Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2154643	01/14/2020
Name of Provider or Supplier	**Street Address, City, State**	
Pam Health Rehabilitation Hospital Of Sugar Land	7622 Branford Place, Sugar Land, 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: D2016 - 42 C.F.R. 493.803 Condition: Successful participation [proficiency testing] D5200 - 42 C.F.R. 493.1230 Condition: General laboratory systems; D5400 - 42 C.F.R. 493.1250 Condition: Analytic systems; D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director; D6033 - 42 C.F.R. 493.1409 Condition: Laboratories performing moderate complexity testing; technical consultant; D6076 - 42 C.F.R. 493.1441 Condition: Laboratories performing high complexity testing; laboratory director; D8100 - 42 C.F.R. 493.1771 Condition: Inspection requirements applicable to all CLIAcertified and CLIA-exempt laboratories. 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.
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor

	compliance history. This CONDITION is not met as evidenced by: Based on review of proficiency testing records and interview of facility personnel, the laboratory failed to successfully participate in a proficiency testing program for the specialty of routine chemistry for the analyte AST. Refer to D2096
D2087	ROUTINE CHEMISTRY CFR(s): 493.841(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute (API) Chemistry proficiency testing records from 2019 and confirmed in interview, the laboratory failed to attain a satisfactory score of at least 80% for the analyte AST (aspartate aminotransferase) for 1 of 2 testing events. The findings were: 1. A review of the laboratory's API from 2019 revealed the laboratory failed to attain a satisfactory score of at least 80% for the analyte AST. API 3rd event AST (0%)) CH-11 98 (expected result 100 - 150) CH-12 111 (expected result 114 - 172) CH-13 155 (expected result 158 - 238) CH-14 167 (expected result 173 - 260) CH-15 195 (expected result 202-305) 2. An interview with the laboratory consultant on 1/14/2020 at 1110 hours in the conference room confirmed the above findings.
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's American Proficiency Institute (API) proficiency testing records for 2019, 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. 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 Chemistry Core API 2nd event for the following 18 analytes: Albumin, Alkaline Phosphatase, ALT, AST, Total Bilirubin, Calcium, Chloride, Cholesterol HDL, Total Cholesterol, CO2, Creatinine, Glucose, Cholesterol LDL, Potassium, Sodium, Total Protein, Triglycerides, and Urea Nitrogen. 2. A review of quality assurance records for 2019 revealed the facility had not notified API nor the

	state agency that they had not started patient testing during the time period of non participation. No records were available for review that the laboratory participated in the past 2 events. Surveyor review of testing records confirmed no patient testing was performed in 2019 until 09/30/19. 3. An interview with the laboratory consultant on 1 /14/20 at 1045 hours in the conference room confirmed the above findings. She stated that the laboratory did not have reagents to run the PT specimens and could not participate.
D2096	ROUTINE CHEMISTRY CFR(s): 493.841(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on review of the laboratory American Proficiency Institute (API) proficiency testing records, and confirmed in interview, the laboratory failed to attain 80% (passing) for the analyte AST for 2 of 2 testing events in Chemistry for 2019. Findings were: 1. Review of the 2019 API proficiency testing records revealed the laboratory failed to attain an 80% for the analyte AST for 2 of 2 testing event for Chemistry. Cross refer to D2087 and D2089 2019 Event 2 AST (0%) NR 2019 Event 3 AST (0%) 2. An interview with the laboratory consultant on 1/14/20 at 1640 hours in the conference room confirmed the above findings.
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, 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 general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: The laboratory failed to monitor and evaluate the overall quality of the general laboratory systems as evidenced by: 1. Failure of the laboratory to review and evaluate proficiency testing (refer to D5211). 2. Failure to ensure an effective QA (Quality Assessment) system was in place to monitor, assess and correct problems in the laboratory general systems(refer to D5291).
