Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2168777	05/06/2021
Name of Provider or Supplier	**Street Address, City, State**	
Avanti Laboratories, Llc	104 Gallery Circle Unit 106, San Antonio, 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 to be out of compliance based on the following CONDITION LEVEL DEFICIENCIES resulting in a finding of IMMEDIATE JEOPARDY: D5300 - 42 C.F.R. 493.1240 Condition: Pre-Analytic Systems D6000 - 42 C.F.R. 493.1403 Condition: Laboratory Director; moderate complexity The immediate jeopardy was abated by the laboratory submitted a letter on 05/06/2021 that it would follow all manufacturer's instructions. Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility representative was given an opportunity to provide evidence of compliance with noted deficiencies and no such evidence was provided prior to survey exit. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing records for 2019, 2020 and 2021, and interview with the staff, it was determined the laboratory personnel failed to sign attestation documents for 3 of 13 proficiency testing events reviewed. The findings were: 1. A review of the laboratory's American Proficiency Institute proficiency testing records for 2019, 2020 and 2021 revealed the following attestation

	documents were missing the required signatures: Chemistry Miscellaneous event 3 of 2019 performed on 08/31/2019 - missing testing personnel and laboratory director (or designee) signatures. Immunology/ Immunohematology Event 3 of 2019 performed on 12/06/2019 - missing testing personnel and laboratory director (or designee) signatures. Hematology Event 1 of 2021 performed on 03/23/2021 - missing laboratory director (or designee) signature. 2. An interview with the general supervisor on 5/4/2021 at 1100 hours in the laboratory revealed the laboratory did not have the signatures on the above attestation documents. This confirmed the 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: Based on review of the laboratory's test menu, review of patient test records, and staff interview, it was revealed the laboratory failed to have documentation of reporting 1674 SARS-CoV-2 IgG/IgM positive and negative test results as required by 400.200 from 01/08/2021 to 5/05/2021. Findings were: 1. A review of the laboratory's test menu revealed the laboratory utilized Abbott SARS-CoV-2 IgG/IgM testing for patient testing. 2. A review of the manufacturer's instructions for use for the Abbott SARS-CoV- IgM assay (H14977R01) and the Abbott SARS-CoV-IgG assay (H14806R05) under the section titled "Intended Use" revealed: "Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities." 3. A 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 January 8, 2021 to May 5, 2021 revealed the laboratory performed the following number of tests (see patient alias lists #1 - #3): Positive COV-2 IgM 184 Positive COV-2 IgG 219 Negative COV-2 IgM 653 Negative COV- IgG 618 5. An interview with the general supervisor on 05/05/2021 at 1330 hours in the laboratory revealed the facility did not report any COVID test results to State or local authorities. This confirmed the findings.
D3009	FACILITIES CFR(s): 493.1101(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements. This STANDARD is not met as evidenced by: Based on review of the laboratory's client list, and staff interview, it was revealed the laboratory failed to have documentation of a license from the state of California to

	allow them to test patient samples from the state. The findings were: 1. A review of the laboratory's client list revealed the facility tested patient samples from four facilities in California. 2. The laboratory was asked to provide documentation of a California license which would allow them to test the samples from the state. No license was provided. 3. An interview with the owner of the laboratory on 05/05/2021 at 1000 hour by phone revealed he assumed the previous laboratory director had applied for it, but he wasn't sure where it was. This confirmed the 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 the laboratory's submitted CMS 209, review of the laboratory's policies, review of the laboratory's personnel records and staff interview it was revealed the laboratory failed to have documentation of performing competency assessments on the general supervisor. The findings were: 1. A review of the laboratory's submitted CMS 209 revealed the laboratory identified 1 general supervisor. 2. A review of the laboratory's policy titled "Competency Assessment of Technical Personnel" revealed: "Competency assessments for Supervisors and Consultants shall be performed according to the same schedule as testing personnel, i. e., semi-annually for the first year and annually thereafter." 3. A review of the laboratory's personnel records revealed the general supervisor had been employed by the the laboratory for over a year. Thus, two competency assessements were required. 4. The laboratory was asked to provide documentation of two competency assessments being performed on the general supervisor during his first year of employment. No documentation was provided. 5. An interview with the general supervisor on 05/05/2021 at 1430 hours in the laboratory revealed his competency had never been assessed. This confirmed the findings.
