Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0707586	06/03/2021
Name of Provider or Supplier	**Street Address, City, State**	
Gulf Coast Health Center, Inc	2548 Memorial Blvd, Port Arthur, 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	The laboratory was found out of compliance with the CLIA regulations. The conditions not met were: 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; 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.
D2089	ROUTINE CHEMISTRY CFR(s): 493.841(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3)The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on review of the laboratory policy, CMS national database, laboratory's American Proficiency Institute (API) proficiency testing records from 2019 to 2021, quality assurance records, testing records and confirmed in interview, the laboratory failed to participate for all analytes in the specialty of Chemistry for the second event of 2019. The findings were: 1. Review of the laboratory policy Proficiency Testing (LAB005, effective 1/20/20) under Testing/Service Interruptions revealed "In the event testing cannot be performed due to supplies, equipment or personnel changes Gulf Coast HC will notify the testing/survey agency via phone. Notifications should

	be made prior to the deadline of testing if at all possible." 2. A review of the CMS national proficiency testing database revealed a score of "0" for the specialty of Chemistry on the 2nd event of 2019 for this facility. 3. A review of the laboratory's API proficiency testing records for the second event of 2019 revealed the laboratory failed to participate in the proficiency testing and received a score of 0 NR (not reported) for 2019 Chemistry Core API 2nd event for the following 16 analytes: ALT, ALBUMIN, ALK PHOS, AST, TOTAL BILI, CA, TOTAL CL, CHOLESTEROL, HDL, CREATINE, GLUCOSE, K, NA, TOTAL PROTEIN, TRIGL, and BUN. 4. A review of quality assurance records for 2019 revealed the facility had not notified API nor the state agency that they had discontinued chemistry patient testing during the time period of non participation. Surveyor review of testing records confirmed no patient testing were performed from 05/2019 to 12/2020. Cross refer to 5215 5. An interview with the testing person #1 on 6/2/21 at 1135 hours in the conference 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 21 SARS-CoV-2 positive and negative Antigen test results as required by 400.200 for 5 of 5 days reviewed from 10/01/2020 to 6/3/2021. Findings were: 1. Review of the Instructions for Use for the Sofia 2 SARS Antigen FIA test cassettes (1438905EN00 (03/21)) 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 SARS Antigen FIA test cassettes on 01/20/21. 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 21 of 21 patient positive and negative test records for 5 of 5 days of testing (5/27/21, 2/26/21, 1/25/21, 1/20/21, 1/21/21). Refer to Covid Antigen Patient Alias list. 7. An interview with the testing person #1 on 6/3 /21 at 1425 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 4 postive and negative SARS-CoV-2 Antibody test results as required by 42 CFR 493.41 and 493.1100(a) for 3 of 3 days reviewed from 10/1/2020 to 6/3/2021. Findings were: 1. Review of the Instructions for Use for the Ecotest COVID-19 IgG/IgM Rapid Test Device cassette (Number:1110032033 REV1.4 Effective date: 2020-09-22) 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 Ecotest COVID-19 IgG/IgM Rapid Test Device on 1 /12/21. 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 4 of 4 postivie and negative patient test records for 3 of 3 days of testing (1/19/21, 1/14/21, 1/12/21). Refer to Covid Antibody Patient Alias list. 5. An interview with the testing person #1 on 6/3/21 at 1535 hours in the laboratory confirmed the above findings.
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 2019-2020, Competency Policy, and confirmed in an interview revealed that the laboratory failed to document 1 of 1 technical consultant (TC) competency assessment. The findings were: 1. Review of Competency Evaluation (Policy# LAB 104) under "Scheduling of Competency Tests" revealed "All employees are required to participate in the program annually and new employees semi-annually." 2. Review of technical consultant competency assessments from 2019-2020 revealed the laboratory had no documentation of competency assessment for technical consultant (TC). 3. Confirmed in an interview with testing personnel #1 (TP#1) on 6/3/21 at 3:08 pm in the lab confirmed technical consultant competency assessment was not documented.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on review of the CMS national database, 2019 to 2021 American Proficiency Institute (API) proficiency testing records, and confirmed in interview, the laboratory failed to verify the accuracy of their chemistry testing after receiving an artificial score of 100% for 4 of 7 of the chemistry proficiency testing events reviewed. Findings were: 1. Review of the CMS national database revealed the laboratory received "100" for all 16 analytes for 4 of 7 API testing events in 2019 to 2021. 2019 3rd event; 2020 1st, 2nd, 3rd events ALT (SGPT) ALBUMIN ALK PHOS AST (SGOT) BILI, TOTAL CA, TOTAL CL CHOLESTEROL, TOTAL CHOLESTEROL, HDL CREATINE GLUCOSE (NON-WAIVED) K NA TOTAL

	PROTEIN TRIGL BUN 2. Review of the laboratory API test records revealed the laboratory received "100" for Not Graded for the above 4 proficiency testing events for all 16 analytes. 2019 3rd event; 2020 1st, 2nd, 3rd events ALT (SGPT) ALBUMIN ALK PHOS AST (SGOT) BILI, TOTAL CA, TOTAL CL CHOLESTEROL, TOTAL CHOLESTEROL, HDL CREATINE GLUCOSE (NON-WAIVED) K NA TOTAL PROTEIN TRIGL BUN 3. An interview with the testing person #1 on 6/2/21 at 1135 hours in the conference room confirmed the above findings.
