Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2130192	05/14/2021
Name of Provider or Supplier	**Street Address, City, State**	
Grace Er	1851 Pearland Parkway, Pearland, 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 TX00374137. 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 IMMEDIATE 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 TX 00374137 was substantiated. Laboratory provided a letter to state agency on 5/19/21 that abated the immediate jeopardy. 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 a review of the manufacturer's instructions for the Siemens Multistix Reagent Strips, a review of the laboratory's quality control records from January 2020 to April 2021, and staff interview, it was revealed the laboratory failed to have documentation of following the manufacturer's instructions for performing quality control testing for 10 of 16 months on the Siemens Multistix Reagent Strips for urinalysis testing from January 2020 to April 2021. Findings include: 1. A review of the manufacturer's instructions for the Siemens Multistix Reagent Strips (Document:

TN30516A, 06/2010) under the section titled 'Quality Control' revealed the following: "Test negative and positive controls when you first open a new bottle." 2. A review of the laboratory's quality control records from January 2020 to April 2021 for the Siemens Multistix Reagent Strips revealed the laboratory runs 2 levels of quality control material each month. 3. Further review of the laboratory's quality control records for each month revealed there is no documentation of the Multistix lot number for the following months, making it impossible to determine if the quality control was run per the manufacturer's instructions ("when you first open a new bottle"): January 2020 February 2020 March 2020 May 2020 July 2020 December 2020 January 2021 February 2021 March 2021 April 2021 4. An interview with testing person #1 (as indicated on the CMS 209 form) on 5/13/21 at 1:25 p.m. in the laboratory, after review of the records, confirmed the above findings. II. Based on a review of the Henry Schein One Step Plus Strep A Dipstick Test Instructional Insert, surveyor observation, a review of patient test records from May 2021, and staff interview, it was revealed that the laboratory failed to follow the manufacturer's instructions by using reagents from multiple kits for Strep A testing on 3 of 3 patient samples in May 2021. Findings include: 1. A review of the Henry Schein One Step Plus Strep A Dipstick Test Instructional Insert (document number 1156110502, 05/15/18) revealed the following: "Only use reagents provided in the kit". 2. Further review of the Henry Schein One Step Plus Strep A Dipstick Test Instructional Insert revealed each kit contained: - 50 Test dipsticks (2 cannisters of 25 test strips) - 2 Reagent A - 2 Reagent B 3. Surveyor observation of the laboratory on 5/13/21 at 9:30 a.m. revealed one kit of Henry Schein One Step Plus Strep A Dipstick Test lot number: STA0042071 expire: 4 /30/22. The following reagents were found inside the kit: - 1 vial containing 23 test dipsticks lot: STA0042053 exp: 3/31/22 - 1 vial containing 3 test dipsticks lot: STA0042053 exp: 3/31/22 - 1 vial containing 21 test dipsticks lot: STA0042053 exp: 3 /31/22 - 2 vials containing 25 test dipsticks lot: STA0042071 exp: 4/30/22 - 2 bottles of Reagent A lot: 20040014 exp: 6/30/22 - 1 bottle of Reagent A lot: 20040013 exp: 6 /30/22 - 3 bottles of Reagent B lot: 0040046 exp: 7/15/22 4. A review of patient test records from May 2021 revealed the laboratory ran the following 3 patient samples using the Henry Schein One Step Plus Strep A Dipstick Test kit with reagents from multiple test kits: Patient ID: 12232009 Run date: 5/12/21 Patient ID: 11151978 Run date: 5/12/21 Patient ID: 08142002 Run date: 5/12/21 5. An interview with testing person #1 (as indicated on the CMS 209 form) on 5/13/21 at 9:40 a.m. in the laboratory, after review of the records, confirmed the above findings. Key: exp = expiration date III. Based on a review of the Henry Schein One Step Plus Pro Mono Test Kit package insert, surveyor observation, a review of patient test records from April and May 2021, and staff interview, it was revealed that the laboratory failed to ensure reliable patient results when 1 of 1 patient's sample was tested for mononucleosis (mono) using the test device from one kit and expired developer solution from another manufacturer's mono kit. Findings include: 1. A review of the Henry Schein One Step Plus Pro Mono Test Kit package insert (document number 1156110502, 05/15/18) revealed the following: "Kit Contents: - 20 test devices - 1 developer solution" 2. Surveyor observation of the laboratory on 5/13/21 at 9:20 a.m. found 1 Henry Schein One Step Plus Pro Mono Test Kit (lot: 229M11A exp: 7/31/21) with an open date of 3/20/21. 3. Further review of the Henry Schein One Step Plus Pro Mono Test Kit revealed the following kit components inside: - 4 test devices lot: 229M11 exp: 9/30/21 - 1 bottle Consult Diagnostics Mononucleosis Developer Solution lot: 229C04091 exp: 2/28/21 *** The developer solution was a different manufacturer and expired.*** 4. A review of patient test records from April and May 2021 revealed the following patient was tested using the Henry Schein One Step Plus Pro Mono Test kit with the expired developer solution: Patient ID: 09021977 Mono test: negative 5. An interview with testing person #1 (as indicated on the CMS 209

	form) on 5/13/21 at 9:40 a.m. in the laboratory, after review of the records, confirmed the above findings. 44697 IV. Based on direct observation and review of manufacture's insert, temperature logs, patient COVID TEST KIT LOGs from 12/30 /20 to 3/23/21, and confirmed in an interview that the laboratory had no mechanism to follow the CareStart COVID-19 Antigen manufacturer's instruction for storage temperature requirement for 4 of 10 days. The findings were: 1. Direct observation of surveyor on 5/14/21 at 10:10 am revealed the CareStart COVID-19 Antigen test kit (Ref RCHM-02071, Lot# CH21A22, Expiration date: June 2021) stored in the receptionist area. 2. Review of CareStart COVID-19 Antigen manufacturer's insert revealed the storage requirement was "Store the test kit as packaged between 1- 30 C." 3. Review of temperature logs revealed the laboratory had no mechanism to monitor the storage temperature following manufacturer's instruction. 4. Review of patient COVID TEST KIT LOGs from 12/30/20 to 3/23/21 revealed 45 of 45 patient COVID nasal swabs/Antigen testing performed without documentation of storage temperatures. Refer to Patient Alias List for COVID Ag and Ab. 5. An interview with testing personnel#5 (TP#5) on 5/14/21 at 10:12 am in the receptionist area confirmed that the receptionist area was not monitoring the storage temperature.