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing records for 2019, 2020 and 2021, review of laboratory's policies and interview with the staff, it was determined the laboratory failed to evaluate its performance for 3 of 3 non-graded analyte proficiency testing results. The findings were: 1. A review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records for 2019, 2020 and 2021 revealed no documentation of review and evaluation of analyte results deemed by API as "Not graded" for the following: Immunology/ Immunohematology Event 1 of 2020, Sample CCP-01 for Anti-CCP (quant) analyte Immunology/ Immunohematology Event 2 of 2020, Sample CCP-04 for Anti-CCP (quant) analyte Immunology/ Immunohematology Event 2 of 2020, Sample VM-07 for Anti-HAV,

	IgG analyte 2. A review of the laboratory's Proficiency Testing Protocol, policy QM0012.02, revealed the laboratory failed to follow its policy for evaluation of ungraded challenges. The policy stated: "5.5.5 ungraded Challenges / Exception Codes 5.5.5.1 Refer to the list of PT Exception codes provided with each PT evaluation report" And "5.5.5.3 Use the PT Self-assessment worksheet (QM0012. 03.03) to document evaluation of ungraded responses." Note: No self-assessment worksheets were found in relation to the above proficiency testing events' "Not graded" analyte results. 3. An interview with the general supervisor on 5/4/2021 at 1600 hours in the laboratory revealed that the laboratory did not review "Not graded" challenges. This confirmed the findings.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing records for 2019, 2020 and 2021, and interview with the staff, it was determined the laboratory failed to verify and evaluate proficiency testing results for 3 of 13 testing events reviewed. The findings were: 1. A review of the laboratory's American Proficiency Institute proficiency testing records for 2019, 2020 and 2021 revealed no documentation of review of proficiency testing results for the following: Immunology/ Immunohematology Event 2 of 2019 Immunology/ Immunohematology Event 3 of 2019 Chemistry Core Event 2 of 2020 2. An interview with the general supervisor on 5 /4/2021 at 1100 hours in the laboratory revealed lack of documentation of evaluation of proficiency testing results. This reconfirmed the findings.
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of manufacturer's instructions, review of shipping records, review of patient test records, review of the laboratory's records, and staff interview, it was revealed the laboratory failed to meet the requirement for preanalytic systems. The findings were: 1. The laboratory failed to follow the manufacturer's instructions for BNP samples (refer to D5311 A), 2. The laboratory failed to follow the manufacturer's instructions for CBC samples (refer to D5311 B), 3. The laboratory failed to follow the manufacturer's instructions for CA 19-9 and CA15-3 samples (refer to D5311 C), 4. The laboratory failed to follow the manufacturer's instructions for removing serum from serum separators (refer to D5311 D), 5. The laboratory failed to have studies to define storage/transport temperatures for Adiponectin samples testing utilitzing a "For Research Use Only" test kit (refer to D5311 E).