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 Form CMS-209, review of laboratory policy, review of the laboratory's personnel records, and confirmed in interview, the laboratory failed to have documentation of a competency assessment for 1 of 1 technical consultant. The findings were: 1. A review of the laboratory's submitted Form CMS-209 (signed by the laboratory director on 1/31/20) revealed the laboratory identified 1 technical consultant. 2. A review of personnel records from 2019-2020 revealed no competency assessments for 1 of 1 technical consultant. 4. An interview with the laboratory consultant on 1/14/20 at 1030 hours in the conference room confirmed the findings. Key: CMS - Centers for Medicare and Medicaid Services
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of the laboratory policy, review of the American Proficiency Institute (API) proficiency testing (PT) records, and confirmed in interview, the laboratory failed to document the review of the proficiency testing performed for 1 of 2 PT events in 2019. Findings were: 1. Review of the laboratory policy Proficiency Testing Protocol (Policy #510) effective 5/4/19 under Ungraded PT Analytes revealed "there are cases where although the laboratory performed and reported PT results, these results have not been scored or evaluated for accuracy or the laboratory may have received scores that do not truly reflect laboratory performance...PT program assigns an artificial score of 0% due to nonparticipation, such as when the laboratory did not test the samples (due to oversight, instrument problems, reagent on backorder, etc), the laboratory fails to submit test results or submission of the results occurred after the cutoff date. When such a situation occurs, the laboratory must perform and document its own verification of accuracy for the analyte, specialty or subspecialty affected...The laboratory may compare its performance against the stated target and allowable range of the PT specimen as defined in the participant summary available from the PT provider...missed cut off dates or failures to submit results - the laboratory will receive a 0% on the survey in these instances; however, upon receipt of the summary report, the laboratory director or designee must determine a self-grade based on the analyte and method results reported. Document on Proficiency Testing Corrective Action Form." 2. Review of the laboratory API PT 2nd event for 2019 revealed no documentation of the self-grade for 12 of 18 analytes performed per the laboratory policy. ALB ALP ALT BUN CHOL CO2 GLU HDL K LDL TOTAL PROTEIN TRIG 3. Review of the 2019 API 2nd event performance review and corrective action documentation revealed "there were multiple unsuccessful scores to include the assays AST, TBIL, CA, CREA, CL, and NA...The laboratory used two scoring methods for AST and ALT (NADH with P5P and All Participants) and the variance was slight with both assays hovering at or below the -2SD. No further corrective action is required" AST 0% TBIL 20% CA 80% CREA 80% CL 60% NA 20% 4. Interview with the laboratory consultant on 1/14/20 at 1320 hours in the conference room revealed she used 2 separate participant groups (AST-NADH with P5P and All Participants) to assess the self grade for AST above. She stated that she "eye-balled" the results and determined she was out of acceptable range. 5. An interview with the API technical support on 2/18/20 at 0935 hours via phone revealed the correct participant summary for the analyte AST was AST-NADH without P5P. She stated that she would not recommend any laboratory to use 2 separate peer groups

	to assess their performance. 6. Review of the correct peer group summary (AST-NADH without P5P) for the analyte AST for the API 2nd event revealed a score of 0%. CH-06: lab result 92 (acceptable range: 102-155) CH-07: lab result 178 (acceptable range: 199-300) CH-08: lab result 148 (acceptable range: 163-245) CH-09: lab result 173 (acceptable range: 193-291) CH-10: lab result 136 (acceptable range: 147-222) 7. An interview with the laboratory consultant on 1/14/2020 at 1640 hours in the conference room confirmed the above findings. She stated that she reviewed those PT results last year and that she can't be expected to remember which peer group data she used to assess the laboratory results.