D5309	TEST REQUEST CFR(s): 493.1241(e) If the laboratory transcribes or enters test requisition or authorization information into a record system or a laboratory information system, the laboratory must ensure the information is transcribed or entered accurately. This STANDARD is not met as evidenced by: Review of patient test records, lab requests and interview of facility personnel found the laboratory failed to accurately enter collection times into the Laboratory Information System (LIS) correctly for seven of seven patient reports between March 2019 and January 2020. The findings included: 1. Review of seven patient reports randomly selected from dates between March 2019 and January 2020 found the collection times did not match the times entered on the requisition as follows: a. Patient 1105419 Collection Date 3/28/2019 9:27 AM Received Date 03/28/2019 9:27 AM b. Patient 1060078 Collection Date 3/20/2019 7:38 AM Received Date 03/20 /2019 7:38 AM c. Patient 1105112 Collection Date 3/18/2019 10:32 AM Received Date 3/18/2019 10:32 AM d. Patient 1059226 Collection Date 3/14/2019 9:32 AM Received Date 3/14/2019 9:32 AM e. Patient 1086800 Collection Date 4/5/2019 9:32 AM Received Date 4/5/2019 9:32 AM f. Patient 1110300 Collection Date 1/23/2020 8: 53 AM Received Date (not documented) g. Patient 1049942 Collection Date 1/23 /2020 1:34 PM Received Date (not documented) 2. Review of seven patient requisitions randomly selected from dates between March 2019 and January 2020 found the collection times did not match the times entered on the requisition as follows: a. Patient 1105419 Collection Date 3/26/2019 11:13 AM b. Patient 1060078 Collection Date 3/15/2019 6:32 PM c. Patient 1105112 Collection Date 3/11/2019 10: 36 AM d. Patient 1059226 Collection Date 3/14/2019 9:05 AM e. Patient 1086800 Collection Date 4/4/2019 1:50 PM f. Patient 1110300 Collection Date 1/23/2020 8:55 AM g. Patient 1049942 Collection Date 1/23/2020 1:34 PM 3. Interview of testing personnel conducted June 2, 2021 at 11:22 AM confirmed that the laboratory is supposed to enter the date and time of collection from the requisition into the LIS.
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 laboratory policy, surveyor observations, patient final reports, and confirmed in interview, the laboratory failed to follow its policy for specimen labeling for 3 of 4 patient specimens reviewed for chemistry testing on the Alfa Wassermann Ace Axcel chemistry analyzer. Findings included: 1. Review of the laboratory policy Labeling Specimen Tubes (LAB052, effective 8/21/18) revealed "a properly labeled specimen consists of patient's full name, date of birth, date of draw, intials of collector and time specimen was drawn." 2. Surveyor observations on 6/2/21 at 1535 hours in the laboratory revealed 3 of 4 patient specimens with no documentation of the collection date and time per the laboratory policy. Patient ID 67606 Patient ID 67607 Patient ID 67608 3. Review of patient final reports for 6/2/21 revealed the above patient specimens were analyzed and reported. 4. An interview with testing person #1 on 632/21 at 1500 hours in the laboratory confirmed the above findings. II. Based on review of the laboratory and patient test records from 2019 to 2021 and confirmed in interview, the laboratory failed to establish a policy and/or procedure that included the specimen acceptability and rejection for 16 of 16 chemistry analytes performed. Findings included: 1. Review of the laboratory records from 2019 to 2021 revealed the laboratory performed the following 16 chemistry analytes. ALBUMIN ALT (SGPT) ALK PHOS AST (SGOT) BILI, TOTAL CA, TOTAL CL CHOLESTEROL, TOTAL CHOLESTEROL, HDL CREATINE GLUCOSE (NON-WAIVED) K NA TOTAL PROTEIN TRIGL BUN 2. Random review of 14 ACE Alfa Wassermann package inserts revealed the following specimen stability: a. ACE Albumin (REF SA2001) under specimen collection, storage and handling revealed "specimen stable at 4 C for up to 72 hours and frozen at -20 C for 6 months or indefinitely at -70 C" b. ACE ALT (REF SA1052) under specimen collection, storage and handling revealed "specimen stable for 7 days at 4- 8 C and -20 C" c. ACE Alkaline Phosphatase (REF SA2002) under specimen collection, storage and handling revealed "specimen stable at 4 - 8 C and 2 months at -20 C" d. ACE AST (REFSA1053) under specimen collection, storage and handling revealed "specimen activity is stable for 28 days at 4 - 8 C and at least one year at -20 C." e. ACE Total Bilirubin (REF SA1008) under specimen collection, storage and handling revealed "specimen stable for 7 days refrigerated (4-8C) and for 6 months frozen (-20 C)." f. ACE Calcium-Arsenazo (REF SA1009) under specimen collection, storage and handling revealed "specimen stable for 7 days at 20-25C, 3 weeks at 4-8C, and 8 months at -20C." g. ACE HDL-C (REF SA1043) under specimen collection, storage and handling revealed " Specimen stable when stored in the refrigerator at 4C for 1 to 7 days." h. ACE BUN/Urea (REF SA2024) under specimen collection, storage and handling revealed "specimen stable for 7 days refrigerated (4-8C or frozen (-20 C) for 1 year." i. ACE Creatinine (REFSA1012) under specimen collection, storage and handling revealed "specimen stable for 7 days refrigerated (4-8C) and for 3 months frozen (-20 C)." j. ACE Cholesterol (REF SA1010) under specimen collection, storage and handling revealed "specimen stable for 7 days refrigerated (4-8C) and for 3 months frozen (-20 C)." k. ACE Direct Bilirubin (REF SA1007) under specimen collection, storage and handling revealed "specimen stable for 7 months refrigerated (4-8C) and for 6 months frozen (-20 C)." l. ACE Glucose (REF SA1014) under specimen collection, storage and handling revealed "specimen stable for 8 hours at 25 C, 72 hours at 4 C." m. ACE Total Protein (REFSA1022) under specimen collection, storage and handling revealed "specimen stable at 4 C for up to 72 hours and 6 months frozen (-20 C) or indefinitely at -70C." n. ACE Triglycerides (REFSA1023) under specimen collection, storage and handling revealed "specimen stable 4-7 days at 4C." 3. Review of the laboratory policy available revealed no documentation of the specimen acceptability and rejection for the above tests. 4. An interview with the testing person #1 on 6/3/21 at 1500 hours in the laboratory confirmed the above

	findings. III. Based on review of the laboratory and patient test records from 2019 to 2021 and confirmed in interview, the laboratory failed to establish a policy and/or procedure that included the specimen acceptability and rejection for 6 of 6 hematology analytes performed. Findings included: 1. Review of the laboratory records from 2019 to 2021 revealed the laboratory performed the following 6 hematology analytes. CELL I.D. OR WBC DIFF RBC HCT (NON-WAIVED) HGB (NON-WAIVED) WBC PLATELETS 2. Review of the laboratory policy available revealed no documentation of the specimen acceptability and rejection for the above tests. 3. An interview with the testing person #1 on 6/3/21 at 1500 hours in the laboratory confirmed the above findings. IV. Based on surveyor observations, review of manufacturer's instructions, laboratory and patient test records from 6/2/21, and confirmed in interview, the laboratory failed to establish the room temperature specimen stability for 13 of 16 analytes on the Alfa Wassermann ACE Axcel chemistry analyzer. Findings included: 1. Surveyor observations on 6/2/21 at 1535 hours in the laboratory revealed the laboratory stored 4 serum specimens for testing on the ACE Axcel chemistry analyzer at room temperature prior to testing. Patient ID 67606 Patient ID 67607 Patient ID 67608 Patient ID 67610 2. Random review of the package inserts for 13 of 16 analytes performed on the ACE Axcel chemistry analyzer revealed no documentation of the room temperature specimen stability. ACE Albumin Reagent (REF SA2001) ACE Total Protein (REF SA1022) ACE Alkaline Phosphatase (REF SA2002) ACE ALT (REF SA1052) ACE AST (REF SA1053) ACE BUN/Urea Reagent (REF SA2024) ACE Magnesium (REF SA2019) ACE Creatinine (REF SA1012) ACE Cholesterol (REF SA1010) ACE Direct Bilirubin (REF 1007) ACE Total Bilirubin (REF SA1008) ACE Glucose (REF SA1014) ACE Triglycerides (REF SA1023) 3. Review of the patient test records from 6/2/21 revealed the laboratory analyzed and reported the above 4 patient tests. 4. An interview with the testing person #1 on 6/3/21 at 1500 hours in the conference room confirmed the above findings. She confirmed that all specimens are stored at room temperature prior to analysis.