D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, review of shipping records, review of patient test records, review of the laboratory's records, and staff interview, it was revealed the laboratory failed to: A) Follow the manufacturer's instructions for BNP samples for 11 of 20 records reviewed, B) Follow the manufacturer's instructions for CBC samples for 15 of 25 records reviewed, C) Follow the manufacturer's instructions for CA 19-9 and CA15-3 samples for 6 of 10 records reviewed, D) Follow the manufacturer's instructions for removing serum from serum separators for 20 of 20 records reviewed, E) Have studies to define storage/transport temperatures for Adiponectin samples The findings were: A) BNP samples 1. A review of the manufacturer's for the Architec BNP assay (page 3) under the section titled "Specimen Storage" revealed: " - Whole blood samples, stored at 2-8C must be tested within 24 hours of collections. - Whole blood samples, stored at room temperature must be tested within 4 hours of collection." 2. The laboratory received all BNP samples as whole blood samples collected in EDTA. 3. A sampling of patient samples shipped to the laboratory 4/24/2021 to 05/01/2021 and review of the test reports for each sample revealed the following specimens received outside 2-8C and thus, were required to be tested within 4 hours of collection: a) specimen: NUM43 collected: 01:00 pm on 04/30 /2021 received: 05/01/2021 receipt temperature: 19.9C tested: 12:27 pm on 05/01 /2021 elapsed time: 23 hours 27 minutes b) specimen: RYN47 collected: 04:00 pm on 04/30/2021 received: 05/01/2021 receipt temperature: 17.8C tested: 12:16 pm on 05/01 /2021 elapsed time: 20 hours 16 minutes c) specimen: EOFF58 collected: 04:15 pm on 04/28/2021 received: 05/01/2021 receipt temperature: 17.8C tested: 12:24 pm on 05 /01/2021 elapsed time: 68 hours 9 minutes d) specimen: CLA77 collected: 08:30 am on 04/30/2021 received: 05/01/2021 receipt temperature: 17.8C tested: 12:14 pm on 05 /01/2021 elapsed time: 27 hours 44 minutes e) specimen: UKU64 collected: 01:48 pm on 04/28/2021 received: 04/29/2021 receipt temperature: 18.6C tested: 04:33 pm on 04 /29/2021 elapsed time: 26 hours 45 minutes f) specimen: BELL56 collected: 10:10 am on 04/28/2021 received: 04/29/2021 receipt temperature: 20.9C tested: 04:30 pm on 04 /29/2021 elapsed time: 30 hours 20 minutes g) specimen: HEI75 collected: 08:30 am on 04/28/2021 received: 04/29/2021 receipt temperature: 13.3C tested: 04:19 pm on 04 /29/2021 elapsed time: 31 hours 49 minutes h) specimen: NIS37 collected: 09:33 am on 04/27/2021 received: 04/28/2021 receipt temperature: 23.4C tested: 04:53 pm on 04 /28/2021 elapsed time: 31 hours 20 minutes i) specimen: KEL58 collected: 11:00 am on 04/27/2021 received: 04/28/2021 receipt temperature: 20.6C tested: 11:50 am on 04 /28/2021 elapsed time: 24 hours 50 minutes j) specimen: PAR44 collected: 10:25 am on 04/27/2021 received: 04/28/2021 receipt temperature: 20.6C tested: 11:47 am on 04 /28/2021 elapsed time: 25 hours 22 minutes k) specimen: FRA53 collected: 04:00 pm on 04/23/2021 received: 04/24/2021 receipt temperature: 17.0C tested: 02:29 pm on 04 /24/2021 elapsed time: 22 hours 29 minutes 4. The laboratory was asked to provide documentation of establishment studies to support accepting samples outside the manufacturer's requirments. No documentation was provided. 5. An interview with

