Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D1079189	01/25/2021
Name of Provider or Supplier	**Street Address, City, State**	
Us Med Care Llc	7682 Hwy 23 Suite B, Belle Chasse, 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/Complaint (LA 00056821) survey was performed at US Med Care, LLC-CLIA ID 19D1079189 on January 21, 2021 through January 25, 2021. US Med Care, LLC was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.1250 CONDITION: Analytic Systems 42 CFR 493.1290 CONDITION: Postanalytic 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 42 CFR 493.1421 CONDITION: Laboratories performing moderate complexity testing, Testing Personnel
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 policy, CMS-209 form, the laboratory failed to establish written policies and procedures to assess competency of Testing Personnel. Findings: 1. Review of the laboratory's CMS- 209 (Laboratory Personnel Report) form received via email on January 25, 2021 revealed three (3) personnel listed as Testing Personnel. 2. Review of the laboratory's "Standard Operating Procedures" document received via email on January 25, 2021 under "Staff Training" section revealed "New hire laboratory training with return demonstrations & 6 month review. Yearly procedure manual review and laboratory in-service including blood borne pathogen training. Staff informed of any lab changes by memo or meeting." 3. Further review of the laboratory's "Standard Operating Procedures" revealed the laboratory did not include a written policy for competency of testing personnel that included frequency of performance as initial, semi-annual, and annual thereafter. The minimal

	requirement of the following six (6) procedures was not included: a) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. b) Monitoring the recording and reporting or test results. c) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records. d) Direct observation of performance of instrument maintenance and function checks. e) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. f) Assessment of problem solving skills.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures and interview with personnel, the laboratory failed to verify the accuracy of COVID-19 antigen IgG/IgM at least twice annually. Findings: 1. Review of the laboratory's "Standard Operating Procedures" document received via email on January 25, 2021 under "Proficiency Testing" section revealed "N/A." 2. In interview on January 21, 2021 at 10:47 am, the Testing Personnel (Owner) stated the laboratory does not perform proficiency testing. 3. The laboratory did not provide to the surveyor patient test records prior to January 2021 or the date the laboratory began performing COVID-19 patient testing.
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 direct observation, 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 establish a complete policy and procedure manual. Refer to D5401. 2. The laboratory failed to establish a policy and procedure manual. Refer to D5403. 3. The laboratory failed to have the procedures approved and signed by the Laboratory Director. Refer to D5407. 4. The laboratory failed to monitor the room temperature of the laboratory where testing and supplies were stored per manufacturer requirements for the Healgen COVID-19 IgG/IgM Rapid Test Cassette. Refer to D5413. 5. The laboratory failed to perform performance verification studies that included accuracy and precision studies for COVID testing on the Healgen COVID-19 IgG/IgM Rapid Test Cassette. Refer to D5421. 6. The laboratory failed to perform positive and negative controls for the Healgen COVID-19 IgG/IgM Rapid Test Cassette. Refer to D5449. 7. The laboratory failed to document the internal control results for the Healgen COVID-19 IgG/IgM Rapid Test Cassette testing for eighty

	eight (88) of eighty eight (88) patients reviewed. Refer to D5481. 8. The laboratory failed to establish procedures to monitor, assess, and correct problems, identified with the analytic system. Refer to D5791.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures, the laboratory failed to establish a complete policy and procedure manual. Findings: 1. Review of the laboratory's "Standard Operating Procedures" document received via email on January 25, 2021 revealed the laboratory did not have written policies and procedures that included the following: a) Corrective action: to address failures that may occur in the preanalytic, analytic, and post analytic systems b) Maintenance: how often to perform, required function checks and frequency c) Retention of records requirements d) Twice a year verification for accuracy of COVID testing to include frequency, acceptability criteria, and corrective action plan e) Performance specification: detailed procedures for performing accuracy and precision (day-to-day, run-to-run, and within-run, as well as, operator variance), reportable and reference range studies, and actions to take when data from the studies fail to meet acceptability criteria f) Complaint Investigations g) Communication h) Reporting of SARS COV-2 test results to state public health agency i) Temperature monitoring: including corrective action for temperatures outside of acceptable range 2. In interview on January 21, 2021 at 10:46 am, the Testing Personnel (Owner) stated the laboratory's policies were located on a computer that was in use by the nurse for virtual visits. The Testing Personnel (Owner) further stated at 12:00 pm, policies/procedures, personnel education and training records were located on the computer that was in use for virtual visits. The computer was not available during the onsite visit.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the

	protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures, the laboratory failed to establish a policy and procedure manual. Findings: 1. Review of the laboratory's "Standard Operating Procedures" revealed the following procedures were not included: a) Detailed policies and procedures for patient preparation; specimen collection, specimen type, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. b) Step-by-step performance of the procedure, including test calculations c) Preparation of solutions, controls, reagents, stains, and other materials used in testing d) Quality Control to include, but not limited to: What quality control is required, frequency of performance; who is to monitor and corrective actions for unacceptable results e) Reportable range for test results for the test system as established or verified f) Corrective action to take when control results fail to meet the laboratory's criteria for acceptability g) Limitations in the test methodology; including interfering substances h) Reference intervals (normal values) i) Imminently life-threatening test results, or panic or alert values j) Pertinent literature references k) Laboratory's system for entering results in the patient record and reporting patient test results l) Course of action if test system becomes inoperable 2. In interview on January 21, 2021 at 10:46 am, the Testing Personnel (Owner) stated the laboratory's policies were located on a computer that was in use by the nurse for virtual visits. The Testing Personnel (Owner) further stated at 12:00 pm, policies/procedures, personnel education and training records were located on the computer that was in use for virtual visits. The computer was not available during the onsite visit.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures, the laboratory failed to have the procedures approved and signed by the Laboratory Director. Findings: 1. Review of the laboratory's "Standard Operating Procedures" document received via email on January 25, 2021 revealed the Laboratory Director did not approve/sign the procedures.
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 direct observation by surveyor, review of manufacturer insert, and interview with the Testing Personnel/Owner, the laboratory failed to monitor the room temperature of the laboratory where testing and supplies were stored per manufacturer requirements for the Healgen COVID-19 IgG/IgM Rapid Test Cassette. Findings: 1. Observation by surveyor on January 21, 2021 at 10:39 am revealed the laboratory had one (1) empty box of Healgen COVID -19 IgG/ IgM Rapid Test Cassette kit (Lot # 2006168EUA). 2. In interview on January 21, 2021 at 10:46 am, the Testing Personnel (Owner) stated the laboratory began using the Healgen test kits two (2) to three (3) months ago. In further interview, the Testing Personnel stated the laboratory was out of the Healgen test kits and planned to use the waived Care Start COVID-19 Antigen tests. 3. Review of the Healgen COVID-19 IgG/IgM Rapid Test Cassette Package insert under "Storage and Stability" section revealed "The kit can be stored at room temperature or refrigerated (2-30 degrees Celsius)."
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures and interview with personnel, the laboratory failed to perform performance verification studies that included accuracy and precision studies for COVID testing on the Healgen COVID-19 IgG/IgM Rapid Test Cassette. Findings: 1. Review of the laboratory's procedures received via email on January 25, 2021 revealed the laboratory did not include a written procedure for performance verification studies. 2. In interview on January 21, 2021 at 10:20 am, the Testing Personnel (Owner) stated validation studies were not done for the Healgen test. 3. The testing personnel provided eighty eight (88) patient COVID antibody test results from January 2, 2021 through January 14, 2021. 4. The laboratory did not provide to the surveyor patient test records prior to January 2021 or the date the laboratory began performing COVID-19 patient testing.
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 laboratory's procedures, manufacturer package insert, patient