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, review of patient test records from Feb 1, 2021 - May 12, 2021 and staff interview, it was revealed the laboratory failed to report 661 SARS-CoV-2 positive and negative Antigen test results as required by 400.200 for 75 of 75 days reviewed from February 1, 2021 to May 12, 2021. Findings include: 1. 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." 2. 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. 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 Antigen patient test records from February 1, 2021 to May 12, 2021 revealed no documentation the laboratory reported 661 of 661 patient positive and negative test records for 75 of 75 days of testing. Refer to Covid Antigen Patient Alias list. 5. An interview with the testing personnel number 1 (as listed on Form CMS 209) on 5/13/21 at 1010 hours in the laboratory confirmed the above findings II. Based on review of the manufacturer's instructions, review of patient test records from Febuary 1, 2021 to May 12, 2021, and staff interview, revealed the laboratory failed to report 20 postive and negative SARS-

	CoV-2 Antibody test results as required by 42 CFR 493.41 and 493.1100(a) for 14 of 14 days when testing occurred. 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 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 February 1, 2021 to May 12, 2021 revealed no documentation the laboratory reported 20 of 20 postivie and negative patient test records for 14 of 14 days of testing. Refer to Covid Antibody Patient Alias list. 5. An interview with the testing personnel number 1 (as listed on Form CMS 209) on 5/13/21 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: Based on a review of the laboratory's records and staff interview, it was revealed that the laboratory failed to retain documentation of the IQCP (Individualized Quality Control Plan) for the Alere Triage meter. Findings include: 1. A review of the laboratory's records revealed the laboratory failed to retain documentation of the IQCP for the Alere Triage meter to support the laboratory's reduction in the frequency of quality control testing to every 30 days for the following analytes: CK-MB (creatine kinase myocardial band) TNI (troponin) MYO (myoglobin) DDIM (d-dimer) 2. An interview with testing person #1 (as indicated on the CMS 209 form) on 5/14/21 at 10:40 a.m. in the laboratory, after review of the records, confirmed the above 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 proficiency tests (PT) records from 2019 to 2021, Proficiency Testing policy (2017), and confirmed in an interview revealed the laboratory failed to retain attestation sheets for 7 of 7 PT events. 1. Review of Proficiency Testing policy (2017) revealed "All records, reports, and corrective actions must be retained for 2 years." 2. Review of CMS155 report revealed the laboratory participated in the following events: 2019 Event 1 for both chemistry with a score 0f 100 and hematology with a score of 96 specialties 2019 Event 2 for both chemistry with a score 0f 100 and hematology with a score of 97 specialties 2019 Event 3 for both chemistry with a score 0f 100 and hematology with a score of 0 specialties 2020

	Event 1 for both chemistry with a score 0f 100 and hematology with a score of 100 specialties 2020 Event 2 for both chemistry with a score 0f 100 and hematology with a score of 80 specialties 2020 Event 3 for both chemistry with a score 0f 100 and hematology with a score of 95 specialties 2021 Event 1 for both chemistry with a score 0f 100 and hematology with a score of 96 specialties 3. Review of proficiency tests records revealed 7 of 7 PT events missing attestation sheets. 2019 Event 1 for both chemistry and hematology specialties 2019 Event 2 for both chemistry and hematology specialties 2019 Event 3 for both chemistry and hematology specialties 2020 Event 1 for both chemistry and hematology specialties 2020 Event 2 for both chemistry and hematology specialties 2020 Event 3 for both chemistry and hematology specialties 2021 Event 1 for both chemistry and hematology specialties 3. An interview with testing personnel#1 (TP#1) on 5/14/21 at 1035 on the phone confirmed the above findings.
D3039	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(5) Quality system assessment records. Retain all laboratory quality system assessment records for at least 2 years. This STANDARD is not met as evidenced by: Based on a review of the laboratory's Quality Assurance Plan, a review of the laboratory's quality assurance records from July 2019 to April 2021, and staff interview, it was revealed that the laboratory failed to retain documentation of performing quality assurance reviews for 21 of 21 months from July 2019 to April 2021. Findings include: 1. A review of the laboratory's Quality Assurance Plan revealed the laboratory will evaluate the following: - Patient test management - Quality control - Instrumentation - Proficiency Testing - Comparison of test results - Relationship of patient information to patient results - Personnel assessment - Communications - Laboratory Errors - Complaints "Our laboratory uses this Quality Assurance Program to improve the laboratory services we provide to our physicians and patients. We will perform a quality review at least monthly and review the results with the laboratory director or technical consultant for their approval. The record of our Quality Assurance reviews are filed with this plan and are available for review by the director, consultant, staff, and laboratory surveyors." 2. A review of the laboratory's quality assurance records revealed there was no documentation of the laboratory performing the quality assurance reviews for 21 of 21 months from July 2019 to April 2021. 3. An interview with testing person #1 (as indicated on the CMS 209 form) on 5/14/21 at 10:05 a.m. in the nurse's station, after review of the records, confirmed that the records were not available for review.
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 technical consultant (TC) competency assessment from 2017 to 2020, Competency assessment for technical consultant policy (2017), and confirmed

	in an interview revealed that the laboratory failed to follow its own policy to document competency assessment for 2020 for 1 of 1 technical consultant. The findings were: 1. Review of Competency Assessment for Technical Consultant policy (2017) 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 technical consultant competency assessments revealed the technical consultant was last assessed on 08/14/2018. 3. Confirmed with testing personnel#5 (TP#5) on 5/14/21 at 10:43 am in the lab confirmed technical consultant competency assessment for 2020 was not documented.