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 American Proficiency Institute (API) proficiency testing (PT) records, laboratory records, and confirmed in interview, the laboratory failed to document the proficiency testing evaluation for an unsatisfactory score for 1 of 2 PT events in 2019. Findings were: 1. Review of the 2019 API 3rd event Performance Review and Corrective Action Documentation dated 10/30/19 revealed "to further the investigation, technical support adjusted the calibration factor for AST and asked testing personnel to recalibrate, QC, and rerun the ASP PT samples. The P-500 does not have enough of peer groups participating in the API to provide its users with a good peer group review. Technical support then obtained the AST results from all P-500 users (see attached Excel Sheet) and determined the laboratory obtained an AST score of 100% when comparing Sugarland PT AST to all other P-500 users. Thus, the laboratory has performed a self-grade with a new score of 100% for AST." 2. Review of the laboratory PT records available for review on the date of survey on 1/14/20 revealed a run on 10/7/19 for AST for proficiency samples CH-11 - CH-15. Each record had written on it "repeat data" with "repeat" crossed out and "orig" written over it. CH-11 92 CH-12 106 CH-13 150 CH-14 159 CH-15 185 3. An interview with the API technical support on 2/18/20 at 0935 hours via phone revealed the correct participant summary for the analyte AST was AST-NADH without P5P. She stated that there were enough peer group data for the Diatron Pictus 500 analyzer; thus, why the laboratory was given a score originally. 4. Review of the API peer data (AST - NADH without P5P) revealed the above run on 10/7/19 were still outside the acceptable range, which resulted with a score of 0%. CH-11 92 (expected result 100 - 150) CH-12 106 (expected result 114 - 172) CH-13 150 (expected result 158 - 238) CH-14 159 (expected result 173 - 260) CH-15 185 (expected result 202-305) 5. Review of all PT records available on the date of survey revealed no documentation of instrument printouts to account for the self-grade of 100% for AST per the corrective action. 6. An interview with the laboratory consultant on 1/14/20 at 1645 hours in the conference room confirmed the above findings. She provided an excel spreadsheet that had results that were within the API data set above, but she was unable to provide the documentation that corresponds to the test results from the spreadsheet.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Review of the laboratory policy, American Proficiency Institute (API) proficiency testing (PT) records, and confirmed in interview, the laboratory failed to ensure an effective QA (Quality Assessment) system was in place to monitor, assess and correct problems in the laboratory general systems. Findings were: 1. Review of the laboratory policy Proficiency Testing Protocol (Policy # 510) effective 5/4/19 revealed "Unsatisfactory PT Performance: The laboratoy has failed a single testing event for that analyte; take corrective action to identify the cause, correct it, and document the corrective action on the PT Failure Log; Unsusscessful PT Performance: The laboratory has failed to achieve a minimum satisfactory score in two consecutive or two of three consecutive testing events for an analyte, specialty, or subspecialty. Perform corrective action to indentify the cause, correct it, and document the corrective action on the PT Failure Log...A review and comparison of all proficiency test reports will be conducted to look for any shifts or trends in reporting, as the laboratory may well be scoring acceptable results, but these results may be either "just in" - either high or low end, indicating troubleshooting of the method or instrument may be warranted. This will serve to alleviate future failures in proficiency test reporting" 2. Review of the 2019 API 2nd event performance review and corrective action documentation revealed "there were multiple unsuccssful scores to include the assays AST, TBIL, CA, CREA, CL, and NA...The laboratory used two scoring methods for AST and ALT (NADH with P5P and All Participants) and the variance was slight with both assays hovering at or below the -2SD. No further corrective action is required" 3. Review of the laboratory API proficiencyy testing records revealed the laboratory received a 0% for AST for the following PT event (API 3rd event) in 2019. Cross refer to D2087 4. An interview with the laboratory consultant on 1/14/20 at 1610 hours in the conference room confirmed the above findings.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of the laboratory records, FDA CLIA database, laboratory policy, and confirmed in interview, the laboratory failed to document preanalytical studies for 11 of 12 reagents that is non-FDA approved for testing on the Diatron Pictus 500 chemistry analyzer. Findings were: 1. Review of the laboratory records from 2019-2020 revealed the laboratory used the following 11 non-FDA approved reagents for testing on the Diatron Pictus 500 chemistry analyzers. Diatron Total Protein (Biuret) Reagent (PI: DTRTPT2.03, Rev: 06/15/12) "in use 6/26/19" Diatron Calcium Arsenazo reagent (PI: DTCAA2.02, Rev: 03/29/17) "in use 6/26/19" Diatron Total Bilirubin Reagent (PI: DTRBN2.04, Rev: 05/22/17) "in use 6/26/19" Diatron Alkaline

	Phosphatase (Liquid) Reagent (PI: DTRALP2.05, Rev: 03/29/17) "in use 6/26/19" Diatron Albumin (BCG) Reagent (PI: DTRALB2.05, Rev 03/29/17) "in use 6/26/19" Diatron ALT (SGPT) Reagent (PI: DTRALT2.04, Rev 11/05/15) "in use 6/26/19" Diatron AST (SGOT) Reagent (PI: DTRAST2.05, Rev 03/29/17) "in use 6/26/19" Diatron Urea Nitrogen (BUN) Reagent (PI: DTRBUN2.05, Rev 03/29/17) "in use 6/26 /19" Diatron Carbon Dioxide Reagent (PI DTRCO2.05, Rev 03/29/17) "in use 6/26 /19" Diatron Creatinine (Single Vial) Reagent (PI: DTRCRE2.05, Rev 03/29/17) "in use 6/26/19" Pointe Scientific Liquid Glucose (Hexokinase) Reagent set (P803-G7517-02, Rev.01/18) "n use 11/27/19" 2. Review of the FDA CLIA database revealed no documentation the above reagents were FDA approved for the Diatron Pictus 500 chemistry analyzer. 3. Review of the laboratory policy Specimen Collection /Labeling (Policy 310) effective 5/4/19 revealed under Specimen Stability "test all samples within 24 hours and store at 2-8 C." 4. Review of the laboratory records available revealed no documentation of the preanalytical studies for the above analytes to verify the 24 hour specimen stability at 2-8C for the Diatron Pictus 500 chemistry analyzer. 5. An interview with the laboratory consultant on 1/14/20 at 1250 hours in the conference room confirmed the above findings. She was unaware the reagents were not FDA approved.
