticky note with the letters AIN attached to the box. 2. Interview with testing personnel #4 as listed on the CMS form 209 and acknowledged that she started working at the facility in July. During interview conducted on 9/15/20 at 2:50 PM in the laboratory confirmed she has not performed any external quality control and there was no quality control material in the laboratory. Email dated 9/16/20 at 5:53 PM from the Vice President of Operations confirmed there was no documentation of quality control for the antibody tests. Key: CMS is the Centers for Medicare and Medicaid

D5787

TEST RECORDS
CFR(s): 493.1283(a)

The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).

This STANDARD is not met as evidenced by:
Based on random review of the testing logs and interview, the laboratory failed to maintain the records system to include the dates and results of all specimen testing. The findings included: I. Review of the COVID-19 testing logs with the ID AAY in the laboratory on 9/15/2020 for the Healgen One Step Rapid Test kit showed a date at the top of the page of 7/6/2020. 14 of 14 patients were tested on the page and the times listed in the following order without dates: Test ID Time: AAY1 3:20 AAY2 3:

55 AAY3 2:47 AAY4 9:24 AAY5 9:28 AAY6 2:34 AAY7 3:06 AAY8 11:20 AAY9 9:10 AAY10 2:11 AAY11 11:35 AAY12 3:31 AAY13 12:33 AAY14 12:00 II. Review of the 2 COVID-19 testing logs labeled AIN (dated 7/28/2020), and the page labeled AIN and AIO with no date found in the laboratory on 9/15/20 for the Hangzhou Deangel Biological test kit (as identified as Antibody on the test log using box AIN and matched to the Hangzhou Deangel Biological kit with the sticky note AIN attached to it) showed no dates of testing for 37 of 37 patient test records reviewed. AIN testing log dated 7/28/2020 found: Test ID Time: AIN1 9:45 AIN2 12:36 AIN3 09:26 AIN4 11:32 AIN5 11:33 AIN6 11:34 AIN7 11:35 AIN8 12:25 AIN9 12:24 AIN10 11:40 AIN11 12:25 AIN12 1:02 AIN13 11:00 AIN14 3:35 AIN15 illegible AIN16 12:15 AIN17 9:22 AIN18 12:45 AIN19 11:11 AIN20 9:13 AIN21 3:22 AIN22 12:23 AIN23 12:23 AIN24 3:15 AIN25 3:23 Review of Covid-19 testing log AIN/AIO found the laboratory failed to include the date of testing for 12 of 12 patients tested. Test IDs included on this page were: Test ID Time: 01 11:11 AIN2 9:00 AIN3 4:40 AIN4 12:05 AIN5 4:30 AIN6 4:05 AIN7 4:05 AIN8 9:05 AIN9 10:50 AIN10 illegible AIN11 2:45 AIN12 3:10 During surveyor observation in the laboratory on 9/15/2020 at 0930 showed the Hangzhou Deangel Biological test kit had a sticky note AIN attached to it. III. Review of testing logs AIN dated 7/28/20 showed 2 out of 51 patient results without the results recorded. Review of the COVID-19 testing logs for the Healgen One Step Rapid Test kit box ID AAY dated 7/6/2020 and Hangzhou Deangel Biological test kit (as identified as Antibody on the test log using box AIN and matched to the Deangel Biological kit with the sticky note AIN attached to it) showed 2 of 51 patients tested without the documentation of the test result: the date of 7/29/2020 at the header on the page for specimens AIN13 & AIN15. IV. Interview with the Vice President of Operations on 9/15/20 at 3:30 PM in the area next to the storage room verified the testing logs were missing dates of collection and some were missing results. Email dated 9/16/20 at 5:53 PM from the Vice President of Operations confirmed what was provided the surveyor is what they have available.