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 review of policies, test reports, quality control records, and manufacturer's instructions, the laboratory failed to meet the requirements for the analytic systems, as evidenced by: Findings were: 1.The laboratory failed to establish their own control means and acceptable ranges and failed to verify controls prior to use as instructed by the manufacturer. Refer to D5469 2. The laboratory failed to document two levels of quality control each day of patient testing for chemistry and hematology testing. Refer to D5447-I, II, III 3. The laboratory failed to have an effective quality control program in place to ensure the accuracy and reliability of patient test results for chemistry and hematology testing. Refer to D5441-I, II 4. The laboratory failed to document the

	required maintenance procedures on ACE Axcel for 30 of 30 daily maintenance, 10 of 10 weekly maintenance, and 5 of 5 months reviewed from January to May in 2021. Refer to D5429
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 review of the manufacturer's instructions, surveyor observations, laboratory quality control and patient test records from 06/2021, and confirmed in interview, the laboratory failed to ensure no control material was used beyond its revised expiration date for 3 of 16 analytes tested on the Alfa Wassermann ACE Axcel chemistry analyzer. Findings included: 1. Review of the package insert for the Alfa Wassermann Level 1 (lot 1501UNCM, exp 11/28/24) and Level 2 (lot 1166UECM, exp 11/28/24) chemistry controls (Ref C-4, Ref C-5) under storage and stability "reconstituted at 2-8 C (when stored tightly capped); ALP, ALT, and AST: 5 days; all other analytes: 7 days" 2. Surveyor observations on 6/3/21 at 1430 hours in the laboratory refrigerator an opened bottle of Level 1 and Level 2 of quality control with an opened date of "5 /26/21" lot 1501UNCM, exp 11/28/24 lot 1166UECM, exp 11/28/24 3. Review of the laboratory records revealed the laboratory used the above quality controls for ALP, ALT, and AST beyond the 5 day open stability on 6/2/21. 4. Review of the laboratory patient test records for 6/2/21 revealed the laboratory performed ALP, ALT, and AST for the following 5 patients: 67606; 67607; 67608; 67609, and 67610. 5. An interview with the testing person #1 on 6/3/21 at 1500 hours in the laboratory confirmed the above findings. She stated that she thought the open stability was 7 days.
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 a review of ACE Axcel Clinical Chemistry System Operator's Manual, review of the laboratory's maintenance records, patient records, and confirmed in an interview revealed the laboratory failed to document the required maintenance procedures on ACE Axcel for 30 of 30 daily maintenance, 10 of 10 weekly maintenance, and 5 of 5 months reviewed from January to May in 2021. The Findings were: 1. Review of ACE Axcel Clinical Chemistry System Operator's Manual (P/N 701417, Rev. E - 8/18) under page 268 revealed "The following preventive maintenance procedures are required for the system: Daily (DM-1) Remove Condensation from Reagent Compartment (DM-2) Daily Touchplate Cleaning (DM-3) Clean Exterior of Probe (DM-4) Clean Probe Alignment (DM-5) Clean and Condition ISE Weekly (WM-1) Clean ISE Sample Port (WM-2) Clean Exterior Surface of Instrument (WM-3) Inspect Air Filters and Clean if Necessary (WM-4) Weekly Touchplate Cleaning Monthly (MM-1) Rinse Probe and Fluid Lines with

	Bleach (MM-2) Clean Cap Assemblies (MM-3) Calibrate Table Offset, Sample Delay, and Optics (MM-4) Clean ISE Reference Housing" 2. Random review of the laboratory's maintenance records revealed the laboratory had no documentation of performing the required maintenance procedures on ACE Axcel for 30 of 30 daily maintenance, 10 of 10 weekly maintenance, and 5 of 5 months from January to May in 2021. Daily: 1/21/21 1/22/21 1/23/21 1/24/21 1/25/21 2/4/21 2/5/21 2/6/21 2/7/21 2 /8/21 2/18/21 2/19/21 2/20/21 2/21/21 2/22/21 3/4/21 3/5/21 3/6/21 3/7/21 3/8/21 3/25 /21 3/26/21 4/15/21 4/16/21 4/17/21 4/18/21 5/1/21 5/2/21 5/8/21 5/9/21 Weekly: 1/14 /21-1/18/21 1/21/21-1/25/21 2/4/21-2/8/21 2/11/21-2/15/21 2/18/21-2/22/21 3/4/21-3/8 /21 3/11/21-3/15/21 3/18/21-3/22/21 4/15/21-4/19/21 5/6/21-5/10/21 Monthly: January, 2021 Feburary, 2021 March, 2021 April, 2021 May, 2021 3. Random review of patient records from 4/7/21-5/24/21 revealed the following 60 patient testing without required maintenance procedures performed on Ace Axcel. 4/7/21 Patient: 1107133 Accession#: 67031 4/16/21 Patient: 1029730 Accession#: 66968 Patient: 1011111 Accession#: 66970 Patient: 1002262 Accession#: 66971 Patient: 1090689 Accession#: 66975 Patient: 1116181 Accession#: 66977 Patient: 1063254 Accession#: 66978 Patient: 1073004 Accession#: 66979 Patient: 1090712 Accession#: 66980 Patient: 1070425 Accession#: 66982 Patient: 1010521 Accession#: 66983 Patient: 1044549 Accession#: 66984 Patient: 1063526 Accession#: 66985 Patient: 1008429 Accession#: 66986 Patient: 1096740 Accession#: 66987 Patient: 1037812 Accession#: 66989 Patient: 1042881 Accession#: 66990 Patient: 1018924 Accession#: 66992 Patient: 1049641 Accession#: 66993 Patient: 1111901 Accession#: 67084 Patient: 1051441 Accession#: 67153 4/28/21 Patient: 1115583 Accession#: 67145 Patient: 1105831 Accession#: 67148 Patient: 1055545 Accession#: 67150 Patient: 1116251 Accession#: 67156 Patient: 1079811 Accession#: 67157 Patient: 1116365 Accession#: 67159 Patient: 1089726 Accession#: 67162 Patient: 1022997 Accession#: 67164 Patient: 1069069 Accession#: 67165 Patient: 1052284 Accession#: 67166 Patient: 1088646 Accession#: 67168 Patient: 1011626 Accession#: 67169 5/3/21 Patient: 1016017 Accession#: 67211 Patient: 1047319 Accession#: 67215 Patient: 1026992 Accession#: 67216 Patient: 1007556 Accession#: 67217 Patient: 1112244 Accession#: 67218 Patient: 1015607 Accession#: 67221 Patient: 1104257 Accession#: 67222 Patient: 1009775 Accession#: 67223 Patient: 1013200 Accession#: 67224 Patient: 1077168 Accession#: 67225 Patient: 1116456 Accession#: 67227 Patient: 1016979 Accession#: 67228 Patient: 1033050 Accession#: 67231 Patient: 1026969 Accession#: 67247 Patient: 1007849 Accession#: 67261 Patient: 1035515 Accession#: 67263 Patient: 1075795 Accession#: 67292 Patient: 1061940 Accession#: 67293 5/14/21 Patient: 1019149 Accession#: 67594 5/21/21 Patient: 1017637 Accession#: 67481 Patient: 1016962 Accession#: 67489 Patient: 1111010 Accession#: 67491 Patient: 1096740 Accession#: 67492 5/24/21 Patient: 1020935 Accession#: 67508 Patient: 1088589 Accession#: 67509 Patient: 1078179 Accession#: 67510 Patient: 1063146 Accession#: 67514 4. An interview with testing person #1 (TP#1) on 6/3/21 at 3:08 pm in the laboratory confirmed the above findings. Key: DM = Daily Maintenance WM = Weekly Maintenance MM = Monthly Maintenance
