Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2066463	05/14/2021
Name of Provider or Supplier	**Street Address, City, State**	
Grace Er	10900 Gulf Freeway, #B102, Houston, 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 recertification survey was performed in response to complaint TX00374136. The laboratory failed to meet the following conditions of the CLIA regulations found at CFR 42 493.1 through 493.1780 resulting in the following IMMEDIATELY JEOPARDY findings: D5300 - 42 C.F.R. 493.1240 Condition: Preanalytic systems; D5400 - 42 C.F.R. 493.1250 Condition: Analytic systems; D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director; D6033 - 42 C.F.R. 493.1409 Condition: Laboratories performing moderate complexity testing; technical consultant; D6063 - 42 C.F.R. 493.1421 Condition: Laboratories performing moderate complexity testing; testing personnel; Complaint TX00374136 was substantiated. Laboratory provided a letter to state agency on 5/19/21 that abated the immediate jeorpardy. Testing is only performed per the manufacturer's instructions. The facility representative was given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit.
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: I. Based on review of the manufacturer's instructions, laboratory maintenance records from 2020 to 2021, and confirmed in interview, the laboratory failed to follow the manufacturer's instructions to document required maintenance for the Piccolo Xpress chemistry analyzer. Findings were: 1. Review of the Piccolo Xpress operation manual under Maintenance & Services revealed "clean the analyzer's external case and display at least weekly." 2. Review of the Piccolo Xpress Quality Assurance from September 2020 to April 2021 revealed no documentation of the 31 of 32 required

weekly maintenance. September 2020 October 2020 November 2020 December 2020 January 2021 February 2021 March 2021 April 2021 3.An interview with the testing person #1 on 5/14/21 at 0920 hours in the laboratory confirmed the above findings. II. Based on review of the manufacturer's instructions, laboratory quality control and patient test records from August 2020 to April 2021, and confirmed in interview, the laboratory failed to follow the manufacturer's instructions and document negative and positive controls for the Siemens Multistix for urinalysis. Findings were: 1. Review of the package insert for the Siemens Multistix 10SG reagent strips under quality control revealed "test positive and negative quality controls with new lots, new shipments of reagents, and when you open a new bottle of reagent strips. Test reagents monthly that are stored for more than 30 days." 2. Surveyor observations on 5/14/21 at 0930 hours in the laboratory revealed an opened Siemens Multistix 10SG reagent strips (lot 011082, exp 5/31/22) with no documentation of an opened date. 3. Review of the laboratory quality control records from August 2020 to April 2021 available revealed no documentation of the lot number when control were documented. 4. Review of the laboratory quality control records from August 2020 to April 2021 revealed no documentation of quality control for 4 of the 8 months reviewed. April 2021 December 2020 September 2020 August 2020 5. Random review of the laboratory patient test records from August 2020 to April 2021 revealed the laboratory performed 9 urinalysis patients. Refer to urinalysis patient alias list. 6. An interview with the testing person #1 on 5/14/21 at 1010 hours in the laboratory confirmed the above findings. He acknowledged that the laboratory should document the lot number and quality control performed. III. Based on manufacturer's instructions, surveyor observations, review of laboratory quality control and patient test records from May 2021, and confirmed in interview, the laboratory failed to follow the manufacturer's instructions and document at least one level of quality control each day of testing for the HemoCue glucose meter. Findings were: 1. Review of the package insert for the Hemocue Glucose 201 Microcuvettes and Glucose 201 analyzer under quality control revealed "the hemocue glucose 201 system must be verified on the days of testing using at least one level of commercially available controls." 2. Surveyor observations on 5/14/21 at 1050 revealed testing person # 16 performing a glucose analysis using the hemocue glucose analyzer. 3. Review of the laboratory quality control records from 2020 to 2021 revealed no documentation of at least 1 level of quality control for the hemocue on 5/14/21. 4. Review of the laboratory records revealed the laboratory reported glucose of 152. Refer to glucose patient alias. 5. An interview with testing person #1 on 5/14/21 at 1100 hours in the laboratory confirmed the above findings. IV. Based on review of the manufacturer's instructions, surveyor observations, laboratory and patient test records from 2020 to 2021, and confirmed in interview, the laboratory failed to follow the manufacturers instructions for storage of the AccessBio CareStart Covid-19 Antigen Rapid diagnostic test. Findings were: 1. Review of the package insert for the AccessBio CareStart Covid-19 Antigen Rapid diagnostic test (IFU-RCHM71-E Revision number: E, Effective date: Apr. 15, 2021) under storage and stability revealed "Store the test kit as packaged between 1 - 30C." 2. Surveyor observations on 5/13/21 at 1050 hours revealed a box of opened AccessBio CareStart Covid-19 Antigen Rapid diagnostic test stored in a cabinet in the check in area of the facility. 3. An interview with the testing person #3 on 5/13/21 at 1052 hours in the check in area confirmed that the test kits are stored in the front prior to use. 4. Review of the laboratory and patient records from January 2021 to May 2021 revealed the laboratory performed 724 Covid Antigen tests. 5. Review of the laboratory records from 2020 to 2021 revealed no documentation of the laboratory monitoring the temperature of the check in area. 6. An interview with the testing person #1 on 5/14 /21 at 0935 hours in the laboratory confirmed the above findings. V. Based on review of the manufacturer's instructions, surveyor observations, laboratory and patient test