the general supervisor on 05/05/2021 at 1430 hours in the laboratory confirmed the findings. B) CBC Samples 1. A review of the manufacturer's instructions for the Sysmex XN hematology analyzer (Code No. BV237179, June 2017) under the section titled "Whole Blood Stability" revealed the following: - All analytes were stable for 24 hours at room temperature (18 to 26C), - Analytes were stable for 48 hours at refrigerated temperature (2 to 8C) except: Hematocrit: 24 hours MCV: 24 hours IG%: 12 hours 2. A sampling of patient samples shipped to the laboratory 02/23/2021 to 05 /01/2021 and review of the test reports for each sample revealed the following specimens received outside 2 to 8C and outside 18 to 26C: a) specimen: SIL48 collected: 11:10 am on 02/22/2021 received: 02/23/2021 receipt temp: 10.5C tested: 07:20 pm on 02/23/2021 elapsed time: 32 hours 10 minutes b) specimen: ASH73 collected: 09:55 am on 02/24/2021 received: 02/25/2021 receipt temp: 11.7C tested: 06:58 pm on 02/25/2021 elapsed time: 32 hours 57 minutes c) specimen: BAN56 collected: 12:50 pm on 03/01/2021 received: 03/02/2021 receipt temp: 10.9C tested: 01:50 pm on 03/02/2021 elapsed time: 23 hours d) specimen: HIA79 collected: 11:00 am on 04/01/2021 received: 04/02/2021 receipt temp: 12.1C tested: 11:37 am on 04/02 /2021 elapsed time: 24 hours 37 minutes e) specimen: MAR81 collected: 12:25 pm on 04/30/2021 received: 05/01/2021 receipt temp: 14.6C tested: 11:25 am on 05/01/2021 elapsed time: 23 hours f) specimen: LUK collected: 08:40 am on 04/30/2021 received: 05/01/2021 receipt temp: 14.6C tested: 11:17 am on 05/01/2021 elapsed time: 26 hours 37 minutes g) specimen: ADC63 collected: 09:30 am on 04/30/2021 received: 05/01/2021 receipt temp: 14.6C tested: 11:19 am on 05/01/2021 elapsed time: 25 hours 49 minutes 3. Surveyor observation of CBC samples received by the laboratory on 05/05/2021 at 1030 hours revealed the following samples which were received at room temperature, but were tested more than 24 hours past collection: a) specimen: RODR62 collected: 10:30 am 05/04/2021 received: 05/05/2021 receipt temp: 19.3C tested: 12:49 pm on 05/05/2021 elapsed time: 26 hours 19 minutes b) specimen: EL12565 collected: 10:01 am on 05/04/2021 received: 05/05/2021 receipt temp: 20.6 C tested: 08:58 am on 05/06/2021 elapsed time: 46 hours 57 minutes c) specimen: ZA52 collected: 09:10 am on 05/04/2021 received: 05/05/2021 receipt temp: 19.3C tested: 09:19 on 05/06/2021 elapsed time: 48 hours 9 minutes d) specimen: MIT97 collected: 09:53 am on 05/04/2021 received: 05/05/2021 receipt temp: 19.8C tested: 09:09 am on 05/06/2021 elapsed time: 47 hours 16 minutes e) specimen: COO66 collected: 01:33 pm on 05/04/2021 received: 05/05/2021 receipt temp: 19.8C tested: 08:52 am on 05/06/2021 elapsed time: 43 hours 19 minutes f) specimen: MAY68 collected: 11:20 am on 05/04/2021 received: 05/05/2021 receipt temp: 19.3C tested: 12:05 pm on 05/05/2021 elapsed time: 24 hours 45 minutes g) specimen: MURO47 collected: 11:20 am on 05/04/2021 received: 05/05/2021 receipt temp: 19.3C tested: 12:10 pm on 05/05/2021 elapsed time: 24 hours 50 minutes h) specimen: MAR22 collected: 09:00 am on 05/04/2021 received: 05/05/2021 receipt temp: 19.3C tested: 02:21 pm on 05/05/2021 elapsed time: 29 hours 21 minutes 4. The laboratory was asked to provide documentation of establishment studies to support accepting samples outside the manufacturer's requirements. No documentation was provided. 5. An interview with the general supervisor on 05/06/2021 at 1230 hours in the laboratory confirmed the findings. C) CA 19-9 and CA 15-3 samples 1. A review of the manufacturer's instructions for the Architect CA 19-9 XR assay (page 3) under the section titled "Specimen Storage" revealed: "Specimens may be stored for up to 7 days at 2 to 8C prior to being tested. If testing will be delayed more lthan 7 days, serum or plasma should be stored frozen to -20C or colder" The manufacturer did not define the acceptable time samples could be at temperatures outside the stated ranges. 2. A review of the manufacturer's instructions for the Architect CA 15-3 assay (page 3) under the section titled "Specimen Storage" revealed: "Specimens may be stored for up to 7 days at 2 to 8C prior to being tested. If testing will be delayed more lthan 7