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: I. Based on review of the laboratory's procedures, quality control records and interview of facility personnel, the laboratory failed to have an effective quality control program in place to ensure the accuracy and reliability of patient test results for complete blood counts (CBC) using the Sysmex XP 300 (SN B1754). Findings included: 1. Review of the laboratory's own written procedure titled Laboratory Internal Quality Control (effective 1/15/2020) found on pate 1 under the heading Policy: "All procedures performed in the laboratory are controlled for both accuracy and precision. Control material must be retained (such as instrument tapes and package inserts) for at least two years. Results of quality control testing shall be reviewed daily by the laboratory testing personnel and at least monthly by the Manager or designee. All quality control results must be within established guidelines before patient results are released." 2. Review of Hematology quality control records for January 2020 found no documentation of the laboratory testing at least two levels of quality control materials on eight of thirteen dates when patient specimens were reported. a. January 2, 2020 b. January 3, 2020 c. January 6, 2020 d. January 7, 2020 e. January 9, 2020 f. January 13, 2020 g. January 14, 2020 h. January 16, 2020 Levy Jennings graphs (used to assess performance of quality control materials over time) were requested but not provided. 3. Interview of testing person conducted June 2, 2021 at 3:20 PM confirmed that there was no other documentation of quality control materials being tested in January of 2020. She stated that she cannot print any hematology quality control records from the analyzer or LabDaq. All the information she has available for review has been provided. She went on to say that she did not work during that time. She was on maternity leave. At 3:24 PM, she stated that she prints instrument printouts and gives those to the provider for review. 38387 II. Based on review of the laboratory quality control and patient test records from 2019 to 2021, and confirmed in interview, the laboratory failed to monitor over time the accuracy and precision for 5 of 5 quality control lot numbers for the Alfa Wassermann chemistry analyzer. Findings included: 1. Random review of the quality control data from 2019 and 2021 revealed the laboratory used the following 5 quality control lot numbers for the following 8 analytes Chol, Trig, NA, K, ALP, TP, Alb, CO2. lot 1213UNCM lot 1501UNCM lot 937UECM lot 677UECM lot 889UNCM 2. Review of the laboratory records available revealed no documentation the laboratory monitored over time the accuracy and precision of the above quality controls. 3. Random review of patient test records from 01/2019 to 03/2019 and 04/2021 to 05 /2021 revealed the laboratory performed 15 patient testing using the above quality controls for the 8 analytes: Chol, Trig, NA, K, ALP, TP, Alb, CO2. 1/09/19: 60191, 60196 1/22/19: 60414, 60415 2/06/19: 60739, 60740 2/12/19: 60748 3/05/19: 61270, 61268 5/20/21: 67433 5/21/21: 67467 4/21/21: 67046, 67047 4/22/21: 67068, 67069 4. An interview with the testing person #1 on 6/3/21 at 1500 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's procedure, patient test records, and interview of facility personnel, the laboratory failed to include and document two control materials of different concentrations at least once each day patient specimens were tested for complete blood counts (CBC) using the Sysmex XP 300 (SN B1754). Findings included: 1. Review of the laboratory's own written procedure titled Laboratory Internal Quality Control (effective 1/15/2020) found on pate 1 under the heading Policy: "All procedures performed in the laboratory are controlled for both accuracy and precision. Control material must be retained (such as instrument tapes and package inserts) for at least two years. Results of quality control testing shall be reviewed daily by the laboratory testing personnel and at least monthly by the Manager or designee. All quality control results must be within established guidelines before patient results are released." 2. Review of Hematology quality control records for January 2020 found no documentation of the laboratory testing at least two levels of quality control materials on eight of thirteen dates when patient specimens were reported. a. January 2, 2020 b. January 3, 2020 c. January 6, 2020 d. January 7, 2020 e. January 9, 2020 f. January 13, 2020 g. January 14, 2020 h. January 16, 2020 3. Review of patient test records found the laboratory tested 16 patient specimens for CBC between January 2, 2020 and January 16, 2020 without testing at least two levels of quality control material: a. January 2, 2020 - 2 patients tested and reported b. January 3, 2020 - 4 patients tested and reported c. January 6, 2020 - 1 patient tested and reported d. January 7, 2020- 2 patients tested and reported e. January 9, 2020- 1 patient tested and reported f. January 13, 2020- 1 patient tested and reported g. January 14, 2020- 1 patient tested and reported h. January 16, 2020- 4 patients tested and reported 4. Interview of testing person conducted June 3, 2021 at 1:12 PM confirmed that there was no other documentation of quality control materials being tested in January of 2020. She stated that she cannot print any hematology quality control records from the analyzer or LabDaq. All the information she has available for review has been provided. She went on to say that she did not work during that time. She was on maternity leave. 