	records from 2020 to 2021, and confirmed in interview, the laboratory failed to follow the manufacturers instructions to ensure training for 22 of 22 operators for the AccessBio CareStart Covid-19 Antigen Rapid diagnostic test. Findings were: 1. Review of the package insert for the AccessBio CareStart Covid-19 Antigen Rapid diagnostic test (IFU-RCHM71-E Revision number: E Effective date: Apr. 15, 2021) under conditions of Authorization for Laboratory revealed: "All operators using your product must be appropriately trained in performing and interpreting the results of your product, use appropriate personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling." 2. Review of the laboratory records revealed the laboratory started Covid-19 Antigen testing in 07 /2020. 3. Review of the laboratory records from 2020 to 2021 revealed no documentation of the training for 22 of 22 testing person for the AccessBio CareStart Covid-19 Antigen Rapid diagnostic test. 4. An interview with the testing person # 3 on 5/13/21 at 1410 hours in the break room confirmed the above findings. She stated that there were some videos that were provided but she didn't know if training was documented.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on a review of the American Proficiency Institute (API) proficiency testing records from 2020 to 2021, laboratory policy, and confirmed in interview, the laboratory failed to document the attestation to the routine integration of the samples into the patient workload using the laboratory's routine methods by the laboratory director and/or testing person for 3 of 7 test events reviewed. The findings were: 1. Review of the API proficiency test records from 2020 to 2021 revealed no documentation of the attestation to the routine integration of the samples into the patient workload using the laboratory's routine methods by the laboratory director and /or testing person for 3 of 7 test events reviewed. 2020 3rd event Hematology (Red Cell Count (RBC); Hematocrit (HCT); Hemaglobin (Hgb); White blood count (WBC); Platelet (PLT); and Cell ID) 2021 1st event Chemistry (Creatine kinase-MB (CK-MB)) 2021 1st event Hematology (Red Cell Count (RBC); Hematocrit (HCT); Hemaglobin (Hgb); White blood count (WBC); Platelet (PLT); and Cell ID) 2. Review of the laboratory policy Proficiency Testing signed by the laboratory director on 2/19/19 revealed "the attestation statement shall be signed and dated by testing personnel and the lab director at the time of testing." 3. An interview of testing person # 5 on 5/13/21 at 1520 hours in the break room confirmed the above findings.
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible

	case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: I. Based on review of the manufacturer's instructions, laboratory and patient test records from 2020-2021, and confirmed in interview, the laboratory failed to report 724 SARS-CoV-2 positive and negative Antigen test results as required by 400.200 for 73 of 73 days reviewed from 01/08/2021 to 5/14/2021. Findings were: 1. Review of the Instructions for Use for the AccessBio CareStart Covid-19 Antigen Rapid diagnostic test (IFU-RCHM71-E Revision number: E Effective date: Apr. 15, 2021) under CONDITIONS OF AUTHORIZATION FOR THE LABORATORY revealed "authorized laboratories using your product will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate." 2. Review of the laboratory test records from 2020 to 2021 revealed the laboratory started SARS-CoV-2 Antigen patient testing using AccessBio CareStart Covid-19 Antigen Rapid diagnostic test on 6/16/20. 3. Review of the Instructions for Use for the Sofia 2 Flu + SARS Antigen FIA test cassettes under CONDITIONS OF AUTHORIZATION FOR THE LABORATORY revealed "authorized laboratories using your product will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate." 4. Review of the laboratory test records from 2020 to 2021 revealed the laboratory started SARS-CoV-2 Antigen patient testing Sofia 2 Flu + SARS Antigen FIA test cassettes on 02/2021. 5. Review of the laboratory policies available revealed no documentation of a policy /procedure related to SARS-CoV-2 test reporting. 6. Review of the laboratory SARS-CoV-2 Antigen patient test records from 2021 revealed no documentation the laboratory reported 724 of 724 patient positive and negative test records for 73 of 73 days of testing. Refer to Covid Antigen Patient Alias list. 7. An interview with the testing person #1 on 5/14/21 at 1010 hours in the laboratory confirmed the above findings II. Based on review of the manufacturer's instructions, laboratory and patient test records from 2020-2021, and confirmed in interview, the laboratory failed to report 12 postive and negative SARS-CoV-2 Antibody test results as required by 42 CFR 493.41 and 493.1100(a) for 6 of 6 days reviewed from 01/08/2021 to 5/14/2021. Findings were: 1. Review of the Instructions for Use for the Healgen Covid-19 IgG /IgM Rapid Test cassette (Ref: GCCOV-402a, Revision 2020-5-2) under CONDITIONS OF AUTHORIZATION FOR THE LABORATORY revealed "authorized laboratories using your product will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate." 2. Review of the laboratory test records from 2020 to 2021 revealed the laboratory started SARS-CoV-2 IgG/IgM patient testing using Healgen Covid-19 IgG /IgM Rapid Test cassette on 6/16/20. 3. Review of the laboratory policies available revealed no documentation of a policy/procedure related to SARS-CoV-2 test reporting. 4. Review of the laboratory SARS-CoV-2 IgG/IgM patient test records from 2021 revealed no documentation the laboratory reported 12 of 12 postivie and negative patient test records for 6 of 6 days of testing. Refer to Covid Antibody Patient Alias list. 5. An interview with the testing person #1 on 5/14/21 at 1010 hours in the laboratory confirmed the above findings.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) 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. This STANDARD is not met as evidenced by: I. Based on review of the laboratory quality control records from 2020 to 2021, patient test records, and confirmed in interview, the laboratory failed to retain the INDIVIDUALIZED QUALITY CONTROL PLAN (IQCP) for the Quidel Triage testing for CKMB, Troponin, Myoglobin, and DDimer that reduced the frequency of quality control to once monthly. Findings were: 1. Review of the laboratory quality control records from September 2020 to May 2021 revealed the laboratory performed monthly quality control for the Triage CKMB, Troponin, Myoglobin, and DDimer testing. 4/29/21 CKMB, Myoglobin, TROP, DDimer level 1 lot 03661 level 2 lot 03673 4/01/21 DDimer Level 1 lot 03652 level 2 lot 03669 2/27/21 CKMB, Myoglobin, TROP, DDimer level 1 lot 03656 level 2 lot 03669 1/23/21 CKMB, Myoglobin, TROP, DDimer level 1 lot 03656 level 2 lot 03669 11/26/20 CKMB, Myoglobin, TROP, DDimer Level 1 lot 03653 Level 2 lot 03668 10/12/20 CKMB, Myoglobin, TROP, DDimer Level 1 lot 03652 level 2 lot lot 03664 (no DDimer) 9/19 /20 CKMB, Myoglobin, TROP, DDimer Level 1 lot 03553 level 2 lot 03664 2. Review of the laboratory records available revealed no documentation of the IQCP to reduce the frequency of quality control for the above testing to every 30 days. 3. Review of the CMS116 revealed the laboratory performed 1872 chemistry testing annually. 4. An interview with the testing person #1 on 5/14/21 at 1000 hours in the laboratory confirmed the above findings. He was unaware of where the IQCP was kept. 44698 II. Based on random review of the laboratory's quality control records for the Cell-Dyn Emerald hematology analyzer for 2021 and 2020, review of a random sampling of patient records and interview with the staff it was revealed the laboratory failed to retain documentation of background checks for the minimum required time of 2 years for 5 of 15 days reviewed. The findings were: 1. A random review of the Cell-Dyn Emerald hematology analyzer quality control records for 2021 and 2020 revealed the quality control performed included 3 levels of controls and background checks on each day of testing. 2. A random review of the laboratory's quality control records for the Cell-Dyn Emerald hematology analyzer revealed the laboratory performed quality control on the following days: 05/10/2021 04/26/2021 03/06/2021 05/07/2021 04/18/2021 02/27/2021 05/06/2021 04/07/2021 02/16/2021 05/05/2021 03 /23/2021 10/25/2020 05/04/2021 03/07/2021 09/22/2020 3. A further review of the quality control records for the Cell-Dyn Emerald hematology analyzer revealed the laboratory failed to retain documentation of the background checks for 5 of 15 days reviewed for days quality controls were performed. The missing documentation was from: 10/25/2020 02/16/2021 03/06/2021 03/07/2021 05/05/2021 4. A review of a random sampling of patient records revealed patient sample testing was performed on the following days: On 05/07/2021 samples tested for patients 01181992 and 07131992 On 05/06/2021 samples tested for patients10221976 and 12.17.1989 5. In an interview on 5/13/21 at 1300 hours in the laboratory, testing person number 3 (as listed on the CMS Form 209 and signed by the medical director on 05/13/2021) stated that he was unaware of having to retain background check records as it was part of the instrument startup. This confirmed the findings.
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years.

	This STANDARD is not met as evidenced by: Based on review of CMS report 155, laboratory policy, American Proficiency Institute (API) proficiency testing (PT) records from 2020 to 2021, and confirmed in interview, the laboratory failed to retain the proficiency testing records for 5 of 7 PT events reviewed. . Findings were: 1. The CMS report 155 showed PT event scores for the following test events: 2020 1st event Hematology 2020 1st event Chemistry 2020 2nd event Hematology 2020 2nd event Chemistry 2020 3rd event chemistry 2. Review of the laboratory policy Proficiency Testing signed by the laboratory director on 2/19/19 revealed "all records, reports, and corrective actions must be retained for 2 years." 3. A review of API proficiency testing (PT) records revealed no documentation of the PT records to include testing records, signed attestation statements, PT results and scores from the provider, documentation of review and records of any corrective actions for the above PT events. 4. An interview of testing person # 5 on 5/13/21 at 1520 hours in the break room confirmed the above findings. KEY: CMS- Center for Medicare and Medicaid Services
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 policy, personnel records from 2020 to 2021, and confirmed in interview, the laboratory failed to follow its policy to document the competency assessments for 1 of 1 technical consultant. Findings were: 1. Review of the laboratory policy Competency for the Technical Consultant signed 2/19/19 revealed "It is the policy of this lab for the laboratory director to assess the competency of the technical consultant every two years." 2. Review of the Competency Assessment for the Technical Consultant revealed the laboratory director assessed his competency in 02/2019. No documentation was available for review for the 02/2021 competency. 3. An interview with testing person #1 on 5/14/21 at 1330 hours in the laboratory confirmed the above findings.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on a review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records from 2020 and 2021, laboratory policy, and confirmed in interview, the laboratory failed to document the review of the results by the laboratory director or designee for 2 of 7 test events reviewed. The findings were: 1. A review of the laboratory API records from 2020 and 2021 revealed no documentation of the review of the results for 2 of 7 testing events. 2020 3rd event Hematology 2021 1st event Hematology 2. Review of the laboratory policy Proficiency Testing signed by the laboratory director on 2/19/19 revealed "testing