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 a review of the manufacturer's instructions, a review of the laboratory's records, and staff interview, it was revealed that the laboratory failed to monitor and evaluate the overall quality of the preanalytic systems. (Refer to D5311-I, II)
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: I. 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 December 2020 to May 2021 revealed the laboratory had performed 20 Covid Antibody testing. 6. An interview with the laboratory director via phone on 5/14 /21 at 1330 hours confirmed the above findings. 41687 II. Based on a review of the laboratory's policies, surveyor observation, a review of patient test records from May 2021, and staff interview, it was revealed that the laboratory failed to follow its policy 6 of 17 times for not documenting the time of collection on the patient's blood specimen tubes. Findings include: 1. A review of the laboratory's policy titled 'Specimen Collection and Handling' revealed the following: "Blood collection tubes should be labeled with the following: - Patient's name - Secondary ID - Time and date of collection - Initials of specimen collector" 2. Surveyor observation of the laboratory on 5/14/21 at 9:30 a.m., when looking through the specimen storage refrigerator, found the following 6 of 17 blood specimen tubes that did not include the time of collection: Patient ID: 12131973 Lithium heparin tube Patient ID: 04131958 EDTA tube Patient ID: 04131958 Lithium heparin tube Patient ID: 08261976 EDTA tube Patient ID: 08261976 Lithium heparin tube Patient ID: 02252005 EDTA tube 3. A review of the laboratory's patient test records from May 2021 revealed the following 4 patient samples were resulted when no collection time was documented: Patient ID: 12131973 Test: Comprehensive metabolic panel Resulted: 5/13/21 Patient ID: 04131958 Test: Complete blood count and Comprehensive metabolic panel Resulted: 5/11/21 Patient ID: 08261976 Test: Complete blood count and Comprehensive metabolic panel Resulted: 5/11/21 Patient ID: 02252005 Test: Complete blood count and D-Dimer Resulted: 5/9/21 4. An interview with testing person #1 (as indicated on the CMS 209 form) on 5/13/21 at 4:30 p.m. in the laboratory, after review of the records, 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: Based on a review of the manufacturer's instructions, a review of the laboratory's records, and staff interview, it was revealed that the laboratory failed to monitor and evaluate the overall quality of the analytic systems. Findings include: 1. The laboratory failed to follow the manufacturer's instructions for the collection of 6 of 6 patient's blood samples for testing in the laboratory. (Refer to D5411) 2. The laboratory failed to have documentation of temperature monitoring of the freezer for 7 of 12 months in 2020 where laboratory reagents were stored. (Refer to D5413 I) 3. The laboratory failed to document the refrigerator (MED) temperatures for 1 of 10 days where reagents used for cardiac panel patient testing were stored. (Refer to D5413 II) 4. The laboratory failed to document the revised expiration dates on 3 of 3 Cell-Dyn 18 Plus Control vials used for the Abbott Cell-Dyn Emerald hematology analyzer. (Refer to D5415) 5. The laboratory failed to ensure 3 of 3 quality control materials were not beyond the open tube stability prior to reporting patient results on

	the Abbott Cell-Dyn Emerald hematology analyzer. (Refer to D5417) 6. The laboratory failed to have documentation of performing 5 of 5 verification studies for SARS CoV-2 antibody testing using the Healgen COVID-19 IgG/IgM Rapid Test Cassette. (Refer to D5421) 7. The laboratory's maintenance records, and staff interview, it was revealed the laboratory failed to have documentation of performing required maintenance. (Refer to D5429 I) 8. The laboratory failed to have documentation of performing the required maintenance procedures on the Alere Triage meter. (Refer to D5429 II) 9. The laboratory failed to have documentation of perform calibration every six months. (Refer to D5437) 10. The laboratory failed to have a method in place to monitor quality control values over time to detect shifts and trends for 4 of 5 analytes tested on the Alere Triage meter. (Refer to D5441) 11. The laboratory failed to have documentation of running two levels of quality control material for each day of patient testing for 6 of 92 days in March 2021 to May 2021 on the Alere Triage meter. (Refer to D5447) 12. The laboratory failed to have documentation of performing quality control testing each day of patient testing for 14 of 14 days. (Refer to D5449) 13. The laboratory failed to verify new lot numbers of external quality control before placing them into use. (Refer to D5469) 14. The laboratory failed to document 6 of 10 days of corrective action when the temperature were out of range. (Refer to D5785)
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on a review of the manufacturer's instructions for the BD Vacutainer Blood Collection System, surveyor observation, a review of patient test records, and staff interview, it was revealed the laboratory failed to follow the manufacturer's instructions for the collection of 6 of 6 patient's blood samples for testing in the laboratory. Findings include: 1. A review of the manufacturer's instructions for the BD Vacutainer Blood Collection System (VDP40161-WEB-09 06/2019) revealed the following: "BD Vacutainer SST Tubes: Overfilling or under filling of tubes will result in an incorrect blood-to-additive ratio and may lead to incorrect analytic results or poor product performance." 2. Surveyor observation in the laboratory on 5/14/21 at 10: 00 a.m., when looking through the laboratory's sample storage refrigerator, found the following 6 patient samples where the tube was filled less than halfway: BD lavender top EDTA tube Patient ID: 03291955 BD lavender top EDTA tube Patient ID: 12061932 BD green top lithium heparin tube Patient ID: 12061932 BD lavender top EDTA tube Patient ID: 06041990 BD green top lithium heparin tube Patient ID: 09021977 BD green top lithium heparin tube Patient ID: 12051983 3. A review of the laboratory's patient test records revealed the laboratory used the underfilled samples to run the following laboratory tests: Patient ID: 03291955 Test: Complete Blood Count Run date: 5/10/21 Patient ID: 12061932 Test: Complete Blood Count, General Chemistry Panel Run date: 4/15/21 Patient ID: 06041990 Test: Complete Blood Count, Cardiac Panel, D-Dimer Run date: 4/3/21 Patient ID: 09021977 Test: Comprehensive Metabolic Panel Run date: 4/8/21 Patient ID: 12051983 Test: General Chemistry Panel Run date: 5/13/21 4. An interview with testing person #15 (as indicated on the CMS 209 form) on 5/14/21 at 10:20 a.m. in the laboratory, confirmed