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 review of the laboratory policies and procedures and interview of facility personnel found the laboratory failed to have a written policy to monitor, assess and correct problems in the analytic laboratory systems specified at 493.1251 through 493.1283. 1. The laboratory failed to ensure that test kits were maintained at the appropriate temperature as specified in the manufacturers instructions for use. (See D5413) 2. The laboratory failed to validate the test systems for accuracy, precision, specificity, sensitivity and other performance specifications as required when using an alternate specimen (fingerstick blood specimens). (See D5423) 3. The laboratory failed to test negative and positive control specimens at least once each day when using the Healgen and Deangel IgG/IgM COVID 19 test methods. (See D5449)

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 test reports, testing logs, and interview, the laboratory failed to include the name and address of the laboratory location where the test was performed and failed to include the specimen source for 6 of 6 reports reviewed. I. Review of the test reports showed all the reports had the following locations on the report: Total Primary Care, Total Men's Primary Care, and Total Care Primary Care with no address. The reports did not indicate at which facility and address the testing was performed. The following Test IDs shown on the testing logs with the patient names selected for review of the test reports: AIN9 (with Antibody AIO at the top of the page) dated 9/5/20 on the test report, AIO 01 (with Antibody AIO at the top of the page) dated 8/22/20 on the test report, AIN13 (with Antibody at the top of the page) dated 8/6/20 on the test report, AIN14 (with Antibody at the top of the page) dated 6/06/20 on the test report, AAY1 (with Antibody at the top of the page) dated 6/26/20 on the test report, and AAY05 (with Healgen-AAY at the top of the page) dated 7/10/20 on the test report. II. Review of the test reports showed all the reports did not indicate the specimen source. The following Test IDs shown on the testing logs with the patient names selected for review of the test reports: AIN9 (with Antibody AIO at the top of the page) dated 9/5/20 on the test report, AIO 01 (with Antibody AIO at the top of the page) dated 8/22/20 on the test report, AIN13 (with Antibody at the top of the page) dated 8/6/20 on the test report, AIN14 (with Antibody at the top of the page) dated 6/06/20 on the test report, AAY1 (with Antibody at the top of the page) dated 6/26/20 on the test report, and AAY05 (with Healgen-AAY at the top of the page) dated 7/10/20 on the test report. Interview with the Vice President of Operations on 9/15/20 at 3:30 pm in the area next to the storage room verified the test reports were missing the information.

D6076

LABORATORY DIRECTOR
CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:

Review the CMS Report 209 Laboratory Personnel Report and interview of facility personnel found that the laboratory failed to have a laboratory director qualified to provide general supervision of high complexity testing using the Healgen COVID 19 IgG/IgM rapid test and the Hangzhou Deangel Biological COVID 19 IgG/IgGM rapid test with an alternate specimen (fingerstick blood). (See D6079, D6082, D6086, D6087, D6093, D6094, D6100, D6102, D6103 and D6106)

D6079

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

Review the CMS Report 209 Laboratory Personnel Report and interview of facility personnel found that the laboratory failed to have a laboratory director qualified to provide general oversight and administration of the laboratory performing high complexity testing using the Healgen COVID 19 IgG/IgM rapid test and the Hangzhou Deangel Biological COVID 19 IgG/IgM rapid test with an alternate specimen (fingerstick blood). The findings included: 1. The laboratory was asked to provide education records for all testing personnel at 9:55 AM on September 15, 2020 and failed to do so. Education and training records were requested again at 11:29 AM but were not provided. 2. Interview of the vice president of operations conducted September 15, 2020 at 2:25 PM confirmed no additional records would be provided.

D6082

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(1)

The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policies, manufacturer's instructions, verification records, and interview a facility personnel, the laboratory director failed to ensure the quality of services for preanalytical systems. The laboratory director failed to ensure verification studies to support the use of alternate specimen types (fingerstick blood specimens) when using the Healgen COVID 19 IgG/IDM rapid test cassette. The laboratory director failed to ensure the laboratory did not use test kits (Hangzhou Deangel biological COVID 19 rapid test cassette) that were not approved for use in testing patient specimens or had been granted Emergency Use Authorization (EUA) by the FDA. (See D5311 and D5423)

D6086

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(3)(ii)