	personnel should review, sign and date the score sheets." 3. An interview of testing person # 5 on 5/13/21 at 1520 hours in the break room confirmed the above findings. She stated that the technical consultant may have them.
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, review of the laboratory's preanalytical studies, review of the laboratory policy, and review of patient records, the laboratory failed to meet the requirements for preanalytic systems, as evidenced by: 1. The laboratory failed to follow the manufacturer's instructions for specimen collection for Covid-19 antibody testing using the Healgen Covid-19 IgG/IgM Rapid Test cassette for all Covid antibody tests reviewed. Refer to D5311
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, laboratory and patient test records from 2020 to 2021, and confirmed in interview, the laboratory failed to follow the manufacturer's instructions for specimen collection for Covid-19 antibody testing using the Healgen Covid-19 IgG/IgM Rapid Test cassette for all Covid antibody tests reviewed. Findings were: 1. Review of the Instructions for Use for the Healgen Covid-19 IgG/IgM Rapid Test cassette (Ref: GCCOV-402a, Revision 2020-5-2) under specimen collection revealed "Covid-19 IgG/IgM Rapid test cassette (whole blood /serum/plasma) can be performed using either venous whole blood, serum or plasma. 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." 2. An interview with testing person #3 on 5/13/21 at 1010 hours in the laboratory confirmed that the laboratory used fingerstick blood for Covid Antibody testing using Healgen Covid-19 IgG/IgM Rapid Test cassette. 3. An interview with testing person #1 on 5/14/21 at 0940 hours in the laboratory confirmed that the laboratory used fingerstick blood for Covid Antibody testing using Healgen Covid-19 IgG/IgM Rapid Test cassette. 4. Review of the laboratory records available revealed no establishment studies for fingerstick blood for the Covid antibody testing using Healgen Covid-19 IgG/IgM Rapid Test cassette. 5. Review of the laboratory

	records from June 2020 to May 2021 revealed the laboratory has performed 1013 Covid Antibody testing. 6. An interview with the laboratory director via phone on 5/14 /21 at 1330 hours confirmed the above findings.
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: The laboratory did not have an effective mechanism by which to monitor & evaluate the overall quality of the analytic systems, to identify & correct problems for each specialty & subspecialty of testing performed by the laboratory in the following areas: Procedure manual (see D5403); Test systems (see D5413); verification studies (see D5421) and Control procedures (see D5441, D5447, D5449, D5469).
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 and patient test records from 2020 to 20201, laboratory policies, and confirmed in interview, the laboratory failed to include all required components of a procedure for 1 of 10 laboratory tests reviewed (Covid-19 IgG/IgM Rapid test cassette). Findings were: 1. Review of the laboratory test records from 2020 to 2021 revealed the laboratory started Covid-19 antibody patient testing using the EUA approved Healgen Covid-19 IgG/IgM Rapid Test Cassette on 6/16/20. 2. Review of the laboratory policies and procedures available revealed the laboratory used the manufacturer's Instructions for Use (IFU) as its procedure for Covid-19