	log, and interview with personnel, the laboratory failed to perform positive and negative controls for the Healgen COVID-19 IgG/IgM Rapid Test Cassette. Findings: 1. Review of the laboratory's "Standard Operating Procedure" under "Controls" section revealed "Performed by all staff per Laboratory and manufacturer's recommendations on CLIA waived test kits. Documentation of control results maintained electronically for two years." 2. Review of the Healgen package insert provided by laboratory on January 21, 2021 "Revision Date: 2020-04-11" under "Quality Control" revealed "Control standards are not supplied with this kit." 3. Review of the Healgen package insert "Revision Date: 2020-5-2" under "Quality Control" section revealed the "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. Additional controls may be required according to guidelines or local, state, and/or federal regulations (such as 42 CFR 493.1256) or accrediting organizations." 4. In interview on January 21, 2021 at 10:47 am, the Testing Personnel (Owner) stated the test kits do not have controls. The Testing Personnel confirmed the laboratory did not perform external positive and negative controls on test kits. 5. The testing personnel provided eighty eight (88) patient COVID antibody test results from January 2, 2021 through January 14, 2021. 6. The laboratory did not provide to the surveyor patient test records prior to January 2021 or the date the laboratory began performing COVID-19 patient testing.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures, manufacturer's insert, patient log, and interview with personnel, the laboratory failed to document the internal control results for the Healgen COVID-19 IgG/IgM Rapid Test Cassette testing for eighty eight (88) of eighty eight (88) patients reviewed . Findings: 1. Review of the laboratory's "Standard Operating Procedure" under "Controls" section revealed "Performed by all staff per Laboratory and manufacturer's recommendations on CLIA waived test kits. Documentation of control results maintained electronically for two years." 2. Further review of the laboratory's "Standard Operating Procedure" under "Documentation" section revealed "Includes date, time, test, specimen source if applicable, client ID, results, testing personnel initials, test kit number and indication that internal controls were acceptable if applicable, legible. Results documented per procedure manual." 3. Review of the Healgen package insert under "Quality Control" revealed "A procedural control is included in the test. A red line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique." 4. The testing personnel provided eighty eight (88) patient COVID antibody test results from January 2, 2021 through January 14, 2021. 5. Review of the laboratory's patient log and results revealed the laboratory did not have documentation of the internal procedural control for the identified patients. 6. In interview on January 21, 2021 at 10:47 am, the Testing Personnel (Owner) stated the test kits do not have controls. The Testing Personnel confirmed the laboratory did not

	have documentation of controls. 7. The laboratory did not provide to the surveyor patient test records prior to January 2021 or the date the laboratory began performing COVID-19 patient testing.
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 direct observation by surveyor, record review, and interview with personnel, the laboratory failed to establish procedures to monitor, assess, and correct problems, identified with the analytic system. Findings: 1. Review of the laboratory's "Standard Operating Procedures" document received via email on January 25, 2021 revealed the laboratory did not include written quality assessment procedures to monitor the analytic system. 2. Further review of the laboratory's "Standard Operating Procedures" document revealed the laboratory included a blank "PROCEDURE MANUAL, ESTABLISHMENT AND VERIFICATION OF PERFORMANCE STANDARDS, CORRECTIVE ACTIONS, AND COMPARISON OF TEST RESULTS -- DATA COLLECTION FORM." The document had the following "Criteria" listed: "Procedure Manual, Establishment and Verification of Performance Standards, Corrective Action, and Comparison of Test Results." 3. The laboratory did not identify the following issues within the analytic system: a) The laboratory failed to establish a complete policy and procedure manual. Refer to D5401. b) The laboratory failed to establish a policy and procedure manual. Refer to D5403. c) The laboratory failed to have the procedures approved and signed by the Laboratory Director. Refer to D5407. d) The laboratory failed to monitor the room temperature of the laboratory where testing and supplies were stored per manufacturer requirements for the Healgen COVID-19 IgG/IgM Rapid Test Cassette. Refer to D5413. e) The laboratory failed to perform performance verification studies that included accuracy and precision studies for COVID testing on the Healgen COVID-19 IgG/IgM Rapid Test Cassette. Refer to D5421. f) The laboratory failed to perform positive and negative controls for the Healgen COVID-19 IgG/IgM Rapid Test Cassette. Refer to D5449. g) The laboratory failed to document the internal control results for the Healgen COVID-19 IgG/IgM Rapid Test Cassette testing for eighty eight (88) of eighty eight (88) patients reviewed. Refer to D5481.
D5800	POSTANALYTIC SYSTEMS CFR(s): 493.1290 Each laboratory that performs nonwaived testing must meet the applicable postanalytic systems requirements in 493.1291 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 postanalytic systems and correct identified problems as specified in 493. 1299 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by:

	Based on review of laboratory procedures and interview with personnel, the laboratory failed to ensure the overall quality of the postanalytic systems. Findings: 1. The laboratory failed to maintain documentation of patient final test reports for eighty eight (88) of eighty eight (88) patients reviewed. Refer to D5803. 2. The laboratory failed to include all required information on the final test report. Refer to D5805. 3. The laboratory failed to establish procedures to monitor, assess, and correct problems identified with the postanalytic system. Refer to D5891.
D5803	TEST REPORT CFR(s): 493.1291(b) Test report information maintained as part of the patient's chart or medical record must be readily available to the laboratory and to CMS or a CMS agent upon request. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures and interview with personnel, the laboratory failed to maintain documentation of patient final test reports for eighty eight (88) of eighty eight (88) patients reviewed. Findings: 1. Review of the laboratory's "Standard Operating Procedures" under "Results Notification" section revealed "All results given to client at time of testing. Positive results reviewed by MD /DO/NP." 2. In interview on January 21, 2021 at 10:50 am, the Testing Personnel (Owner) stated the results are written on the doctor's prescription pad and given to the patients. The patients are to give their results to their primary care physician. The Testing Personnel further stated the laboratory does not have documentation of final reports other than the patient log. 3. The testing personnel provided the surveyor with a Healgen test log of eighty eight (88) patient COVID antibody test results from January 2, 2021 through January 14, 2021. No test report was maintained by the laboratory for the eighty eight (88) patient COVID antibody tests on the Healgen test log. 4. The laboratory did not provide to the surveyor patient test records prior to January 2021 or the date the laboratory began performing COVID-19 patient testing.
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 the patient test report provided in the complaint and interview with personnel, the laboratory failed to include all required information on the final test report. Findings: 1. In interview on January 21, 2021 at 10:50 am, the Testing Personnel (Owner) stated the results are written on the doctor's prescription pad and given to the patients. The patients are to give their results to their primary care physician. The Testing Personnel further stated the laboratory does not have documentation of final reports other than the patient log. 2. Review of the test report

	provided to the CLIA Program in the complaint revealed the following handwritten script on a prescription pad: "The above client has tested reactive for COVID19 by way of IgG/IgM rapid testing. Recommend quarantine & retest. Any questions, please call." 3. The following information was not included on the patient test result: a) The test performed by the laboratory b) Specimen Source (whole blood, capillary sample, serum/plasma) c) The specific test result including, but not limited to: expected results of each immunoglobulin (IgG & IgM), corresponding manufacturer details for interpretation of results, use of manufacturer detailed terminology (positive, negative, invalid) for interpretation of results. d) Reference intervals, normal values or expected results e) Statement related to test kit use for Emergency Use Authorization (EUA) only 4. The testing personnel provided the surveyor with a Healgen test log of eighty eight (88) patient COVID antibody test results from January 2, 2021 through January 14, 2021. No test report was maintained by the laboratory for the eighty eight (88) patient COVID antibody tests on the Healgen test log. 5. The laboratory did not provide to the surveyor patient test records prior to January 2021 or the date the laboratory began performing COVID-19 patient testing.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures and interview with personnel, the laboratory failed to establish procedures to monitor, assess, and correct problems identified with the postanalytic system. Findings: 1. The laboratory failed to maintain documentation of patient final test reports for eighty eight (88) of eighty eight (88) patients reviewed. Refer to D5803. 2. The laboratory failed to include all required information on the final test report. Refer to D5805.
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, 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 D6013. 2. The Laboratory Director failed to ensure laboratory personnel performed testing as required. Refer to D6014. 3. The Laboratory Director failed to ensure that a quality control program was maintained to assure quality laboratory services were provided. Refer to D6020. 4. The Laboratory Director failed to ensure that a quality assessment (QA) program was established to assure the quality of laboratory services provided. Refer to D6021. 5. The Laboratory Director failed to ensure patient final test reports for the Healgen COVID-19 IgG/IgM Rapid Test Cassette included pertinent information. Refer to D6026. 6. The