The laboratory director must ensure that 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 review of the laboratory's policies, manufacturer's instructions, verification records, and interview a facility personnel, the laboratory director failed to ensure verification studies were performed to support the use of alternate specimen types (fingerstick blood specimens) when using the Healgen COVID 19 IgG/IDM rapid test cassette and the Hangzhou Deangel biological COVID 19 rapid test cassette. (See D5311 and D5423)</p>
<p>D6087</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii)</p> <p>The laboratory director must ensure that 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 review of the laboratory's policies, manufacturer's instructions, verification records, and interview a facility personnel, the laboratory director failed to ensure testing personnel were performing test procedures as instructed by the manufacturer when using the Healgen COVID 19 IgG/IDM rapid test cassette and the Hangzhou Deangel biological COVID 19 rapid test cassette. (See D5311 and D5449)</p>
<p>D6093</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, manufacturer's instructions, verification records, and interview a facility personnel, the laboratory director failed to ensure the quality control program had been established and maintained for COVID 19 testing using the Healgen COVID 19 IgG/IDM rapid test cassette and the Hangzhou Deangel biological COVID 19 rapid test cassette. (See D5449)</p>
<p>D6094</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, manufacturer's instructions, verification records, and interview a facility personnel, the laboratory director failed to establish and maintain a quality assurance program for COVID 19 testing using the Healgen COVID 19 IgG/IDM rapid test cassette and the Hangzhou Deangel biological COVID 19 rapid test cassette. (See D 5791)</p>

<p>D6100</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(10)</p> <p>The laboratory director must ensure that a general supervisor provides on-site supervision of high complexity test performance by testing personnel qualified under 493.1489(b)(4).</p> <p>This STANDARD is not met as evidenced by: Based on review of patient test records, policies and procedures, and interview of facility personnel, found the laboratory director failed to ensure that a general supervisor provided the appropriate on site supervision of testing personnel performing high complexity testing. (See D 6141)</p>
<p>D6101</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(11)</p> <p>The laboratory director must employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's personnel records, patient test records and staff interview, it was revealed the laboratory director failed to ensure the laboratory had a technical supervisor in general supervisor with the appropriate documentation of education and training to provide oversight and supervision of individuals performing high complexity testing. The findings included: 1. Personnel records were requested during interview conducted on September 15, 2020 at 9:55 AM and again at 11:29 AM but were not provided. 2. Interview of the vice president of operations conducted September 15, 2020 at 2:25 PM confirmed that he could not provide any additional records.</p>
<p>D6102</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12)</p> <p>The laboratory director must 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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's personnel records, patient test records and staff interview, it was revealed the laboratory director failed to ensure that 10 of 10 testing personnel had documentation of education and training to perform high complexity testing. The findings included: 1. Personnel records were requested during interview conducted on September 15, 2020 at 9:55 AM and again at 11:29 AM but were not provided. 2. Interview of the vice president of operations conducted September 15, 2020 at 2:25 PM confirmed that he could not provide any additional records.</p>

D6103

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(13)

The laboratory director must 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.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's personnel records, patient test records and staff interview, it was revealed the laboratory director failed to ensure that 10 of 10 testing personnel had documentation of education and training to perform high complexity testing. The findings included: 1. Competency assessment records were requested during interview conducted on September 15, 2020 at 9:55 AM and again at 11:29 AM but were not provided. 2. Interview of the vice president of operations conducted September 15, 2020 at 2:25 PM confirmed that he could not provide any additional records.

D6108

LABORATORY TECHNICAL SUPERVISOR

CFR(s): 493.1447

The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart.

This CONDITION is not met as evidenced by:

Based on a review of the CMS-209 Laboratory Personnel Report, CMS-116, laboratory records and confirmed in interview the facility the laboratory failed to employ personnel to provide Technical supervision that met the qualifications of technical supervisor for the high complexity tests performed. (refer to D6109)

D6109

TECHNICAL SUPERVISOR QUALIFICATIONS

CFR(s): 493.1449

The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical supervision for each of the specialties and subspecialties of service in which the laboratory performs high complexity tests or procedures. The director of a laboratory performing high complexity testing may function as the technical supervisor provided he or she meets the qualifications specified in this section.