days, serum or plasma should be stored frozen to -20C or colder" The manufacturer did not define the acceptable time samples could be at temperatures outside the stated ranges. 3. A sampling of patient samples from 04/14/2021 to 04/28/2021 revealed the following specimens which were received by the laboratory outside the required storage temperature for CA 19-9 and tested by the facility: a) specimen: MILB70 collected: 09:55 am on 04/28/2021 received: 04/29/2021 receipt temp: 20.9C report date: 04/30/2021 b) specimen: DEBO61 collected: 09:40 am on 04/22/2021 received: 04/23/2021 receipt temp: 16.0C report date: 04/24/2021 c) specimen: TRAN48 collected: 09:20 am on 04/21/2021 received: 04/22/2021 receipt temp: 16.9C report date: 04/22/2021 d) specimen: THR71 collected: 10:08 am on 04/14/2021 received: 04/15/2021 receipt temp: 16.2C or 17.2C report date: 04/16/2021 e) specimen: SUGI27 collected: 11:30 on 04/14/2021 received: 04/15/2021 receipt temp: 16.2C or 17.2C report date: 04/16/2021 f) specimen: SUGI51 collected: 11:15 am on 04/14/2021 received: 04/15/2021 receipt temp: 16.2C or 17.2C report date: 04/16/2021 4. A sampling of patient samples from 04/14/2021 to 04/28/2021 revealed the following specimens which were received by the laboratory outside the required storage temperature for CA 15-3 and tested by the facility: a) specimen: MILB70 collected: 09:55 am on 04/28/2021 received: 04/29/2021 receipt temp: 20.9C report date: 04/30/2021 b) specimen: DEBO61 collected: 09:40 am on 04/22/2021 received: 04/23/2021 receipt temp: 16.0C report date: 04/24/2021 c) specimen: TRAN48 collected: 09:20 am on 04/21/2021 received: 04/22/2021 receipt temp: 16.9C report date: 04/22/2021 d) specimen: THR71 collected: 10:08 am on 04/14/2021 received: 04/15/2021 receipt temp: 16.2C or 17.2C report date: 04/16/2021 e) specimen: SUGI27 collected: 11:30 on 04/14/2021 received: 04/15/2021 receipt temp: 16.2C or 17.2C report date: 04/16/2021 f) specimen: SUGI51 collected: 11:15 am on 04/14/2021 received: 04/15/2021 receipt temp: 16.2C or 17.2C report date: 04/16/2021 5. The laboratory was asked to provide documentation of establishment studies to support accepting samples outside the manufacturer's requirements. No documentation was provided. 6. An interview with the general supervisor on 05/05/2021 at 1345 hours in the laboratory confirmed the findings. E) removing serum from serum separator 1. A review of the manufacturer's instructions for the Architect Cortisol assay (page 3) under the section titled "Specimen Storage" revealed: "If testing will be delayed for more than eight hours, remove plasma or serum from the serum or plasma separator, red blood cells or clot." 2. A review of the manufacturer's instructions for the Architect Anti-TPO assay (page 3) under the section titled "Specimen Storage" revealed: "If testing will be delayed for more than eight hours, remove plasma or serum from the serum or plasma separator, red blood cells or clot." 3. A review of the manufacturer's instructions for the Architect CK-MB assay (page 3) under the section titled "Specimen Storage" revealed: "If testing will be delayed for more than eight hours, remove plasma or serum from the serum or plasma separator, red blood