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 laboratory policies, review of quality control records, review of patient final reports, and confirmed in interview, the laboratory failed to monitor and evaluate the overall quality of its analytic systems. Refer to D5411, D5421, D5423, D5439, D5469
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, surveyor observations, and confirmed in interview, the laboratory failed to follow the manufacturer's instructions for reagent storage on the Diatron Pictus 500 chemistry analyzer. Findings were: 1. Review of the package inserts for the following reagents revealed "once opened and stored onboard the analyzer, the reagent is stable for 30 days." Diatron ALT (SGPT) Reagent (PI: DTRALT2.04, Rev 11/05/15) Diatron ALB (BCG) Reagent (PI: DTRALB2.05, Rev 03/29/17) Diatron Total Bilirubin Reagent (PI: DTRBN2.04, Rev 05/22/17) Diatron

	ALT (SGPT) Reagent (PI: DTRALT2.04, Rev 11/05/15) Diatron AST (SGOT) Reagent (PI: DTRAST2.05, Rev 03/29/17) Diatron Urea Nitrogen (BUN) Reagent (PI: DTRBUN2.05, Rev 03/19/17) 2. Review of the package inserts for the following reagents revealed "once opened and stored onboard the analyzer, the reagent is stable for 10 days." Diatron Alkaline Phosphatase (Liquid) Reagent (PI: DTRALP2.05, Rev: 03/29/17) 3. Review of the package inserts for the following reagents revealed "once opened and stored onboard the analyzer, the reagent is stable for 15 days." Diatron Creatinine (single vial) Reagent (PI: DTRCRE2.05 Rev 03/2017) 4. Review of the package inserts for the following reagents revealed "once opened and stored onboard the analyzer, the reagent is stable for 20 days." Diatron Carbon Dioxide Reagent (PI: DTRCO2.05, Rev 03/29/17) Diatron Total Protein Reagent (PI: DTRTPT2.03, Rev 06 /15/12) 6. Observations on 1/14/2020 at 1410 hours in the laboratory revealed the following reagents on board the Diatron Pictus 500 chemistry analyzer: "CO2" "ALT 12/2/19" "BUN 12/16" "ALB 12/11" "ALP 12/3" "AST 12/30" "CREAT Jan" "GLUC 12/6" "TP" "Total Bili 12/16" 7. An interview with the primary testing person on 1/14 /2020 at 1400 hours in the laboratory revealed she unloads the reagents at the end of day and stored them in the refrigerator. She reloads them again the following day. She was unaware that she was not storing the reagents per the manufacturer's instructions.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, surveyor observations, and confirmed in interview, the laboratory failed to document the identity, preparation, and revised expiration date for the reagents on the Diatron Pictus 500 chemistry analyzer. Findings were: 1. Review of the package inserts for the following reagent revealed "working reagent is stable for 4 weeks when stored at 2-8 C." JAS Diagnostics Alkaline Phosphatase Liquid Reagent (PI: ALP2.JS02, Rev: 10/19/09) 2. Review of the package inserts for the following reagents revealed "once opened and stored onboard the analyzer, the reagent is stable for 30 days." Diatron ALT (SGPT) Reagent (PI: DTRALT2.04, Rev 11/05/15) Diatron ALB (BCG) Reagent (PI: DTRALB2.05, Rev 03/29/17) Diatron Total Bilirubin Reagent (PI: DTRBN2.04, Rev 05/22/17) Diatron ALT (SGPT) Reagent (PI: DTRALT2.04, Rev 11/05/15) Diatron AST (SGOT) Reagent (PI: DTRAST2.05, Rev 03/29/17) Diatron Urea Nitrogen (BUN) Reagent (PI: DTRBUN2.05, Rev 03/19/17) 3. Review of the package inserts for the following reagents revealed "once opened and stored onboard the analyzer, the reagent is stable