	that sometimes patient's blood samples are hard to collect and as long as there is enough sample to run on the analyzer, they use the sample. This confirms 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: I. Based on a review of the laboratory's policies, a review of manufacturer's instructions, surveyor observation of storage conditions for the laboratory supplies, a review of the laboratory's freezer temperature logs from 2020, and staff interview, it was revealed the laboratory failed to have documentation of temperature monitoring of the freezer for 7 of 12 months in 2020 where laboratory reagents were stored. Findings include: 1. A review of the laboratory's policy titled 'Daily Laboratory Duties' revealed the following: "Morning Startup: - Read and record temperatures for all Laboratory Temperature Control devices (incubators, heat blocks, water baths, refrigerators, freezers). Evening Shutdown: - Ensure that all reagents are properly stored for the evening." 2. A review of the manufacturer's instructions for the Triage Total 5 Controls (26601 Rev A 05/2018) revealed the following storage requirements: "Store frozen at -20C or colder in a non-defrosting freezer." 3. Surveyor observation of the laboratory on 5/13/21 at 2:20 p.m., when looking through the freezer, found the following laboratory reagents: 1 box of Triage Total 5 Controls Lot: C3661AN exp: 11 /14/21 1 box of Triage Total 5 Controls Lot: C3673AN exp: 11/7/21 4. A review of the laboratory's Grace ER Refrigerator & Freezer Temperature Logs for 2020 revealed no documentation of the laboratory monitoring the temperature of the freezer for the following 7 months in 2020: June July August September October November December 5. An interview with testing person #1 (as indicated on the CMS 209 form) on 5/14/21 at 10:15 a.m. in the nurses station, after review of the records, confirmed the above findings. 44697 II. Based on review of Refrigerator & Freezer Temperature Log (MED) (Service Ref# H15371) from 2/1/21-5/13/21, patient results, Daily Laboratory Duties policy, and confirmed in an interview revealed that the laboratory failed to document the refrigerator (MED) temperatures for 1 of 10 days where reagents used for cardiac panel patient testing were stored. The findings were: 1. Review Refrigerator & Freezer Temperature Log (MED) revealed "Refrigerator needs to be at +36 to +46 F (2 to 8 C). +40F is the ideal temperature." 2. Random review of Refrigerator & Freezer Temperature Log (MED) from 2/1/21 to 5/13/21 revealed no temperature documentation for 1 of 10 days. 5/4/21 3. Review of Daily Laboratory Duties policy under Morning Startup section revealed "Read and record temperatures for all Laboratory Temperature Control devices (incubators, heat blocks, water baths, refrigerators, freezers)." 4. Random sampling of reagents in the Refrigerator (MED) for patient testing revealed the manufacturer's insert for storage environment is 2 to 8 C (35 to 46 F). Quidel Triage Cardiac Panel (Ref 97000HS, Lot# T11871N, Expiration date: 7/29/21) 5. Random review of patient results from 2/15/21 to 5/9/21, 1 of 1 patient cardiac panel testing was performed when the Refrigerator (MED)

	without temperature documentation. 5/4//21 Patient ID: 06071963 Cardiac tests ran time: 3:57 pm and 4:01 pm. 6. An interview with testing personnel #1 (TP#1) on 5/13 /21 at 12:30 pm in the lab confirmed the above findings. III. Based on review of Temperature and Freezer Log (LAB) (Service Ref# H14755) from 1/1/21-5/13/21, Daily Laboratory Duties Policy, manufacturer's package inserts, and confirmed in an interview that the laboratory failed to document the refrigerator temperatures for 7 of 10 days where reagents used for patient CBC testing were stored. The findings were: 1. Review Refrigerator & Freezer Temperature Log (LAB) revealed "Refrigerator needs to be at +36 to +46 F (2 to 8 C). +40F is the ideal temperature." 2. Random review of Refrigerator & Freezer Temperature Log (LAB) from 2/1/21 to 5/13/21 revealed 7 of 10 days without documentation of Refrigerator (LAB). 1/14/21 2/10/21 2 /20/21 3/13/21 3/21/21 4/26/21 5/7/21 3. Random sampling of reagents in the Refrigerator (LAB) for patient testing revealed the manufacturer's insert for storage environment is 2 to 10 C. Cell-DYN 18 Plus Control L (Ref 09H69L, Lot# L1039, Expiration date: 5/28/21) Cell-DYN 18 Plus Control N (Ref 09H69N, Lot# N1039, Expiration date: 5/28/21) Cell-DYN 18 Plus Control H (Ref 09H69H, Lot# H1039, Expiration date: 5/28/21) 4. Random review of patient results from 1/9/21 to 5/7/21, 7 of 10 patient CBC testing were performed when the Refrigerator (LAB) without temperature documentation. 1/14/21 Patient ID: 01061975 Test ran time: 12:03 am 2 /10/21 Patient ID: 09.21.1962 Test ran time: 9:40 pm 2/20/21 Patient ID: 09.15.1980 Test ran time: 6:26 pm 3/13/21 Patient ID: 08201957 Test ran time: 1:54 pm 3/21/21 Patient ID: 10171979 Test ran time: 6:19 am 4/26/21 Patient ID: 03161955 Test ran time: 1:29 am 5/7/21 Patient ID: 01251961 Test ran time: 3:46 pm 5. An interview with testing personnel#1 (TP#1) on 5/13/21 at 12:30 pm in the lab confirmed the above findings. IV. Based on direct observation and review of manufacture's insert, temperature logs, patient logs from 12/30/20 to 3/23/21, and confirmed in an interview that the laboratory had no mechanism to follow the Healgen COVID-19 IgG /IgM Rapid Test manufacturer's instruction for storage temperature requirement 5 of 10 days . The findings were: 1. Direct observation of surveyor on 5/14/21 at 10:10 am revealed the Healgen COVID-19 IgG/IgM Rapid Test (Ref GCCOV-4029, Lot# 2006167EUA, Expiration date: 5/31/2022) stored in the receptionist area. 2. Review of Healgen COVID-19 IgG/IgM Rapid Test manufacturer's insert revealed the storage requirement was "The kit can be stored at room temperature or refrigerated (2-30C)." 3. Review of temperature logs revealed the laboratory had no mechanism to monitor the storage temperature following manufacturer's instruction. 4. Review of Daily Laboratory Duties policy under Morning Startup section revealed "Read and record temperatures for all Laboratory Temperature Control devices (incubators, heat blocks, water baths, refrigerators, freezers). Also note and record room temperature." 5. Random review of patient logs from 12/30/20 to 3/23/21 revealed 7 of 10 patient testing performed without documentation of storage temperatures. Refer to Patient Alias List for COVID Ag and Ab. 6. An interview with testing personnel#5 (TP#5) on 5/14/21 at 10:12 am in the receptionist area confirmed that the receptionist area was not monitoring the temperature.