38387 II. Based on review of the laboratory quality control and patient test records from 04/2021 to 05/2021, and confirmed in interview, the laboratory failed to document two levels of quality control each day of patient testing for 2 of 5 days reviewed for chemistry testing on the Alfa Wassermann ACE Axcel chemistry analyzer. Findings included: 1. Random review of the quality control records from 04/2021 to 05/2021 revealed the following 2 of 5 days when no quality control was documented for the following analytes. 4/21/21 ALT TBILI TP HDL TRIG CHOL 5/21/21 CO2 CL K NA 3. Random review of the above dates revealed the laboratory analyzed and resulted for the above analytes for both dates with no quality control for the following 5 patients. 4/21/21: 67046; 67047 5/21/21: 67481; 67489; 67491 4. An interview with the testing person #1 on 6/3/21 at 1420 hours in the conference room confirmed the above findings. She stated that she was performing QC for ALP, ALT and AST every 5 days and the other analytes every 7 days. She was unaware QC was required every day of testing. 44697 III. Based on a review of the laboratory's policy, random review of the laboratory's quality control records for the ACE Axcel from April to May, 2021, review of patient test records,

	and confirmed in an interview revealed that the laboratory failed to have documentation of running two levels of quality control (QC) material for each day of patient testing for 7 of 10 days. The findings were: 1. Review of Laboratory Internal Quality Control (Policy#: LAB108) under 'For Quantitative Assays' revealed "At least two concentrations of analyte in matrix control materials are used where possible and clinical levels should reflect values encountered in patient specimens." 2. Random review of the laboratory's quality control records for ACE Axcel (SN# 20020507) from 4/7/21 to 5/24/21 revealed no documentation of two levels of quality control materials 7 of 7 days prior to patient testing for the following analytes: Cholesterol (CHOL) High Density Lipoprotein (HDL) Triglycerides (TRIG) Dates: 4/7/21 4/16 /21 4/28/21 5/3/21 5/14/21 5/21/21 5/24/21 3. Random review of the laboratory's quality control records for ACE Axcel (SN# 20020507) from 4/7/21 to 5/24/21 revealedno documentation of running two levels of quality control materials 4 of 7 days prior to patient testing for the following analytes: Glucose Dates: 4/7/21 5/3/21 5 /14/21 5/21/21 4. Random review of the laboratory's quality control records for ACE Axcel (SN# 20020507) from 4/7/21 to 5/24/21 revealed the no documentation of one level of quality control materials 3 of 7 days prior to patient testing for the following analytes: Glucose Dates: 4/16/21 5/28/21 5/24/21 5. Random review of patient test records from 4/7/21 to 5/24/21 revealed 60 of 60 patient's results for the above analytes were reported on days when there was no documentation of two levels of quality control material. Date: 4/7/21 Patient Accession#: 67031 Date: 4/16/21 Patient Accession#: 66968 Patient Accession#: 66970 Patient Accession#: 66971 Patient Accession#: 66975 Patient Accession#: 66977 Patient Accession#: 66978 Patient Accession#: 66979 Patient Accession#: 66980 Patient Accession#: 66982 Patient Accession#: 66983 Patient Accession#: 66984 Patient Accession#: 66985 Patient Accession#: 66986 Patient Accession#: 66987 Patient Accession#: 66989 Patient Accession#: 66990 Patient Accession#: 66992 Patient Accession#: 66993 Patient Accession#: 67084 Patient Accession#: 67153 Date: 4/28/21 Patient Accession#: 67145 Patient Accession#: 67148 Patient Accession#: 67150 Patient Accession#: 67156 Patient Accession#: 67157 Patient Accession#: 67159 Patient Accession#: 67162 Patient Accession#: 67164 Patient Accession#: 67165 Patient Accession#: 67166 Patient Accession#: 67168 Patient Accession#: 67169 Date: 5/3/21 Patient Accession#: 67211 Patient Accession#: 67215 Patient Accession#: 67216 Patient Accession#: 67217 Patient Accession#: 67218 Patient Accession#: 67221 Patient Accession#: 67222 Patient Accession#: 67223 Patient Accession#: 67224 Patient Accession#: 67225 Patient Accession#: 67227 Patient Accession#: 67228 Patient Accession#: 67231 Patient Accession#: 67247 Patient Accession#: 67261 Patient Accession#: 67263 Patient Accession#: 67292 Patient Accession#: 67293 Date: 5/14 /21 Patient Accession#: 67594 Date: 5/21/21 Patient Accession#: 67481 Patient Accession#: 67489 Patient Accession#: 67491 Patient Accession#: 67492 Date: 5/24 /21 Patient Accession#: 67508 Patient Accession#: 67509 Patient Accession#: 67510 Patient Accession#: 67514 4. An an interview with a testing personnel#1 (TP#1) on 6 /2/21 at 3:15 pm in the lab 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 manufacturer's instructions, laboratory quality control and patient test records from 2019 to 2021, and confirmed in interview, the laboratory failed to establish the acceptable ranges for 5 of 5 quality control lot numbers for the Alfa Wassermann chemistry analyzer. Findings included: 1. Review of the package insert for the Alfa Wassermann Level 1 (lot 1501UNCM, exp 11/28/24) and Level 2 (lot 1166UECM, exp 11/28/24) chemistry controls (Ref C-4, Ref C-5) under Assay Values revealed "Each laboratory should establish its own mean and precision parameters." 2. Random review of the quality control data from 2019 and 2021 revealed the laboratory used the following acceptable quality control ranges for the following 5 quality control lot numbers for the following 8 analytes Chol, Trig, NA, K, ALP, TP, Alb, CO2. lot 1213UNCM Chol: 101 - 115 Trig: 93 - 115 NA: 136 - 155.4 K: 3.82 - 4.48 ALP: 60 - 78 TP: 4.4 - 5.0 Alb: 2.9 - 3.5 CO2: 12.4 - 17.2 lot 1501UNCM Chol: 101 - 115 Trig: 93 - 115 NA: 128.5 - 146.9 K: 3.7 - 4.4 ALP: 57.2 - 74.8 TP: 4.4 - 5.0 Alb: 2.6 - 3.2 CO2: 12.9 - 16.9 lot 937UECM Chol: 198 - 226 Trig: 157 - 195 NA: 117.9 - 134.7 K: 6.75 - 7.41 ALP: 341- 445 TP: 6.9 - 7.9 Alb: 4.1 - 4.9 CO2: 27.9 - 36.5 lot 677UECM Chol: 198 - 226 Trig: 157 - 195 NA: 117.9 - 134.7 K: 6.75 - 7.41 ALP: 341 - 445 TP: 6.9 - 7.9 Alb: 4.1 - 4.9 CO2: 27.9 - 36.5 lot 889UNCM Chol: 101 - 115 Trig: 93 - 115 NA: 136 - 155.4 K: 3.82 - 4.48 ALP: 60 - 78 TP: 4.4 - 5.0 Alb: 2.9 - 3.5 CO2: 12.4 - 17.2 3. Review of the laboratory records available revealed no documentation the laboratory established the above quality control ranges. 