for 10 days." Diatron Alkaline Phosphatase (Liquid) Reagent (PI: DTRALP2.05, Rev: 03/29/17) 4. Review of the package inserts for the following reagents revealed "once opened and stored onboard the analyzer, the reagent is stable for 15 days." Diatron Creatinine (single vial) Reagent (PI: DTRCRE2.05 Rev 03 /2017) 5. Review of the package inserts for the following reagents revealed "once opened and stored onboard the analyzer, the reagent is stable for 20 days." Diatron Carbon Dioxide Reagent (PI: DTRCO2.05, Rev 03/29/17) Diatron Total Protein Reagent (PI: DTRTPT2.03, Rev 06/15/12) 6. Observations on 1/14/2020 at 1410 hours in the laboratory revealed the following reagents on board the Diatron Pictus

	500 chemistry analyzer with no documentation of the reagent identity (lot number) preparation date, or revised expiration date for 10 of 10 reagents. Sampling of the reagents on board included: "CO2" "ALT 12/2/19" "BUN 12/16" "ALB 12/11" "ALP 12/3" "AST 12/30" "CREAT Jan" "GLUC 12/6" "TP" "Total Bili 12/16" 7. An interview with the primary testing person on 1/14/2020 at 1400 hours in the laboratory confirmed the above findings. She was unaware that the laboratory was required to label the reagents with the identity, preparation and expiration dates.
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 laboratory policy, manufacturer's instructions, observations, patient test reports, and confiirmed in interview, the laboratory failed to ensure no expired reagents were used for chemistry testing on the Diatron Pictus 500 chemistry analyzer. Findings were: 1. Review of the laboratory policy Reagent Handling and Storage (Policy #400) effective 5/4/19 revealed "monitor all reagents for exipration dates by testing personnel daily before patient testing begins." 2. Review of the package inserts for the following reagents revealed "working reagent is stable for 4 weeks when stored at 2-8 C." JAS Diagnostics Alkaline Phosphatase Liquid Reagent (PI: ALP2.JS02, Rev: 10/19/09) 3. Review of the package inserts for the following reagents revealed "once opened and stored onboard the analyzer, the reagent is stable for 30 days." Diatron ALT (SGPT) Reagent (PI: DTRALT2.04, Rev 11/05/15) 4. Review of the package inserts for the following reagents revealed "once opened and stored onboard the analyzer, the reagent is stable for 10 days." Diatron Alkaline Phosphatase (Liquid) Reagent (PI: DTRALP2.05, Rev: 03/29/17) 5. Review of the laboratory policy Reagent Handling and Storage (Policy #400) effective 5/4/19 revealed a chart with the "open stability for ALT as 30 days; ALP as 10 days." 6. Observations on 1/14/2020 at 1410 hours revealed the following reagents on board on the Diatron Pictus 500 chemistry analyzer: ALT "12/2/19" ALP "12/3" 7. An interview with the primary testing person on 1/14/2020 at 1400 hours in the laboratory confirmed that the dates written on the reagent on board are when the reagents were put into use. 8. Review of the dates put into use revealed the reagents were on board past the open stability dates. ALT "12/2/19" open stability expired 1/2/2020 ALP "12 /3" open stability expired 12/13/19 9. Review of the patient test logs revealed the laboratory performed ALT and ALP with the above expired reagents. Refer to patient alias list. 10. An interview with the laboratory consultant on 1/14/2020 at 1430 hours in the conference room confirmed the above findings. She was unaware that the testing person was not following the laboratory protocol.