cells or clot." 4. An interview with the general supervisor on 05/05/2021 at 1100 hours in the laboratory and confirmed by testing personnel number 1 (as listed on Form CMS 209) revealed the laboratory received samples for the identified tests with the serum still on the serum separator gel. Facilities did not remove the serum from the serum separator gel. 5. A sampling of cortisol samples from 04/27/2021 to 04/30/2021 revealed the following samples which were tested more than 8 hours after collection without being removed from the serum separator: a) specimen: SA55 collected: 09:30 am on 04/27/2021 tested: 06:22 am on 04/28/2021 elapsed time: 20 hours 48 minutes b) specimen: SWI82 collected: 12:00 pm on 04/27/2021 tested: 06:09 am on 04/28/2021 elapsed time: 18 hours 9 minutes c) specimen: SIM59 collected: 10:10 am on 04/27/2021 tested: 05:50 am on 04/28/2021 elapsed time: 19 hours 40 minutes d) specimen: MADD57 collected: 01:43 pm 04/27/2021 resulted: 04:58 am on 04/28/2021 elapsed time: 15 hours 15 minutes e) specimen: ESP49 collected: 09:30 am on 04/28/2021

	tested: 03:17 pm on 04/29/2021 elapsed time: 29 hours 47 minutes f) specimen: ARM82 collected: 09:13 am on 04/28/2021 tested: 03:05 pm on 04/29/2021 elapsed time: 29 hours 47 minutes g) specimen: AYE74 collected: 12:03 pm on 04/28/2021 tested: 02:28 pm 04/29/2021 elapsed time: 25 hours 35 minutes h) specimen: PERE95 collected: 10:25 am on 04/28/2021 tested: 01:59 pm on 04/29/2021 elapsed time: 25 hours 34 minutes i) specimen: FRANCO collected: 12:00 pm on 04/28/2021 tested: 12:15 pm on 04/29/2021 elapsed time: 24 hours 15 minutes j) specimen: FARMER collected: 12:00 pm on 04/30/2021 tested: 07:08 am on 05/01/2021 elapsed time: 19 hours 8 minutes k) specimen: ROBB52 collected: 01:10 pm on 04/30/2021 tested: 06: 51am on 05/01/2021 elapsed time: 17 hours 41 minutes l) specimen: CON35 collected: 02:10 pm on 04/30/2021 tested: 06:38 am on 05/01/2021 elapsed time: 16 hours 28 minutes 6. A sampling of Anti-TPO samples from 04/292021 to 04/30021 revealed the following samples which were tested more than 8 hours after collection without being removed from the serum separator: a) specimen: FOS51 collected: 10: 30 am on 04/29/2021 tested: 07:53 pm on 04/29/2021 elapsed time: 9 hour 23 minutes b) specimen: MUNOZ02 collected: 12:00 pm on 04/30/2021 tested: 03:21 am on 05 /01/2021 elapsed time: 15 hours 21 minutes c) specimen: KOG59 collected: 11:46 am on 04/30/2021 tested: 03:20 am on 05/01/2021 elapsed time: 15 hours 34 minutes d) specimen: WOODARD collected: 12:00 pm on 04/30/2021 tested: 02:20 am on 05/01 /2021 elapsed time: 14 hours 20 minutes e) specimen: MART68 collected: 11:50 am on 04/30/2021 tested: 02:18 am on 05/01/2021 elapsed time: 14 hours 28 minutes f) specimen: FRE collected: 12:00 pm on 04/30/2021 tested: 02:17 am on 05/01/2021 elapsed time: 14 hours 17 minutes 7. A sampling of CK-MB from 04/13/2021 to 04/19 /2021 revealed the following samples which were tested more than 8 hours after collection without being removed from the serum separator: a) specimen: AK173 collected: 03:05 pm on 04/13/2021 tested: 08:45 am on 04/15/2021 elapsed time: 41 hours 40 minutes b) specimen: MUN74 collected: 03:09 pm on 04/19/2021 tested: 10: 25 am on 04/23/2021 elapsed time: 79 hours 16 minutes 8. The laboratory was asked to provide documentation of establishment studies to support accepting samples outside the manufacturer's requirements. No documentation was provided. 