4. Random review of patient test records from 01/2019 to 03/2019 and 04/2021 to 05/2021 revealed the laboratory performed 15 patient testing using the above quality controls for the 8 analytes: Chol, Trig, NA, K, ALP, TP, Alb, CO2. 1/09 /19: 60191, 60196 1/22/19: 60414, 60415 2/06/19: 60739, 60740 2/12/19: 60748 3/05 /19: 61270, 61268 5/20/21: 67433 5/21/21: 67467 4/21/21: 67046, 67047 4/22/21: 67068, 67069 5. An interview with the testing person #1 on 6/3/21 at 1500 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 policy, review of the laboratory quality control records from 04/2019 to 10/2019, and confirmed in interview, the laboratory failed to ensure quality control were acceptable prior to reporting patient test results for 5 of 10 days reviewed for the analytes ALT and/or AST on the Alfa Wasserman ACE Alera chemistry analyzer. Findings included: 1. Review of the laboratory policy Laboratory Internal Quality Control (LAB108, effective 1/15/2020) under Daily Decision revealed "approximately 95% of all control values should fall within a range of X +/-

	2 SD. ...The decision whether to accept or reject a run is based on the set of rules developed by Dr. James Westgard et al. Westgard Rules Observed in the Facility: 1.2s = outside 2 sd. On both two level and three level controls, only one level can be >2sd > 3sd 1.3s = outside 3sd. Reject Run 4.1s = Four consecutive control observations exceed the same 1 SD limit. probable causes are problems with standards or calibration of instrument IF the run is rejected using these rules then: A. Hold patient results B. Repeat the patient and controls. If the repeated run is within acceptable limits patient results can be reported. C. If the repeated run is rejected, use fresh controls and repeat B... E. Document any out of control problems with their solution and outcome." 2. Random review of quality control records from 04/2019 to 10/2019 revealed the following 5 of 10 days when 2 levels of quality control were outside of the acceptable ranges for ALT and/or AST with no documentation of the corrective action. 4/12/19 lot 677UECM ALT: 91 (acceptable range 95-125) lot 889UNCM ALT: 32 (acceptable range 35-47) 4/15/19 lot 889UNCM ALT: 33 (acceptable range 35-47) AST: 34 (acceptable range 38-50) lot 677UECM ALT: 84 (acceptable range 95-125) AST: 142 (acceptable range 159-209) 4/16/19 lot 889UNCM ALT: 31 (acceptable range 35-47) lot 677UECM ALT: 84 (acceptable range 95-125) 4/30/19 lot 889UNCM ALT: 32 (acceptable range 35-47) lot 677UECM ALT: 85 (acceptable range 95-125) 5/1//19 lot 889UNCM ALT: 31 (acceptable range 35-47) lot 677UECM ALT: 77 (acceptable range 95-125) 3. Review of the above dates revealed the laboratory performed ALT and/or AST for the following patients. 4/12/19: 61967; 61969; 61970; 61971 4/15/19: 61981; 61982; 61983; 61984 4/16/19: 62001; 62002; 62003; 62004 4/30/19: 62170; 62172; 62175; 62179 5/01/19: 62188; 62193; 62196; 62199 4. An interview with the testing person #1 on 6/3/21 at 1420 hours in the conference room confirmed the above findings
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Review of the Quality Management Policy (dated01/15/2020), monthly quality assurance reports between January 2020 and January 2021 and interview of facility personnel found the laboratory failed to have an effective process in place to monitor, identify and correct problems identified in the analytic systems. The findings included: 1. Review of the Quality Management Program Policy found under heading IV - Program Authority: "Information is continuously gathered and evaluated from reports, copies of reported results, patient charts, occurence reports, corrective action worksheets, instrument maintenance records, quality control results, and/or employee in-service records. A quarterly QI report is prepared from information and statistics obtained from these sources. The report is to be reviewed by the Laboratory Director and findings forwarded to the appropriate committees, if necessary. As part of the overall quality improvement of analytical variations, all temperature/maintenance logs and quality control data will be monitored daily by the laboratory manager and reviewed monthly by the Laboratory Director. Problems will be resolved on a daily basis and actions documented on the respective "action log". Proficiency testing results will be evaluated upon receipt by the Laboratory Manager. Unacceptable results will be investigated and problems resolved. Corrective actions taken will be

documented on the survey form, and submitted to the designee for review. All statistics and continuous monitors will be evaluated and reported each month. Selection of critical indicators will be determined as problems are identified by occurence reports and/or Laboratory Icident reports, but at least one Category I critical indicator will be evaluated each quarter. Critical indicators will be categorized as follows: (Critical indicators will be added or deleted as necessary.) A. Category I Critical indicators - any situation or problem that directly affects patient care/safety or employee safety. B. Category II Critical Indicators - any situation or problem that may indirectly affect patient care/safety or employee safety. C Category III Critical Indicators - any situation or problem that does not affect the patient or employee welfare, but may affect optimal operation of the laboratory and/ or facility." 