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 records and confirmed in interview, the laboratory failed to document complete verification studies for the hematology testing on the Diatron Abacus hematology analyzer. Findings were: 1. Review of the laboratory policy Equipment Validation (policy #430) effective 5/4/19 revealed under FDA Approved Unmodified Tests: accuracy, precision, reference range or cut-off value, reportable range." 2. Review of the laboratory verification studies for the Diatron Abacus hematology analyzer revealed no documentation of the reference range study or precision study. 3. An interview with the laboratory consultant on 1/14/20 at 1520 hours in the conference room confirmed the above 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: A. Based on review of the FDA CLIA database, review of manufacturer's package insert, laboratory records, and confirmed in interview, the laboratory failed to document complete establishment studies for 12 of 12 reagents that is non-FDA approved for testing on the Diatron Pictus 500 chemistry analyzer. Findings were: 1. Review of the FDA CLIA database revealed the following 12 reagents were not FDA approved for testing on the Diatron Pictus 500 chemistry analyzer. Diatron Total Protein (Biuret) Reagent (PI: DTRTPT2.03, Rev: 06/15/12) Diatron Calcium Arsenazo reagent (PI: DTCAA2.02, Rev: 03/29/17) Diatron Total Bilirubin Reagent (PI: DTRBN2.04, Rev: 05/22/17) Diatron Alkaline Phosphatase (Liquid) Reagent (PI: DTRALP2.05, Rev: 03/29/17) Diatron Albumin (BCG) Reagent (PI: DTRALB2.05, Rev 03/29/17) Diatron ALT (SGPT) Reagent (PI: DTRALT2.04, Rev 11/05/15) Diatron AST (SGOT) Reagent (PI: DTRAST2.05, Rev 03/29/17) Diatron Urea Nitrogen (BUN) Reagent (PI: DTRBUN2.05, Rev 03/29/17) Diatron Carbon Dioxide Reagent (PI DTRCO2.05, Rev 03/29/17) Diatron Creatinine (Single Vial) Reagent (PI: DTRCRE2.05, Rev 03/29/17) Pointe Scientific Liquid Glucose (Hexokinase) Reagent set (P803-G7517-02, Rev.01/18) Pointe Scientific Alkaline Phosphatase (Liquid) Reagent Set (P803-A7516-01, Rev 3/15) 2. Review of the package insert for the 10 Diatron reagents above revealed under intended use "packaged for the ease of use with the Diatron Pictus 400 chemistry analyzers." 3. Review of the laboratory records from 2019-2020 revealed the laboratory used the above 11 of 12 non-FDA approved reagents for testing on the Diatron Pictus 500 chemistry analyzers. Refer to patient alias list Diatron Total Protein (Biuret) Reagent (PI: DTRTPT2.03, Rev: 06/15

/12) "in use 6/26/19" Diatron Calcium Arsenazo reagent (PI: DTCAA2.02, Rev: 03/29 /17) "in use 6/26/19" Diatron Total Bilirubin Reagent (PI: DTRBN2.04, Rev: 05/22 /17) "in use 6/26/19" Diatron Alkaline Phosphatase (Liquid) Reagent (PI: DTRALP2. 05, Rev: 03/29/17) "in use 6/26/19" Diatron Albumin (BCG) Reagent (PI: DTRALB2. 05, Rev 03/29/17) "in use 6/26/19" Diatron ALT (SGPT) Reagent (PI: DTRALT2.04, Rev 11/05/15) "in use 6/26/19" Diatron AST (SGOT) Reagent (PI: DTRAST2.05, Rev 03/29/17) "in use 6/26/19" Diatron Urea Nitrogen (BUN) Reagent (PI: DTRBUN2.05, Rev 03/29/17) "in use 6/26/19" Diatron Carbon Dioxide Reagent (PI DTRCO2.05, Rev 03/29/17) "in use 6/26/19" Diatron Creatinine (Single Vial) Reagent (PI: DTRCRE2.05, Rev 03/29/17) "in use 6/26/19" Pointe Scientific Liquid Glucose (Hexokinase) Reagent set (P803-G7517-02, Rev.01/18) "n use 11/27/19" 4. Review of the laboratory verfication records revealed no documentation of the precision, reference range, sensitivity, specificity, preanalytical studies (cross refer to D5311), and any other performance characteristic required for test performance. 5. An interview with the laboratory consultant on 1/14/2020 at 1250 hours in the conference room confirmed the above findings. She was unaware the above reagents were not FDA approved for the Pictus 500 analyzer. Surveyor requested a letter from the laboratory to state that the reagents FDA approved for the Pictus 400 were FDA approved for the Pictus 500. No documentation were provided by 1/31/20. B. Based on review of laboratory proficiency test records, laboratory verification records, and confirmed in an email, the laboratory failed to document complete establishment studies for the non-FDA approved test for AST on the Pictus 500 analyzer. Findings were: 1. Review of the laboratory verification records revealed the laboratory performed incompleteverification studies for the Diatron AST in March 2019. Cross refer to D5423A 2. Review of an email recevied from the laboratory consultant on 1 /31/2020 revealed the following corrective action for the failed proficiency testing from the 3rd API event for the analyte AST (cross refer to D2087): "Our application specialist looked at the absorbance for each AST PT sample and our factor that was 1800, at the time, to obtain our concentration. She then theoretically calculated this at three different factors of 1900, 2000 and 2200 to see what percentage it will bring the concentration to where it needed to be. We then reran the failed AST proficiency testing samples and those results were then acceptable. We then ran precision studies to confirm the calibration factor is acceptable. The repeated AST PT samples and precision was performed after the adjustment." 