	antibody testing. 3. Review of the IFU revealed no documentation of 5 of 14 required components for Covid-19 antibody testing: (1) Specimen acceptability and rejection criteria, (2) Step-by-step performance of the procedure (3) Control procedures. (4) Corrective action to take when control results fail to meet the laboratory's criteria for acceptability. (5) The laboratory's system for entering results in the patient record and reporting patient results 4. Review of the laboratory records from 2020 to 2021 revealed the laboratory has performed 1013 Covid Antibody patient testing. 5. An interview with the testing person # 1 on 5/14/21 at 0940 hours in the lab confirmed the above findings.
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 the manufacturer's instructions, laboratory and patient test records from 2020 to 2021, and confirmed in interview, the laboratory failed to monitor the storage and testing conditions when performing Covid Antibody testing using the Healgen Covid-19 IgG/IgM Rapid Test cassette for 23 of 23 days reviewed. Findings were: 1. Review of the Instructions for Use for the Healgen Covid-19 IgG/IgM Rapid Test cassette (Ref: GCCOV-402a, Revision 2020-5-2) under storage and stability revealed "the kit can be stored at room temperature or refrigerated (2-30 C)...this test should be performed at 15-30 C. If stored refrigerated, ensure that the pouch and buffer are brought to operating temperature before performing testing..humidity and temperature can adversely affect results (especially with an RH [relative humidity] over 80%)." 2. Review of the laboratory records from June 2020 to May 2021 revealed the laboratory started Covid Antibody testing on 6/16/20. 3. Surveyor observations on 5/13/21 at 1050 hours revealed a box of opened Healgen Covid-19 IgG/IgM Rapid Test cassette (lot 2006167EUA, exp 5/31/22) stored in a cabinet in the check in area of the facility. 4. An interview with the testing person #3 on 5/13/21 at 1052 hours in the check in area confirmed that the test kits are stored in the front prior to use. 5. Random review of the laboratory records from June 2020 to May 2021 revealed no documentation of the room temperature or relative humidity for 23 of 23 days reviewed 6/16/20 6/19/20 6/22/20 7/20/20 7/31/20 8/3/20 8/13/20 8/14/20 8/20 /20 9/1/20 9/4/20 9/21/20 10/8/20 10/10/20 10/22/20 11/6/20 11/16/20 12/1/20 12/15 /20 12/18/20 1/28/21 2/6/21 3/11/21 6. Review of the laboratory records for the above dates revealed the laboratory perform Covid Antibody testing without documentation of the room temperature or relative humidty. Refer to Covid Antibody Patient alias list. 7. An interview with the testing person #1 on 5/14/21 at 1020 hours in the laboratory confirmed the above findings.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other

	supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on surveyor's observation of the Cell-Dyn 18 Plus controls' storage, review of the Cell-Dyn 18 Plus controls' package insert and assay sheet, review of instrument's quality control report for the Cell-Dyn Emerald hematology analyzer and interview with the staff, it was revealed the laboratory failed to document the revised expiration dates of opened/in use controls. The findings were: 1. A review of the Cell-Dyn 18 Plus controls' package insert revealed "Once opened, containers can be used only for the number of days stated on the assay sheet." 2. A review of the Cell-Dyn 18 Plus controls' assay sheet for Lot # 1123 revealed "8 Consecutive-Day Open-Tube Stability". 3. Surveyor's observation of opened Cell-Dyn 18 Plus controls Lot # 1123 in the refrigerator revealed no documentation of open or revised expiration dates on the control vials. The laboratory had no way of monitoring the expiration date of the controls in use. 4. A review of the Cell-Dyn Emerald instrument's quality control report revealed Controls Lot # 1123 was in use starting on 05/05/2021. 5. In an interview on 5/13/2021 at 1315 hours in the laboratory testing person number 3 (as listed on the CMS Form 209 and signed by the medical director on 05/13/2021) stated the controls are good for 7 days from opening but did not know the open date. This confirmed the findings.
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 manufacturer's instructions, laboratory policy, laboratory and patient test records from 2020 to 2021, and confirmed in interview, the laboratory failed to document verification studies for Covid antibody testing using the Healgen Covid-19 IgG/IgM Rapid Test cassette. Findings were: 1. Review of the Instructions for Use for the Healgen Covid-19 IgG/IgM Rapid Test cassette (Ref: GCCOV-402a, Revision 2020-5-2) under intended use "testing is limited to laboratories certified under CLIA, 42 USC 263a, to perform moderate or high complexity tests." 2. Review of the laboratory policy Validation of a New Test System revealed "it is the policy of this lab to validate a new test system prior to using it to report patient results." 3. Review of the laboratory records from June 2020 to May 2021 revealed the laboratory started Covid Antibody testing on 6/16/20. 4. Review of the laboratory records revealed no documentation of the precision and accuracy studies for the Healgen Covid-19 IgG/IgM Rapid Test cassette. 5. Review of the laboratory patient test

	records from June 2020 to May 2021 revealed the laboratory performed 1013 Covid Antibody tests. 6. An interview with the testing person #1 on 5/14/21 at 1040 hours in the laboratory confirmed the above findings.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, laboratory policy, laboratory and patient test records from September 2020 to May 2021, and confirmed in interview, the laboratory failed to document required monthly maintenance for the CellDyn Emerald hematology instrument for 6 of 9 months reviewed. Findings were: 1. Review of the CellDyn Emerald Operator's Manual (9140853D, December 2009) under Preventive Maintenance Schedule revealed "cleaning the system with a bleach solution is performed monthly or as needed when a measurand is repeated rejected." 2. Review of the laboratory policy Instrument Operation and Maintenance signed by the laboratory director on 2/19/19 revealed "maintenance of each piece of laboratory instrumentation shall be in accordance with the manufacturer's recommendations. Document all maintenance performed on the test systems in use." 3. Review of the laboratory Lab To Do list from September 2020 to May 2021 revealed no documentation of the monthly cleaning for 6 of the 9 months reviewed. March 2021 January 2021 December 2020 November 2020 October 2020 September 2020 4. Review of the CMS116 revealed the laboratory performed 7560 hematology tests annually. 5. An interview with the testing person #1 on 5/14/21 at 1015 hours confirmed the above findings.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