This STANDARD is not met as evidenced by:

Review the CMS Report 209 Laboratory Personnel Report and interview of facility personnel found that the laboratory failed to have a technical supervisor qualified to provide general oversight and administration of the laboratory performing high complexity testing using the Healgen COVID 19 IgG/RGM rapid test and the Hangzhou Deangel Biological COVID 19 IgG/RGM rapid test with an alternate specimen (fingerstick blood). The findings included: 1. The laboratory was asked to

	<p>provide education, training and competency assessment records for all personnel at 9:55 AM on September 15, 2020 and failed to do so. Education and training records were requested again at 11:29 AM but were not not provided. 2. Interview of the vice president of operations conducted September 15, 2020 at 2:25 PM confirmed no additional records would be provided.</p>
<p>D6141</p>	<p>GENERAL SUPERVISOR CFR(s): 493.1459</p> <p>The laboratory must have one or more general supervisors who are qualified under 493.1461 of this subpart to provide general supervision in accordance with 493.1463 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Review the CMS Report 209 Laboratory Personnel Report and interview of facility personnel found that the laboratory failed to have a general supervisor qualified to provide general supervision of high complexity testing using the Healgen COVID 19 IgG/RGM rapid test and the Hangzhou Deangel Biological COVID 19 IgG/RGM rapid test with an alternate specimen (fingerstick blood). The findings included: 1. The laboratory was asked to provide education, training and competency assessment records for all personnel at 9:55 AM on September 15, 2020 and failed to do so. Education and training records were requested again at 11:29 AM but were not not provided. 2. Interview of the vice president of operations conducted September 15, 2020 at 2:25 PM confirmed no additional records would be provided.</p>
<p>D6168</p>	<p>TESTING PERSONNEL CFR(s): 493.1487</p> <p>The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493.1495 of this subpart for the volume and complexity of testing performed.</p> <p>This CONDITION is not met as evidenced by: Review of the CMS Report 209 Laboratory Personnel report, personnel records and interview of facility personnel, the laboratory failed to ensure that 10 of 10 testing personnel listed on the CMS report 209 held the minimum education to perform High complexity testing using an alternate specimen (fingerstick blood) for testing patients for COVID 19 with the Healgen Scientific and Hangzhou Deangel Biologic test kits. (see D6171) Review of patient test logs and interview of testing personnel found that testing personnel failed to follow the laboratory's procedure for documenting COVID 19 test results on the patient test logs. (See D6175)</p>
<p>D6171</p>	<p>TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b)</p> <p>(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an</p>

accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

This STANDARD is not met as evidenced by:

Review of the CMS Report 209 Laboratory Personnel report, personnel records, Manufacturer's instructions for use, review of the laboratory's own procedure and interview of facility personnel, the laboratory failed to ensure that 10 of 10 testing personnel listed on the CMS report 209 met the minimum education requirements to perform High complexity testing(using an alternate specimen (fingerstick blood) for

testing patients for COVID 19 with the Healgen Scientific and Hangzhou Deangel Biologic test kits). The findings included: 1. Review of the CMS report 209 Laboratory Personnel Report found the laboratory documented 10 individuals as testing personnel. 2. Personnel records were requested for review September 15, 2020 at 09:55 AM, and again at 11:29 AM, but not provided. 3. Interview of the vice president of operations conducted on September 15, 2020 at 2:25 PM confirmed that he could not provide any additional records.

D6175

TESTING PERSONNEL RESPONSIBILITIES
CFR(s): 493.1495(b)(1)

Each individual performing high complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results.

This STANDARD is not met as evidenced by:
Review of patient test logs, policies and procedures and interview of facility personnel found that the testing personnel failed to follow the laboratory's own policy for documenting patient results on test logs for COVID -19 testing. The findings included: 1. Review of patient test logs found that testing person four had pre filled check marks in the column indicated for internal control (C) for specimens Y13, Y14, and 15 for the log currently in use and dated 9/12/20. Results of (-) were entered for specimens Y13 and Y14, with the testinp personnel's initials and 9-14 written in the form submitted column. 2. Interview of testing person for listed on the CMS report 209 Laboratory Personnel Report conducted on September 15, 2020 at 10:19 AM confirmed that the checkmark insert into the column labeled "C", indicated that the test was performed.