9. An interview with the general supervisor on 05/05/2021 at 1345 hours in the laboratory confirmed the findings. E) Adiponectin samples 1. A review of the manufacturer's instructions for the Diazyme Adiponectin assay (71448 Rev. D) revealed the assay was for "Research Purposes only in USA". In addition, the manufacturer did not define the specimen transport/storage requirements for the assay. Thus, the laboratory was required to perform studies to ensure samples were shipped/stored in a manner that provided accurate and reliable results. 2. A review of the laboratory's procedure titled "Adiponectin (Diazyme)" [effective 09/27/2020] under the section titled "Specimen Requirements" revealed: "6.1 Serum samples can be used for the Diazyme Adiponectin Assay. 6.2 Specimens may be stored at 2 - 8C for up to one week. For long term storage, store at -20C or lower. 6.3 Avoid repeated freez-thaw cycles. 6.4 Do not use highly turbid or highly hemolyzed samples. 6.5 Allow samples to come to room temperature for 30 minutes and are well mixed prior to assay. 3. The laboratory was asked to provide documentation of performing the necessary studies in order to support the specimen handling requirements defined in its procedure. No documentation was provided. 4. The laboratory reported performing testing on 3929 samples since testing began. 5. An interview with the general supervisor on 05/05 /2021 at 1515 hours in the laboratory revealed no studies had been performed. This confirmed the findings.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)

	Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the laboratory's verfication studies and staff interview, it was revealed the facility failed to have documentation of complete studies. The findings were: 1. Based on review of the laboratory's verfication studies for assays performed on Abbott Architect #1 (serial number C402590) in May 2019 revealed the laboratory failed to have documentation of verifying patient normal values. The laboratory tested 77 different assays on the analyzer. Examples on patient normal values not verified include: a) Potassium Male: 1 - 18 years 3.4-5.1 Male: 19 -115 years 3.5-5.1 b) Glucose Male: 1 - 18 years 60 - 100 Male: 19-60 years 70 - 105 Male: 61-115 years 80 - 115 c) Amylase Male: 18-70 years 25-125 Male: 71-115 years 20-160 d) Calcium Male: 1-60 years 8.4-10.2 Male: 61-133 years 8.8-10.2 2. A review of the laboratory's verification studies for assays performed on Abbott Architect #2 (serial number C402592) revealed the facility failed to have documentation of performing reportable range studies for 10 of 14 assays and of verifying normal patient ranges for 14 of 14 assays. a) The assays without documentation of reportable range studies were: Prolactin Progesterone Ferritin FSH DHEA-S Insulin Estradiol Homocysteine Vitamin B12 Folate 3. A review of the laboratory's verification studies for the Sysmex XN-L 330 hematology analyzer (serial number 12201) performed in August 2019 revealed the laboratory failed to have documentation of verifying patient normal values. The following are examples of the normal values used by the laboratory: a) before October 14, 2020 WBC Male 4.23-9.07 Female 3.98-10.0 RBC Male 4.63-6.08 Female 3.93-5.22 HGB Male 13.7-17.5 Female 11.2-15.7 HCT Male 40.1-51.0 Female 34.1-44.9 PLT Male 163-337 Female 182-369 b) After October 14, 2020 WBC Male 4.00-11.0 Female 3.4 10.0 RBC Male 4.0-6.2 Female 3.9-5.2 HGB Male 12.0-17.0 Female 11.0-15.2 HCT Male 36.0-50.0 Female 34.0-44.9 PLT Male 150-450 Female 157-450 4. The laboratory was asked to provide documentation of the missing studies. No documentation was provided. 5. An interview with the general supervisor on 05/05/2021 at 1150 in the laboratory confirmed the findings.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.