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 observation of the controls currently in use for the Abbott Cell-Dyn Emerald hematology analyzer, a review of the assay sheet for the Cell-Dyn 18 Plus Controls, and staff interview, it was revealed that the laboratory failed to document the revised expiration dates on 3 of 3 Cell-Dyn 18 Plus Control vials used for the Abbott Cell-Dyn Emerald hematology analyzer. Findings include: 1. Surveyor observation of the laboratory on 5/13/21 at 10:00 a.m. revealed the following 3 controls currently in use for the Abbott Cell-Dyn Emerald hematology analyzer: Cell-Dyn 18 Plus Control Low Level Lot: L1039 Open date: 5/3/21 Cell-Dyn 18 Plus Control Normal Level Lot: N1039 Open date: 5/3/21 Cell-Dyn 18 Plus Control High Level Lot: H1039 Open date: 5/3/21 2. A review of the Cell-Dyn 18 Plus Control Assay sheet (9231582B 350006-5, August 2018) indicated the open tube stability for the controls as 8 days. 3. An interview with testing person #1 (as indicated on the CMS 209 form) on 5/13/21 at 10:05 a.m. in the laboratory revealed that the laboratory does not write the revised expiration dates on the controls but that they are supposed to. This confirmed the above findings.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on a review of the Cell-Dyn 18 Plus Control assay sheet, surveyor observation, a review of patient tests records, and staff interview, it was revealed that the laboratory failed to ensure 3 of 3 quality control materials were not beyond the open tube stability prior to reporting patient results on the Abbott Cell-Dyn Emerald hematology analyzer. Findings include: 1. A review of the Cell-Dyn 18 Plus Control assay sheet (9231582B 350006-5, August 2018) revealed the following: "8 Consecutive-Day Open-Tube Stability". 2. Surveyor observation of the laboratory on 5 /14/21 at 10:20 a.m. revealed the following 3 controls currently in use for the Abbott Cell-Dyn Emerald hematology analyzer and the indicated open dates on each tube: Cell-Dyn 18 Plus Control Low Level Lot: L1039 Open date: 5/3/21 Cell-Dyn 18 Plus Control Normal Level Lot: N1039 Open date: 5/3/21 Cell-Dyn 18 Plus Control High Level Lot: H1039 Open date: 5/3/21 3. A review of patient test records revealed the following 2 patients were run for complete blood count (CBC) testing on the Cell-Dyn Emerald hematology analyzer when the controls were beyond the open stability date of 5/11/21: Patient ID: 12131973 CBC resulted: 5/13/21 Patient ID: 03011991 CBC resulted: 5/13/21 4. An interview with testing person #15 (as indicated on the CMS 209 form) on 5/14/21 at 10:20 a.m. in the laboratory, after review of the records, confirmed the above 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 a review of the laboratory's policies, a review of the laboratory's test menu, a review of the laboratory's records, and staff interview, it was revealed that the laboratory failed to have documentation of performing 5 of 5 verification studies for SARS CoV-2 antibody testing using the Healgen COVID-19 IgG/IgM Rapid Test Cassette. Findings include: 1. A review of the laboratory's policy titled 'New Procedure Policy' revealed the following: "If the lab starts a new procedure, please perform the following: Perform validation studies: - precision - accuracy - reportable limits - correlations - validate reference values" 2. A review of the laboratory's test menu revealed the laboratory started performing SARS CoV-2 antibody testing using the Healgen COVID-19 IgG/IgM Rapid Test Cassette in July 2020. 3. A review of the laboratory's records revealed the laboratory failed to have documentation of performing the 5 verification studies per the laboratory's policy to ensure accurate and reliable test results. 4. An interview with testing person #5 (as indicated on the CMS 209 form) on 5/14/21 at 10:00 a.m. in the laboratory stated, "We just started running patients using the kit, we did not do any studies." This 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: I. Based on review of the manufacturer's instructions for the Cell Dyn Emerald hematology analyzer, review of the laboratory's maintenance records, and staff interview, it was revealed the laboratory failed to have documentation of performing required maintenance. The findings were: 1. A review of the manufacturer's instructions for the Cell Dyn Emerald hematology analyzer (9140850C - December 2009) under the section titled "Preventative Maintenance" revealed: "Monthly Maintenance Bleach Cleaning Cleaning the system with a bleach solution is performed monthly or as needed when a measurand is repeatedly rejected. Semi-Annual Maintenance Lubricating the Pistons For optimal operation, the syringe pistons should be lubricated every six months." 2. A review of the laboratory's Cell Dyn Emerald maintenance records from March 2019 to April 2021 revealed the laboratory failed to have documentation of the following: a) Missing Monthly Maintenance (3 of 25 months) February 2021 March 2021 April 2021 b) Semi-Annual Maintenance Last documentation was done in February 2020 Thus, 2 semi-annual events were missed as of May 2021 3. The laboratory was asked to provide documentation of the missing maintenance. No documentation was provided. 4. An interview with testing personnel number 1 (as listed on Form CMS 209) on 05/13 /2021 at 1120 hours in the laboratory - after his review of the records- confirmed the findings. 41687 II. Based on a review of the Alere Triage MeterPro User Manual, a review of the laboratory's records, and staff interview, it was revealed that the laboratory failed to have documentation of performing the required maintenance procedures on the Alere Triage meter for 21 of 21 months from July 2019 to April