	Laboratory Director failed to ensure three (3) Testing Personnel had appropriate training and education documentation and the Technical Consultant met experience requirements. Refer to D6029. 7. The Laboratory Director failed to ensure policies and procedures for assessing personnel competency were established and maintained. Refer to D6030. 8. The Laboratory Director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing process. Refer to D6031. 9. The Laboratory Director failed to provide written job descriptions for all laboratory personnel. Refer to 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 review of the laboratory's procedures and interview with personnel, the Laboratory Director failed to ensure performance verification studies were complete. Refer to D5421.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on direct observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed testing as required. Findings: 1. The laboratory failed to verify the accuracy of COVID-19 antigen IgG/IgM at least twice annually. Refer to D5217. 2. The laboratory failed to monitor the room temperature of the laboratory where testing and supplies were stored per manufacturer requirements for the Healgen COVID-19 IgG/IgM Rapid Test Cassette. Refer to D5413.
D6020	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 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 record review and interview with personnel, the Laboratory Director failed to ensure that a quality control program was maintained to assure quality laboratory services were provided. Findings: 1. The laboratory failed to perform positive and negative controls for the Healgen COVID-19 IgG/IgM Rapid Test Cassette. Refer to D5449. 2. The laboratory failed to document the internal control results for the Healgen COVID-19 IgG/IgM Rapid Test Cassette testing for eighty eight (88) of eighty eight (88) patients reviewed. Refer to D5481.
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 by surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was established to assure the quality of laboratory services provided. Findings: 1. The laboratory failed to establish procedures to monitor, assess, and correct problems, identified with the analytic system. Refer to D5791. 2. The laboratory failed to establish procedures to monitor, assess, and correct problems identified with the postanalytic system. Refer to D5891.
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 record review and interview with personnel, the Laboratory Director failed to ensure patient final test reports for the Healgen COVID-19 IgG/IgM Rapid Test Cassette included pertinent information. Findings: 1. The laboratory failed to maintain documentation of patient final test reports for eighty eight (88) of eighty eight (88) patients reviewed. Refer to D5803. 2. The laboratory failed to include all required information on the final test report. Refer to D5805.
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 record review and interview with personnel, the Laboratory Director failed to ensure three (3) Testing Personnel had appropriate training and education documentation and the Technical Consultant met experience requirements. Findings: 1. The laboratory failed to ensure the Technical Consultant met the experience qualifications for a Technical Consultant of moderate complexity testing. Refer to D6035. 2. The laboratory failed to provide documentation that three (3) of three (3) testing personnel met the educational requirements for performing moderate complexity testing. Refer to D6065. 3. The laboratory failed to have documentation of training of all personnel performing moderate complexity testing. Refer to D6066.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures for assessing personnel competency were established and maintained. Refer to D5209.
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, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing process. Findings: 1. The laboratory failed to establish a complete policy and procedure manual. Refer to D5401. 2. The laboratory failed to establish a policy and procedure manual. Refer to D5403. 3. The laboratory failed to have the procedures approved and signed by the Laboratory Director. Refer to D5407.
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 record review, the Laboratory Director failed to provide written job descriptions for all laboratory personnel. Findings: 1. Review of the laboratory's "Standard Operating Procedures" document received via email on January 25, 2021 revealed the laboratory did not have written job descriptions for the following personnel: Laboratory Director Clinical Consultant Technical Consultant Testing Personnel
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. Refer to D6035.
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or

	both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) 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; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: Based on review of the laboratory's CMS-209 form, personnel records, and interview with personnel, the laboratory failed to ensure the Technical Consultant met the experience qualifications for a Technical Consultant of moderate complexity testing. Findings: 1. Review of the laboratory's CMS- 209 (Laboratory Personnel Report) form received via email on January 25, 2021 revealed the Laboratory Director was listed as the Technical Consultant. 2. In interview on January 21, 2021 at 12:00 pm, the Testing Personnel (Owner) stated she did not know who the Technical Consultant was. 3. Review of the Laboratory Director's records on January 21, 2021 at 12:00 pm revealed the laboratory did not have documentation that the Laboratory Director had at least one (1) year of laboratory training or experience in the designated specialty of moderate complexity testing.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to provide documentation to ensure all testing personnel met education and training requirements. Findings: 1. The laboratory failed to provide documentation that three

	(3) of three (3) testing personnel met the educational requirements for performing moderate complexity testing. Refer to D6065. 2. The laboratory failed to have documentation of training of all personnel performing moderate complexity testing. Refer to D6066.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy 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; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on review of the laboratory's CMS-209 form and interview with personnel, the laboratory failed to provide documentation that three (3) of three (3) testing personnel met the educational requirements for performing moderate complexity testing. Findings: 1. Review of the laboratory's CMS- 209 (Laboratory Personnel Report) form received via email on January 25, 2021 revealed three (3) personnel listed as Testing Personnel. 2. In interview on January 21, 2021 at 12:00 pm, the Testing Personnel (Owner) stated the training documents and education for personnel was on the computer. The Testing Personnel further stated the computer the laboratory has was in use for virtual visits. 3. The surveyor on January 21, 2021 at 11:22 am requested via email personnel records. The surveyor also provided to the Testing Personnel (Owner) a paper "Document Request" list that included education and training documents for Testing Personnel. The surveyor was not provided documentation of personnel education records during the on-site survey.
D6066	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's CMS-209 form, procedures, and interview with personnel, the laboratory failed to have documentation of training of all personnel performing moderate complexity testing. Findings: 1. Review of the laboratory's CMS- 209 (Laboratory Personnel Report) form received via email on January 25, 2021 revealed three (3) personnel listed as Testing Personnel. 2. Review of the laboratory's "Standard Operating Procedures" document received via email on January 25, 2021 under "Staff Training" section revealed "New hire laboratory training with return demonstrations & 6 month review. Yearly procedure manual review and laboratory in-service including blood borne pathogen training. Staff informed of any