	This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, laboratory policy, laboratory and patient test records from 2020 and 2021, and confirmed in interview, the laboratory failed to document the calibration verification for the CellDyn Emerald hematology analyzer every 6 months. Findings were: 1. Review of the CellDyn Emerald Operator's manual (9140850C, December 2009) under Section 6 Calibration revealed "calibration should be confirmed on a regular basis according to your laboratory's protocols...criteria should also be established for calibration verification. calibration criteria include: when indicated by quality control data; after major maintenance and service procedures; at least every 6 months" 2. Review of the laboratory policy Instrument Operation and Maintenance signed by the laboratory director on 2/19/19 revealed "calibration of all laboratory instruments will be very 6 months, every time there is a complete change in lot numbers, when controls don't give desires results, or when the instrument has had major maintenance or repairs." 3. Review of the laboratory records from 2020 to 2021 revealed documentation the laboratory performed calibration verification on 03/27/2020. No documentation of the calibration verification for September 2020 nor March 2021 were available for review. 4. Review of the CMS116 revealed the laboratory performed 7560 hematology tests annually. 5. An interview with the testing person #1 on 5/14/21 at 1020 hours in the laboratory confirmed the above findings.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory quality control records from 2020 to 2021 and confirmed in interview, the laboratory failed to have documentation of monitoring quality control values over time for Quidel Triage CKMB, Troponin, Myoglobin, and DDimer testing for 7 of 7 months reviewed. Findings were: 1. Review of the Triage quality control from 09/2020 to 05/2021 revealed no documentation of the laboratory monitoring the quality control values over time for the following 9 quality control lot numbers for the following analytes. CKMB, Myoglobin, TROP level 1 lot 03661 level 2 lot 03673 level 1 lot 03656 level 2 lot 03669 Level 1 lot 03653 Level 2 lot 03668 Level 1 lot 03652 Level 2 lot 03664 Level 1 lot 03553 DDimer level 1 lot 03661 level 2 lot 03673 level 1 lot 03656 level 2 lot 03669 Level 1 lot 03653 Level 2 lot 03668 Level 1 lot 03652 Level 1 lot 03553 2. Review of the CMS116 revealed the laboratory performed 1872 chemistry testing annually. 3. An interview with the testing person #1 on 5/14/21 at 1000 hours in the laboratory confirmed the above findings.

D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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 quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: I. Based on review of the laboratory and quality control records from September 2020 to May 2021 and confirmed in interview, the laboratory failed to document two controls of different concentrations for each day of testing for 8 of 8 days reviewed on the Quidel Triage analyzer for CKMB, Troponin, Myoglobin and/or DDimer. Findings were: 1. Random review of the Master log from September 2020 to May 2021 revealed the following 17 Cardiac and 19 DDimer patients were performed. Refer to Triage patient Alias list. 2. Review of the 23 of 25 dates with Triage patient testing revealed no documentation of the quality control to include 2 levels of differing concentrations for each day of patient testing. 9/08/20 - 1 patient for Cardiac 9/11/20 - 1 patient DDimer 9/12/20 - 1 patient for Cardiac, DDimer 9/14/20 - 1 patient DDimer 9/16/20 - 1 patient for Cardiac 9/17/20 - 1 patient for Cariac 9/21/20 - 1 patient Cardiac, DDimer 9/23/20 - 1 patient DDimer 9/24/21 - 1 patient Cardiac 3/16 /21 - 1 patient Cardiac, DDimer 3/20/21 - 1 patient Cardiac, DDimer 3/22/21 - 1 patient Cardiac, DDimer 3/23/21 - 1 patient Cardiac, DDimer 3/24/21 - 1 patient DDimer 3/27/21 - 1 patient DDimer 4/01/21 - 1 patient DDimer 4/04/21 - 1 patient Cardiac 4/08/21 - 2 patient Cardiac, 1 DDimer 4/19/21 - 1 patient Cardiac, DDimer 4 /25/21 - 1 patient Cardiac, DDimer 4/26/21 - 1 DDimer 4/27/21 - 2 patient Cardiac, 1 DDimer 5/03/21 - 2 patients DDimer 4. An interview with the testing person #3 on 5 /13/21 at 1350 hours in the break room revealed the laboratory performed the triage quality controls monthly. She was however unable to provide the IQCP to reduce the frequency of the quality control to every 30 days. She also acknowledged that the quality control was not performed consistently every 30 days and that it didn't always include all the analytes every month. Cross Refer to D3031. 44698
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, laboratory and patient test records from 2020 to 2021, and confirmed in interview, the laboratory failed to document an external positive and negative quality control each day of testing using the Healgen Covid-19 IgG/IgM Rapid Test cassette for 23 of 23 days reviewed. Findings were: 1. Review of the Instructions for Use for the Healgen Covid-19 IgG/IgM Rapid Test cassette (Ref: GCCOV-402a, Revision 2020-5-2) under quality control revealed "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 293.1256) or accrediting organizations." 2. Review of the laboratory records from June 2020 to May 2021 revealed the laboratory started Covid Antibody testing on 6/16/20. 3. Random review of the laboratory records from June 2020 to May 2021 revealed no documentation of a positive and negative quality control for 23 of 23 days reviewed for 1013 Covid Antibody tests performed. Refer to Covid Antibody Patient alias list. 6/16/20 6/19/20 6/22/20 7/20/20 7/31/20 8/3/20 8/13/20 8/14/20 8/20/20 9/1 /20 9/4/20 9/21/20 10/8/20 10/10/20 10/22/20 11/6/20 11/16/20 12/1/20 12/15/20 12 /18/20 1/28/21 2/6/21 3/11/21 4. Review of the laboratory records for the above dates revealed the laboratory performed 1013 Covid Antibody testing without documentation of quality control. Refer to Covid Antibody Patient alias list. 5. An interview with the testing person #1 on 5/14/21 at 1020 hours in the laboratory confirmed the above findings.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory policy, laboratory quality control records from September 2020 to May 2021, and confirmed in interview, the laboratory failed to verify the acceptability of 2 of 2 quality controls reviewed. A) Cell-Dyn 18 Plus Control B) Quidel Triage Total 5 control Findings were: 1. Review of the laboratory policy Quantitative control validations signed by the laboratory director on 2/19/19 revealed "it is the policy of this lab to validate quantitative controls prior to placing them into use for patient testing." 2. Review of the laboratory policy posted on the laboratory bulletin board New Lot Validation revealed "the new controls must be validated. Please perform and document overlapping controls when changing form an old lot number of controls to a new lot number of controls. Both the new and the old lot number of controls should be performed the same day. If both controls are within acceptable limits, [then] the new lot number of controls is considered validated." A) Cell-Dyn 18 Plus Control 3. Review of the CBC quality control records revealed the laboratory used Cell-Dyn 18 Plus Control. 4. Review of the laboratory CBC quality control from January 2021 to May 2021 revealed no documentation of the new lot validation of the following Cell-Dyn 18 Plus Control. lot 1123, exp 8/20/21 lot 1039, exp 5/28/21 lot 0349, exp 4/02/21 B) Quidel Triage Total 5 control 5. Review of the laboratory Triage quality control records from September 2020 to May 2021 revealed the following quality control lot number with no documentation of the new lot