	2021. Findings include: 1. A review of the Alere Triage MeterPro User Manual (26213en Rev. E 2017/10) states the following preventative maintenance is required: "No maintenance other than paper / battery replacement and periodic external cleaning is required of the operator. The Alere Triage MeterPro requires minimal maintenance. Occasional cleaning of the exterior with mild soap and water solution is sufficient." 2. A review of the laboratory's records revealed the laboratory failed to have documentation of performing the required cleaning procedures on the Alere Triage meter (serial number 00075958) for 21 months from July 2019 to April 2021. 3. An interview with testing person #1 (as indicated on the CMS 209 form) on 5/13/21 at 4:30 p.m. in the laboratory, after review of the records, confirmed that they have never documented the cleaning of the Triage meter.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions for the Cell Dyn Emerald hematology analyzer, review of the laboratory's policies, review of the laboratory's calibration records, and staff interview, it was revealed the laboratory failed to have documentation of perform calibration every six months. The findings were: 1. Based on review of the manufacturer's instructions for the Cell Dyn Emerald (9140850-December 2009) under the section titled "When to Calibrate" revealed: "Calibration should be confirmed on a regular basis according to our laboratory's protocols." 2. A review of the laboratory's policy titled "Instrument Operation and Maintenance" (approved 10/28/2017) revealed: "Calibration of all laboratory instruments will be every six months..." 3. A review of the laboratory's calibration records for the Cell Dyn Emerald from March 2019 to May 2021 revealed the laboratory had documentation of performing calibrations at the following times: March 2019 October 2019 (seven months later) March 2020 (5 month later) 4. The laboratory failed to have documentation of performing calibration as of March 2020, thus 2 calibrations were not documented as being performed - September 2020 and March 2021. 5. The laboratory was asked to provide documentation of performing the missing calibrations. No documentation was provided. 6. An interview with testing personnel number 1 (as listed on Form CMS 209) on 05/13/2021 at 1138 hours in the laboratory revealed calibrations had not been performed since March 2020. This confirmed the 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 a review of the laboratory's quality control records for the Alere Triage meter from 2020 and 2021 and staff interview, it was revealed that the laboratory failed to have a method in place to monitor quality control values over time to detect shifts and trends for 4 of 5 analytes tested on the Alere Triage meter. Findings include: 1. A review of the laboratory's quality control records for the Alere Triage meter (serial number 00075958) from 2020 and 2021 revealed the laboratory ran the Alere Total 5 Controls, levels 1 and 2, every 30 days. 2. Further review of the quality control records from 2020 and 2021 revealed the laboratory failed to have a method in place for monitoring and evaluating quality control results over time for the following 4 analytes tested on the Alere Triage meter: CK-MB (creatine kinase myocardial band) TNI (troponin) MYO (myoglobin) DDIM (d-dimer) 3. An interview with testing person #5 (as indicated on the CMS 209 form) on 5/14/21 at 10:25 a.m. in the laboratory revealed the laboratory only assessed quality control values on the day they are run and did not monitor or evaluate values over time for shifts or trends. This 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: Based on a review of the laboratory's policies, a review of the laboratory's quality control records for the Alere Triage meter for March 2021 to May 2021, a review of patient test records, and staff interview, it was revealed that the laboratory failed to have documentation of running two levels of quality control material for each day of patient testing for 6 of 92 days in March 2021 to May 2021 on the Alere Triage meter. Findings include: 1. A review of the laboratory's policy titled 'Control Policy' revealed the following: "For quantitative testing, two levels of controls shall be run for every procedure on each day of use. Alternatively, IQCP (Individualized Quality Control Plan) will be implemented if the test system meets the criteria." 2. A review of the laboratory's quality control records for the Alere Triage meter from March 2021 to May 2021 revealed the laboratory failed to have documentation of running two levels of quality control material each day of patient testing for the following analytes: CK-MB (creatine kinase myocardial band) TNI (troponin) MYO (myoglobin) DDIM (d-dimer) 3. Further review of the laboratory's quality control records for the Alere

	Triage meter revealed the laboratory runs two levels of control material every 30 days. 4. Testing person #1 (as indicated on the CMS 209 form) was asked on 5/13/21 at 11: 00 a.m. to provide documentation of an IQCP defining the laboratory's quality control procedure for an alternate QC option (two levels every 30 days). No documentation was provided. (Refer to D3031) 4. A review of patient test records from March 2021 to May 2021 revealed the following 6 patient's samples were resulted on days when there was no documentation of two levels of quality control material run on the Alere Triage meter: Date: 5/13/21 Patient ID: 12221942 Date: 5/13/21 Patient ID: 12051983 Date: 5/11/21 Patient ID: 07081981 Date: 5/10/21 Patient ID: 12081952 Date: 4/14/21 Patient ID: 09081980 Date: 3/25/21 Patient ID: 02231976 5. An interview with testing person #1 (as indicated on the CMS 209 form) on 5/13/21 at 11:20 a.m. in the break room, after review of the records, confirmed the above findings. Key: QC = Quality Control
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 for the Healgen COVID-19 IgG /IgM Rapid Test Cassette, review of the laboratory's quality control records, review of patient test records, and staff interview, it was revealed the laboratory failed to have documentation of performing quality control testing each day of patient testing for 14 of 14 days. The findings were: 1. A review of the manufacturer's instructions for the Healgen COVID-19 IgG/IgM Rapid Test Cassette (Ref: CAT:GCCOV-402a) under the section titled "Quality Control" revealed: "Control standards are not supplied with this kit; howver, it is recommended that positive and negative controls be tested as a good laboraotry pracice 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 aorganizations." Thus, the laboratory was required to test external quality control each day of patient testing or develop and Individual Quality Control Plan. 2. A review of the laboratory's quality control records from July 2020 to April 2021 revealed the laboratory failed to have documentation of testing external controls each day of patient testing or of developing an Individual Quality Control Plan (IQCP) to modify the frequency of external control testing. 