2. Review of the 13 quality assurance reports between January 2020 and January 2021 found the technical consultant had identified multiple issues with the quality control program with no corrective actions documented or review by laboratory director. a. January 2020 - Problems identified were marked with NO: Calibration procedures for chemistry analytes were not performed at required frequency with documents retained. New lots verified prior to use (QC 8) Required number done prior to patient testing Quantitative results graphed Reviewed for shifts and trends b. February 2020 - Problems identified were marked with NO: Calibration procedures for chemistry analytes were not performed at required frequency with documents retained. New lots verified prior to use (QC 8) Required number done prior to patient testing Quantitative results graphed Reviewed for shifts and trends c. March 2020 - Problems identified were marked with NO: Calibration procedures for chemistry analytes were not performed at required frequency with documents retained. New lots verified prior to use (QC 8) Required number done prior to patient testing Quantitative results graphed Reviewed for shifts and trends d. April 2020 - Problems identified were marked with NO: Calibration procedures for chemistry analytes were not performed at required frequency with documents retained. New lots verified prior to use (QC 8) Required number done prior to patient testing Quantitative results graphed Reviewed for shifts and trends e. May 2020 - Problems identified were marked with NO: Calibration procedures for chemistry analytes were not performed at required frequency with documents retained. New lots verified prior to use (QC 8) Required number done prior to patient testing Quantitative results graphed Reviewed for shifts and trends f. June 2020 - Problems identified were marked with NO: Calibration procedures for chemistry analytes were not performed at required frequency with documents retained. New lots verified prior to use (QC 8) Required number done prior to patient testing Quantitative results graphed Reviewed for shifts and trends g. July 2020 - Problems identified were marked with NO: Calibration procedures for chemistry analytes were not performed at required frequency with documents retained. New lots verified prior to use (QC 8) Required number done prior to patient testing Quantitative results graphed Reviewed for shifts and trends h. August 2020 - this document is blank i. September 2020 - this document is blank j. October 2020 - Problems identified were marked with NO: Calibration procedures for chemistry analytes were not performed at required frequency with documents retained. New lots verified prior to use (QC 8) Required number done prior to patient testing Quantitative results graphed Reviewed for shifts and trends k. November 2020 - Problems identified were marked with NO: Calibration procedures for chemistry analytes were not performed at required frequency with documents retained. New lots verified prior to use (QC 8) Required number done prior to patient testing Quantitative results graphed Reviewed for shifts and trends l. December 2020 - Problems identified were marked with NO: Calibration procedures for chemistry analytes were not performed at required frequency with documents retained. New lots verified prior to use (QC 8) Required number done prior to patient testing

	Quantitative results graphed Reviewed for shifts and trends m. January 2021 - Problems identified were marked with NO: Calibration procedures for chemistry analytes were not performed at required frequency with documents retained. New lots verified prior to use (QC 8) Required number done prior to patient testing Quantitative results graphed Reviewed for shifts and trends Quarterly QI reviews were requested but not provided. 3. Interview of testing person conducted on June 2, 20201 at 4:19 PM confirmed that corrective actions were not taken when failures in quality assessment were identified.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Review of patient test records, lab requests and interview of facility personnel found the final report for seven of seven patient reports randomly selected between March 2019 and January 2020 failed to include the test report date. The findings included: 1. Review of seven patient reports randomly selected from dates between March 2019 and January 2020 found the originally reported date to be the date the test reports were requested (6/3/2021) for the following patients: a. Patient 1105419 Collection Date 3/28/2019 9:27 AM Received Date 03/28/2019 9:27 AM Originally reported On: 6/3/2021 8:26 AM b. Patient 1060078 Collection Date 3/20/2019 7:38 AM Received Date 03/20/2019 7:38 AM Originally reported On: 6/3/2021 8:23 AM c. Patient 1105112 Collection Date 3/18/2019 10:32 AM Received Date 3/18/2019 10:32 AM Originally reported On: 6/3/2021 8:25 AM d. Patient 1059226 Collection Date 3/14 /2019 9:32 AM Received Date 3/14/2019 9:32 AM Originally reported On: 6/3/2021 8:27 AM e. Patient 1086800 Collection Date 4/5/2019 9:32 AM Received Date 4/5 /2019 9:32 AM Originally reported On: 6/3/2021 8:08 AM f. Patient 1110300 Collection Date 1/23/2020 8:53 AM Received Date (not documented) Originally reported On: 6/3/2021 8:026 AM g. Patient 1049942 Collection Date 1/23/2020 1:34 PM Received Date (not documented) Originally reported On: 6/3/2021 8:05 AM 2. Interview of testing personnel conducted June 32, 2021 at 2:22 PM 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 D6020, D6022, D6028)
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: Review of manufacturer's instructions, laboratory records, quality control records, and patient test reports, the laboratory director failed to ensure the laboratory established and maintained the quality control program for the specialties of Chemistry and Hematology. Findings were: 1.The laboratory failed to establish their own control means and acceptable ranges and failed to verify controls prior to use as instructed by the manufacturer. Refer to D5469 2. The laboratory failed to document two levels of quality control each day of patient testing for chemistry and hematology testing. Refer to D5447-I, II, III 3. The laboratory failed to have an effective quality control program in place to ensure the accuracy and reliability of patient test results for chemistry and hematology testing. Refer to D5441-I, II
D6022	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 and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the laboratory policy, laboratory records and confirmed in interview, the laboratory director failed to ensure that the quality assessment programs were established and maintained to identify failures in quality as they occur. Refer to D5791