	This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, review of the laboratory's establishment studies, and staff interview, it was revealed the laboratory failed to have documentation of performing pre-analytic studies for adoplectin samples. The findings include: 1. A review of the manufacturer's instructions for the Diazyme Adiponectin assay (71448 Rev. D) revealed the assay was for "Research Purposes only in USA". In addition, the manufacturer did not define the specimen transport /storage requirements for the assay. Thus, the laboratory was required to perform studies to ensure samples were shipped/stored in a manner that provided accurate and reliable results. 2. A review of the laboratory's procedure titled "Adiponectin (Diazyme)" [effective 09/27/2020] under the section titled "Specimen Requirements" revealed: "6.1 Serum samples can be used for the Diazyme Adiponectin Assay. 6.2 Specimens may be stored at 2 - 8C for up to one week. For long term storage, store at -20C or lower. 6.3 Avoid repeated freez-thaw cycles. 6.4 Do not use highly turbid or highly hemolyzed samples. 6.5 Allow samples to come to room temperature for 30 minutes and are well mixed prior to assay. 3. The laboratory was asked to provide documentation of performing the necessary studies in order to support the specimen handling requirements defined in its procedure. No documentation was provided. 4. The laboratory reported performing testing on 3929 samples since testing began. 5. An interview with the general supervisor on 05/05/2021 at 1515 hours in the laboratory revealed no studies had been performed. 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 review of the laboratory's quality control records and interview with the staff, it was determined the laboratory failed to document verification of new lots of hematology analyzer's XN-L control materials prior to placing into use for 3 of 3 control lot numbers reviewed. The findings were: 1. A review of the Sysmex hematology analyzer quality control records from November of 2020 to May of 2021 revealed the laboratory did not perform concurrent testing of new and old controls. The control reagents were: XN-L Control Lot 0298 - first tested 11/10/2020; last tested 01/30/2021 XN-L Control Lot 1016 - first tested 02/02/2021; last tested 04/24 /2021 XN-L Control Lot 1100 - first tested 04/27/2021; currently in use 2. In an interview on 05/04/2021 at 1400 hours in the laboratory, testing person #2 (as defined on the facility's CMS Form 209) stated that the laboratory does not perform concurrent control testing, or lot to lot comparison. This confirmed the findings.

D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of the laboratory's records and staff interview, it was revealed the laboratory director failed to provide oversight for the laboratory. The findings were: 1. The laboratory director failed to ensure preanalytic requirements were met (refer to D6007). 2. The laboratory director failed to ensure verification studies were complete (refer to D6013). 3. The laboratory director failed to ensure proficiency test results were reviewed (refer to D6018).
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) 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)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, review of patient test records, and staff interview, it was revealed the laboratory director failed to ensure the laboratory followed manufacturer's preanalytic requirements. The finding were: 1. The laboratory director failed to ensure the manufacturer's instructions for BNP were followed (refer to D5311 A). 2. The laboratory director failed to ensure the manufacturer's instructions for CBC samples were followed (refer to D5311 B), 3. The laboratory director failed to ensure the manufacturer's instructions for CA 19-9 and CA15-3 samples were followed (refer to D5311C), 4. The laboratory director failed to ensure the manufacturer's instructions for removing serum from serum separators was followed (refer to D5311 D), 5. The laboratory director failed to ensure the studies were performed to define storage/transport temperatures for Adiponectin samples (refer to D5311 E).
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;

	This STANDARD is not met as evidenced by: Based on review of the laboratory's verification studies and staff interview, it was revealed the laboratory director failed to ensure studies were complete (refer to D5421).
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing records for 2019, 2020 and 2021, and review of laboratory's policies, it was determined the Laboratory Director failed to ensure proficiency testing reports are reviewed and evaluated for problems requiring corrective action. Refer to D5221.