3. A review of patient test records from February 2, 021 to May 12, 2021 revealed the laboratory performed Healgen IgG/IgM testing on the following days: February 3, 2021 February 8, 2021 February 22, 2021 February 24, 2021 March 8, 2021 March 9, 2021 March 15, 2021 March 18, 2021 March 19, 2021 March 26, 2021 April 9, 2021 April 18, 2021 April 26, 2021 April 28. 2021 4. The laboratory was asked to provide documentation of testing external controls each day of patient testing or of establishing an IQCP to modify the required frequency of quality contol testing. No documentation was provided. 5. An interview with testing personnel number 1 (as listed on Form CMS 209) on 05/13/2021 at 1100 hours in the laboratory revealed the laboratory did not test external quality control material for the Healgen Covid-19 IgG/IgM Rapid Test Cassette. This confirmed the 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 a review of the laboratory's policies, a random review of the laboratory's quality control records from October 2020 to April 2021, and staff interview, it was revealed that the laboratory failed to verify new lot numbers of external quality control before placing them into use for the following analyzers: a) Abbott Cell-Dyn Emerald hematology analyzer b) Alere Triage meter. Findings include: 1. A review of the laboratory's policy titled 'Quantitative Control Validations' revealed the following: "It is the policy of this lab to validate quantitative controls prior to placing them into use for patient testing. New controls shall be run at least once a day for 5 days along with current controls." 2. A random review of the laboratory's quality control records from October 2020 to April 2021 revealed there was no documentation of the laboratory performing lot to lot verifications for the following lot numbers of external quality control materials: a) Abbott Cell-Dyn Emerald Cell-Dyn 18 Plus Control Low Level lot: L0237 expire: 12/11/20 Normal Level lot: N0237 expire: 12/11/20 High Level lot: H0237 expire: 12/11/20 Cell-Dyn 18 Plus Control Low Level lot: L1039 expire: 5/28/21 Normal Level lot: N1039 expire: 5/28/21 High Level lot: H1039 expire: 5/28/21 b) Alere Triage meter Alere Triage Total 5 Control Level 1 lot: C3552AN expire: 3/4/21 Level 2 lot: C3571AN expire: 2/1/21 Alere Triage Total 5 Control Level 1 lot: C3655AN expire: 6/12/21 Level 2 lot: C3665AN expire: 5/14/21 3. An interview with testing person #1 (as indicated on the CMS 209 form) on 5/13/21 at 11:20 a.m. in the break room, after review of the records, confirmed the above findings.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on review of Refrigerator & Freezer Temperature Log (MED) (Service Ref# H15371) from 2/1/21-5/13/21, patient results, Corrective Action Program policy, manufacture's insert, and confirmed in an interview revealed that the laboratory failed to document 6 of 10 days of corrective action when the temperature were out of range.

	The findings were: 1. Review Refrigerator & Freezer Temperature Log (MED) revealed "Refrigerator needs to be at +36 to +46 F (2 to 8 C). +40F is the ideal temperature." 2. Random review of Refrigerator & Freezer Temperature Log (MED) from 2/1/21 to 5/13/21 revealed 1 of 10 days the temperatures were out of range. 5/9 /21 10 C at 7am 5/9/21 9 C at 7 pm 3. Review of Corrective Action Program policy revealed "It is the policy of this lab to take corrective action whenever unexpected events occur and to document the actions taken to correct the unexpected results." 4. Random sampling of reagents in the Refrigerator (MED) for patient testing revealed the manufacturer's insert for storage environment is 2 to 8 C (35 to 46 F). Quidel Triage D-Dimer Test (Ref 98100, Lot# T12016N, Expiration date: 9/23/21) Quidel Triage Cardiac Panel (Ref 97000HS, Lot# T11871N, Expiration date: 7/29/21) 5. Random review of patient results from 2/15/21 to 5/9/21, 1 of 1 patient cardiac panel testing was performed when the Refrigerator (MED) temperature was out of range. 5/9 /21 Patient ID: 02252005 Cardiac tests ran time: 3:48 pm, 4:24 pm, and 4:54 pm. 6. An interview with testing personnel #1 (TP#1) on 5/13/21 at 12:30 pm in the lab confirmed the above 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 a review of the laboratory's records and staff interview, it was revealed that the laboratory director failed to provide overall management and direction for the laboratory. (Refer to D6013, 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 a review of the laboratory's records and staff interview, it was revealed that the laboratory director failed to ensure verification studies were performed on each test system. (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 a review of the manufacturer's instructions, a review of the laboratory's quality control records, and staff interview, it was revealed that the laboratory director failed to ensure a quality control program was established and maintained for the testing that the laboratory performs. (Refer to D5441, D5447, 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 a review of the manufacturer's instructions, a review of the laboratory's records, and staff interview, it was reavealed that the technical consultant failed to provide technical oversight for the laboratory. (Refer to D6036, D6040, D6042, D6054)
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. This STANDARD is not met as evidenced by: Based on a review of the manufacturer's instructions, a review of the laboratory's records, and staff interview, it was revealed that the technical consultant failed to provide technical and scientific oversight of the laboratory. (Refer to D5311, D5411)
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 a review of the laboratory's records and staff interview, it was revealed that the technical consultant failed to ensure the verification studies were performed on each test system. (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 a review of the manufacturer's records, the laboratory's quality control records, and staff interview, it was revealed that the technical consultant failed to establish a quality control program for the testing the laboratory performs. (Refer to D5441, D5447, D5449, D5469)