	validation prior to use for the following analytes. CKMB, Myoglobin, TROP Level 1 lot 03553 lot 03652 lot 03653 lot 03661 lot 03656 Level 2 lot 03664 lot 03668 lot 03669 lot 03673 DDimer Level 1 lot 03553 lot 03652 lot 03653 lot 03656 lot 03661 level 2 lot 03664 lot 03669 lot 03668 lot 03673 6. Review of the CMS116 revealed the laboratory performed 1872 chemistry and 7560 hematology tests annually. 7. An interview with the testing person #1 on 5/14/21 at 1010 hours in the laboratory confirmed the above findings.
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 quality control records for the Cell-Dyn Emerald hematology analyzer for May of 2021, review of the laboratory's "Control Policy", review of patient records and interview with the staff, it was revealed the laboratory failed to ensure controls are acceptable prior to reporting patient results for 2 of 9 testing days reviewed. The findings were: 1.A review of the laboratory's quality control records for the Cell-Dyn Emerald hematology analyzer for May of 2021 revealed the laboratory ran 3 levels of controls (high, normal and low) each day of testing. 2.A review of the instrument's quality control report for controls' Lot # 1123 revealed that 2 of 3 control levels failed on 2 of 9 days patient samples were tested. The failures were: 05/06/2021 high (H1123) control and normal (N1123) control 05/07 /2021 high (H1123) control and normal (N1123) control 3.A review off the laboratory's "Control Policy" signed by the laboratory director on 2/19/19 revealed the policy included the statement "Most importantly, ensure that no patients are reported if controls are out of range" (page 66 of the policy). 4.A review of patient records revealed that patient samples were tested on both 05/06/2021 and 05/07/2021. The patients were: 10221976 tested on 05/06/2021 12.17.1989 tested on 05/06/2021 01181992 tested on 05/07/2021 07131992 tested on 05/07/2021 5.In an interview on 5 /13/2021 at 1125 hours in the laboratory testing person number 3 (as listed on the CMS Form 209 and signed by the medical director on 05/13/2021) stated that if controls fail the controls are repeated until at least two levels of controls pass, and that patients are not tested if quality controls fail. He said he was not aware of patient samples' testing after controls failed. This confirmed the findings.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b) (1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