	lab changes by memo or meeting." 3. In interview on January 21, 2021 at 12:00 pm, the Testing Personnel (Owner) stated the training documents and education for personnel was on the computer. The Testing Personnel further stated the computer the laboratory has was in use for virtual visits. 4. The surveyor on January 21, 2021 at 11: 22 am requested via email personnel training records. The surveyor also provided to the Testing Personnel (Owner) a paper "Document Request" list that included education and training documents for Testing Personnel. The surveyor was not provided documentation of personnel training records during the on-site survey.
D8103	BASIC INSPECTION REQUIREMENTS CFR(s): 493.1773(b)(c)(d) (b) General Requirements. As part of the inspection process, CMS or a CMS agent may require the laboratory to do the following: (b)(1) Test samples, including proficiency testing samples, or perform procedures. (b)(2) Permit interviews of all personnel concerning the laboratory's compliance with the applicable requirements of this part. (b)(3) Permit laboratory personnel to be observed performing all phases of the total testing process preanalytic, analytic, and postanalytic). (b)(4) Permit CMS or a CMS agent access to all areas encompassed under the certificate including, but not limited to, the following: (b)(4)(i) Specimen procurement and processing areas. (b)(4)(ii) Storage facilities for specimens, reagents, supplies, records, and reports. (b)(4)(iii) Testing and reporting areas. (b)(5) Provide CMS or a CMS agent with copies or exact duplicates of all records and data it requires. (c) Accessible records and data. A laboratory must have all records and data accessible and retrievable within a reasonable time frame during the course of the inspection. (d) Requirement to provide information and data. A laboratory must provide, upon request, all information and data needed by CMS or a CMS agent to make a determination of the laboratory's compliance with the applicable requirements of this part. This STANDARD is not met as evidenced by: Based on interview with personnel and email correspondence, the laboratory failed to provide communication with Laboratory Director, copies of personnel records, and access to testing area to ensure the laboratory is in compliance with CLIA Regulations Part 493. Findings: 1. Surveyor was not allowed access to the laboratory testing area during the onsite survey on January 21, 2021. On January 21, 2021 at 10:39 am, the Testing Personnel (Owner) stated the nurse was doing virtual visits. No laboratory tour or observation of test performance was completed by the surveyor while onsite. 2. On January 21, 2021 surveyor sent via email a document request list at 11:22 am (duplicate emailed at 11:24 am). While onsite the surveyor gave the Testing Personnel (Owner) a second paper copy of a "Document Request" list. 3. On January 25, 2021, the laboratory provided the CMS-116, CMS-209, disclosure of ownership and laboratory policy manual to the surveyor by email. 4. The laboratory did not provide the following requested information at the time of the survey or after completion of the onsite survey: a) Testing Personnel Records (Education, Licensure, Competency /Training) b) Technical Consultant Personnel Records (education, license, competency and experience) c) Proficiency Test Records or twice a year verification of accuracy of moderate complexity testing d) Verfication of performance specifications for any new instrumentation and/or tests put in use e) Package Inserts for Quality Control material and Kit Tests f) Log for all patients that had Healgen testing g) Date the laboratory began performing moderate complexity testing h) Contact information for Laboratory Director 5. Surveyor arrived onsite on January 21, 2021 at 9:37 am. Surveyor asked the nursing personnel if the Laboratory Director was

	available. The nursing personnel stated the doctor was not in, he was doing virtual visits. Surveyor instructed the nursing personnel to contact the Laboratory Director and Laboratory Manager of onsite presence. 6. The CLIA State Agency made four (4) attempts to communicate with the Laboratory Director: a) January 25, 2021: Email to laboratory requesting Laboratory Director's contact information b) January 25, 2021: Phone call; message left c) February 2, 2021 : Email to Laboratory Director d) February 24, 2021 - Follow-up email to Laboratory Director 7. The Laboratory Director and laboratory did not respond to the State Agency's contact requests.