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: I. Based on review of annual competency assessments for testing personnel (TP) from 2018 to 2019, Technical Consultant Responsibilities policy (2017), and confirmed in an interview revealed the technical consultant (TC) failed to include 3 of 6 components in Cell-DYN annual competency for 1 of 1 TP (TP#4) in 2019. 1. Review of Technical Consultant Responsibilities policy (2017) revealed "The procedures for evaluation of the competency of the staff must include, but are not limited to: a. Direct observation of routine patient test performance, including patient preparation, if applicable, specimen handling, processing, and testing. b. Monitoring the recording and reporting of test results. c. Review of intermediate test results of worksheets, quality control records, proficiency testing results, and preventive 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 of external proficiency testing samples. f. Assessment of problem solving skills." 2. Review of annual competency assessments records from 2018 to 2019 revealed technical consultant (TC)failed to document 3 annual competency components for Cell-DYN in 2019 for 1 of 1 testing personnel (TP). TP#4, hired on 10/21/2015, missed the following sections of competency components in 2019 Cell-DYN annual competency assessment. 5. Assessment of problem solving skills 6. Evaluating and documenting the performance of individuals responsible for moderate complex testing 7. Able to perform tests without supervision 3. An an interview with a testing personnel#1 (TP#1) on 5/13/21 at 11:28 am in the lab confirmed the above findings. II. Based on review of annual competency assessments of Cell-DYN and Triage system for testing personnel (TP) from 2018 to 2019, Technical Consultant Responsibilities policy (2017), and confirmed in an interview revealed technical consultant (TC) failed to document for 3 of 3 TPs annual competency assessment for 2019. 1. Review of Technical Consultant Responsibilities policy revealed "...Thereafter, evaluations must be performed at least annually unless test methodology or instrumentation changes,...". 2. Review of annual competency assessments records from 2018 to 2019 revealed TC failed to document annual competency assessments in 2019 for 3 of 3 testing personnel (TP). TP#1, hired on 10 /20/2017 TP#7, hired on 11/13/2016 TP#8, hired on 9/16/2015 3. An an interview

	with a testing personnel#1 (TP#1) on 5/13/21 at 11:28 am in the lab confirmed the above findings. III. Based on review of annual competency assessments for testing personnel (TP) for 2020, Technical Consultant Responsibilities policy (2017), and confirmed in an interview the technical consultant (TC) failed to document 4 of 4 TPs annual competency assessment for 2020. 1. Review of Technical Consultant Responsibilities policy revealed "...Thereafter, evaluations must be performed at least annually unless test methodology or instrumentation changes,...". 2. Review of annual competency assessments records for 2020 revealed TC failed to document annual competency assessments in 2020 for 4 of 4 testing personnel (TP). TP#1, hired on 10 /20/2017 TP#4, hired on 10/21/2015 TP#7, hired on 11/13/2016 TP#8, hired on 9/16 /2015 3. An an interview with a testing personnel#1 (TP#1) on 5/13/21 at 11:28 am in the lab confirmed the above findings.
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: I. Based on review of the laboratory's personnel records and confirmed in an interview revealed the laboratory failed to have documentation of the education for 11 of 15 testing personnel (TP) to qualify them to perform moderate complexity testing (refer to D6065). II. Based on review of the laboratory's personnel records and confirmed in an interview revealed the laboratory failed to have documentation of trainings prior to perform the modrerate complexity testing (Cell-DYN hematology analyzer and Triage meter (SN#00075958) for 3 of 15 testing personnel (TP) (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 personnel records and confirmed in an interview revealed the laboratory failed to have documentation of the education for 11 of 15 testing personnel (TP) to qualify them to perform moderate complexity testing. The findings were: 1. Review of the laboratory's personnel records revealed the laboratory failed to have documentation of the education to qualify 11 of 15 testing personnel (TP) to perform moderate complexity testing (TP#2, TP#3, TP#5, TP#6, TP#9,

	TP#10, TP#11, TP#12, TP#13, TP#14, and TP#15). 2. Review of CMS-209, TP#2, TP#3, TP#5, TP#6, TP#9, TP#10, TP#11, TP#12, TP#13, TP#14, and TP#15 are listed as testing personnel (TP). 3. An interview with TP#1 on 5/14/21 at 1:05 pm in the Grace ER Gulf Freeway location breakroom confirmed the above finding.
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: I. Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's records, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of training for 15 of 15 testing personnel who performed COVID testing utilizing the Healgen test kit. The findings were: 1. A review of the laboratory's submitted Form CMS 209 revealed the laboratory identified 15 personnel who performed testing. 2. A review of the laboratory's records revealed the laboratory started performing moderate complexity COVID testing using the Healgen test kit in July 2020. 3. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of performing training for 15 of 15 testing personnel. 4. The laboratory was asked to provide documentation of training on the Healgen test kit. No documentation was provided. 5. An interview with testing personnel number 1 (as listed on Form CMS 209) on 05/13 /2021 at 1054 hours in the laboratory revealed testing personnel were instructed to read the package insert and start testing. This confirmed the findings. 44697 II. Based on review of the laboratory's personnel records, training records, and confirmed in an interview revealed the laboratory failed to have documentation of training records for 3 of 15 testing personnel (TP) prior to perform moderate complex testing for Cell-DYN hematology analyzer and Triage meter (SN#00075958). The findings were: 1. Review of the laboratory's personnel records and training records revealed the laboratory failed to have documentation of training records for 3 of 15 testing personnel (TP) prior to perform moderate complex testing (TP#11, TP#12, and TP#15). 2. Review of CMS-209, TP#11, TP#12, and TP#15 are listed as testing personnel (TP). 3. An interview with TP#1 on 5/14/21 at 1:05 pm in the Grace ER Gulf Freeway location breakroom confirmed the above finding.