	This STANDARD is not met as evidenced by: Based on review of laboratory's policies, random review of the laboratory's Cell-Dyn Emerald hematology analyzer's quality control reports for 2021 and 2020, review of the laboratory's patient testing Master Log and interview with the staff it was revealed the laboratory failed to document performance of corrective actions taken 16 of 16 instances when the instrument failed to meet performance standards for controls. The findings were: 1. Review of laboratory's Control policies signed by the medical director on 2/19/19 revealed policy stating: "It is the policy of this laboratory to do the following when controls are not within range: ...8. Ensure that all remedial action steps are documented." 2. Random review of the Cell-Dyn Emerald hematology analyzer's quality control reports for 2021 and 2020 revealed control failures without documentation of corrective actions as follows: High Level control H1123 failures on: 05/07/2021 05/06/2021 Normal level control N1123 failures on: 05/07/2021 05/06 /2021 Normal level control N1039 failures on: 05/05/2021 05/03/2021 04/07/2021 High level control H1039 failures on: 04/26/2021 04/07/2021 Low level control L1039 failures on: 05/05/2021 03/29/2021 05/03/2021 03/18/2021 04/01/2021 High level control H0181 failures on: 09/17/2020 09/12/2020 3. A review of the Laboratory's patient testing Master Log records revealed 18 patient samples were tested on days with control failures. Refer to CBC Alias List. 4. In an interview on 05 /13/2021 at 1315 hours in the laboratory testing person number 3 (as listed on the CMS Form 209 and signed by the medical director on 05/13/2021) stated that testing personnel does not document corrective action for failed controls since they repeat them until they fall in range. This confirmed the findings.
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 review of instrument verification records, review of patient final reports, and confirmed in interview, the laboratory director failed to provide overall management and direction of the laboratory. (refer to D6013 and D6020)
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 records and confirmed in interview, the laboratory director failed to ensure the laboratory documented complete verification studies in the specialty of Immunology. Refer to D5421
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 review of the laboratory quality control (QC) records and confirmed in interview, the laboratory director failed to ensure the laboratory maintained a quality control program. Refer to D5441, D5449 D5469
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 observation, review of laboratory records, manufacterer's instructions, quality control records and interview it was revealed that the technical consultant failed to provide the required technical oversight for the laboratory (refer toD6036, D6040, and D6042.)
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. This STANDARD is not met as evidenced by: Review of manufacturer's instructions, laboratory records, quality control records, and patient test reports, the Technical Consultant failed to provide technical and scientific oversight of the laboratory. Refer to D5311, D5403
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.

	This STANDARD is not met as evidenced by: Based on review of the laboratory records and confirmed in interview, the technical consultant failed to ensure the laboratory documented complete verification studies in the specialty of Immunology. Refer to D5421
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on review of the laboratory quality control (QC) records and confirmed in interview, the technical consultant failed to ensure the laboratory maintained a quality control program. Refer to D5441, D5447, D5469
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 review of the laboratory's submitted Form CMS-209, review of the laboratory's personnel records, and confirmed in interview, the laboratory failed to have documentation of education for 15 of 22 testing personnel. Refer to D6065
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 CMS-209 and personnel records from 2020 to 2021 and confirmed in interview, the laboratory failed to have documentation of 15 of 22

	testing personnel's education credentials required to perform moderate complexity testing prior to patient testing. Findings were: 1. A review of personnel records revealed that 15 of 22 testing personnel (TP) did not have documentation available, at the time of the survey, for proof of a high school diploma or equivalent to perform moderate complexity testing prior to patient testing. TP #2 (date of hire: 8/30/20) TP #3 (date of hire: 6/10/20) TP #5 (date of hire: 6/26/20) TP #6 (date of hire: 7/17/20) TP# 9 (date of hire: 7/7/2020) TP #10 (date of hire: 2/1/21) TP #11 (date of hire: 5/6 /21) TP # 12 (date of hire: 1/27/21) TP #16 (date of hire: 6/19/20) TP #17 (date of hire: 12/3/20) TP #18 (date of hire: 12/29/20) TP #19 (date of hire: 7/10/20) TP # 20 (date of hire: 2/10/21) TP #21 (date of hire: 2/10/21) TP # 22 (date of hire: 7/6/20) 2. An interview of the testing person #1 on 5/14/21 at 0945 hours in the laboratory confirmed the above findings. He also confirmed all testing persons performed nonwaived testing.
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 manufacturer's instructions, laboratory and patient test records from 2020 to 2021, and confirmed in interview, the laboratory failed to document training for the Covid-19 antibody testing using the Healgen Covid-19 IgG/IgM Rapid Test cassette for 22 of 22 testing personnel. Findings were: 1. Review of the Instructions for Use for the Healgen Covid-19 IgG/IgM Rapid Test cassette (Ref: GCCOV-402a, Revision 2020-5-2) under conditions of authorization for the laboratory revealed "all laboratory personnel using your product must be appropriately trained in immunoassay techniques and use appropriate laboratory and personal protective equipment when handling this kit and use your product in accordance with the authorized labeling. All laboratory personnel using the assay must also be trained in and be familiar with the interpretation of results of the product." 2. Review of the laboratory records from June 2020 to May 2021 revealed the laboratory started Covid Antibody testing on 6/16/20. 3. Review of the laboratory records from 2020 to 2021 revealed no documentation of the training for 22 of 22 testing person for the Healgen Covid-19 IgG/IgM Rapid Test cassette. 4. An interview with the testing person # 3 on 5/13/21 at 1410 hours in the break room confirmed the above findings. She stated that there were some videos that were provided but she didn't know if training was documented.