D6028	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(10) 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)(10) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in

	accordance with the personnel responsibilities described in this subpart; This STANDARD is not met as evidenced by: Based on direct observation, review of laboratory records and confirmed in interview, the Laboratory Director failed to employ a sufficient number of laboratory personnel to perform tests and report test results. Findings included: 1. During a tour of the laboratory on 6/2/21 at 1000 hours, the following analyzers were observed to be in operation: 1 Sysmex XP 300 1 Alfa Wassermann ACE Axcel waived tests included: Osom flu kit; Henry Schein pregnancy tests; Henry Schein Mono test; Discover Plus drug screens; Henry Schein H.pylori; Siemens urinalysis 2. According to records for annual test volume of tests performed the following was revealed for each specialty: Chemistry (includes Urinalysis): 100,000 Hematology: 55,000 Total = 155,000 tests 3. Review of the laboratory records revealed only 1 full time testing person. 4. The laboratory failed to meet the requirements for analytical systems. Refer to D5400. 5. An interview with the testing person on 6/3/21 at 1420 hours in the conference room confirmed the above findings.
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 review of the laboratory policies, testing records, and confirmed in interview, the technical consultant failed to provide technical oversight of the laboratory. Refer to D6036, D6042, D6045, D6054, D6055
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. Findings were: 1.The laboratory failed to establish their own control means and acceptable ranges and failed to verify controls prior to use as instructed by the manufacturer. Refer to D5469 2. The laboratory failed to document two levels of quality control each day of patient testing for chemistry and hematology testing. Refer to D5447-I, II, III 3. The laboratory failed to have an effective quality control program in place to ensure the accuracy and reliability of patient test results for chemistry and hematology testing. Refer to D5441-I, II 4. The laboratory failed to establish and follow its policy for specimen preanalytical requirements. Refer to D5311-I, II, III, IV
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: 38387 Review of manufacturer's instructions, laboratory records, quality control records, and patient test reports, the Technical Consultant failed to establish and maintain the quality control program for the specialties of Chemistry and Hematology. Findings were: 1.The laboratory failed to establish their own control means and acceptable ranges and failed to verify controls prior to use as instructed by the manufacturer. Refer to D5469 2. The laboratory failed to document two levels of quality control each day of patient testing for chemistry and hematology testing. Refer to D5447-I, II, III 3. The laboratory failed to have an effective quality control program in place to ensure the accuracy and reliability of patient test results for chemistry and hematology testing. Refer to D5441-I, II
D6045	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(7) (b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; This STANDARD is not met as evidenced by: Based review of laboratory records, and confirmed in interview, the technical consultant failed to identify training needs for testing personel to follow laboratory policies. Refer to D6070
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: Based on review of annual competency assessments for testing personnel (TP) from 2018-2020, laboratory's Competency Evaluation policy, and confirmed in an interview revealed the technical consultant (TC) failed to document 1 of 1 TP annual competency assessment for Sysmex XP-300 in 2019 and 2020. 1. Review of Competency Evaluation (Policy #: LAB104) under 'Scheduling of Competency Tests' revealed "All employees are required to participate in the program annually..." 2. Review of annual competency assessments records from 2018-2020 revealed testing personnel#1 (TP#1) had no document for annual competency assessments for Sysmex

	XP-300 (SN# B1754) in 2019 and 2020. TP#1, hired on 4/30/2015 3. An an interview with a testing personnel#1 (TP#1) on 6/3/21 at 3:08 pm in the lab confirmed the above findings.
D6055	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 whenever test methodology or instrumentation changes. The individual's performance must be reevaluated to include the use of the new test methodology or instrumentation prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory competency assessments, Competency Evaluation policy, and confirmed in interview revealed the laboratory failed to document competency assessments for 1 of 1 testing personnel for the ACE Axcel analyzer prior to patient testing. The findings were: 1. Review of Competency Evaluation (Policy #: LAB104) under 'Policy' section revealed "If test methodology or instrumentation changes occur, each individual will be re-evaluated to include the use of the new test methodology or instrumentation." 2. Review of the laboratory competency assessments from 2020 and 2021 revealed no documentation of the competency for the ACE Axcel analyzer (SN# 20020507) prior to patient testing for 1 of 1 testing personnel (TP#1). 3. An an interview with a testing personnel#1 (TP#1) on 6/2/21 at 1: 18 pm in the lab confirmed the ACE Axcel was implemented in December, 2020 performing the same testing analytes as previous chemistry analyzer ACE Alera. 4. An an interview with a testing personnel#1 (TP#1) on 6/3/21 at 3:08 pm in the lab confirmed no documentation of competency for ACE Axcel prior to the patient testing.
D6070	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(1) Each individual performing moderate complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory policy, surveyor observations, and confirmed in interview, the laboratory testing personnel failed to follow the lab policy for sample processing and analyzing (refer to D5311-I, D5447-I, II, III).