3. Review of the laboratory verfication records revealed no documentation of the accuracy, reference range, sensitivity, specificity, preanalytical studies (cross refer to D5311), and any other performance characteristic required for test performance after the absorbance factor was changed for AST. 4. Review of the email from the laboratory consultant on 1/31/2020 revealed the laboratory only performed precision studies after the absorbance factor was changed: "The performance of precision studies after the adjustment of the calibration factor confirms the instrument is functioning as intended with the consideration of the instrument temperature and laboratory environment. If the precision studies were not acceptable, the process would repeat itself. The factors can be adjusted a little or a lot, and it is so very dependent on a lot of things. The performance of full blown validation studies are not the first step in troubleshooting the issue. Therefore, the precision studies verified the issue was resolved. All data is on file in the laboratory, precision studies, and the repeat AST included." No other studies were documented or assessed. This confirmed the findings. C. Based on review of the laboratory policy, linearity studies, and confirmed in interview, the laboratory failed to document the accurate reportable range used for 8 of 12 non FDA approved reagents on the Diatron Pictus 500 chemistry analyzer. Findings were: 1. Review of the laboratory policy Reportable Range Protocol (Policy #340) effective 5/4/19 revealed the following reportable ranges for the following analytes: Total Protein >15.7 g/dL Triglycerides

	0.8 - 800 g/dL ALT 1 - 450 U/L AST 1 - 600 U/L CO2 0.6 - 40 mEq/L CHOL 1.36 - 750 mg/dL Creatinine 0 - 20 mg/dL GLU 1 - 500 mg/dL 2. Review of the laboratory linearity studies for the Diatron Pictus 500 analyzer revealed no documentation to verify the above reportable range. 3. An interview with the laboratory consultant on 1 /14/2020 at 1250 hours in the conference room confirmed the above findings. She acknowledged that she needed to review those ranges and update them.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of the laboratory records and confirmed in interview, the laboratory failed to document the calibration verification for the Diatron Abacus hematology analyzer and the Diatron Pictus 500 chemistry analyzer. Findings were: 1. Review of the laboratory policy Calibration and Calibration Verification (Policy #440) effective 5 /4/19 revealed under required frequency of calibration "laboratories must calibrate per the following protocol: when first placed into service; every 6 months." 2. Review of the laboratory verification studies revealed documentation the laboratory performed the linearity studies for the Diatron Pictus 500 chemistry analyzer and Diatron Abacus hematology analyzer in 03/2019. 3. Review of the laboratory records revealed no calibration verification for the Diatron Pictus 500 chemistry analyzer nor the Diatron Abacus hematology analyzer in 09/2019. 4. An interview with the laboratory consultant on 1/14/20 at 1425 hours in the conference room confirmed the above findings. She stated that since the laboratory did not start patient testing until November 2019 that the laboratory did not have to perform the calibration verification. She was unaware that the calibration verification is required whenever the instrument was installed and every 6 months thereafter.
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:
Review of the laboratory policy, manufacturer's instructions, laboratory quality control records, and confirmed in interview, the laboratory failed to document control procedures that could detect immediate errors for testing on the Diatron Pictus 500 chemistry analyzer. Findings were: 1. Review of the laboratory policy Quality Control Program (Policy #500), with an effective date 5/4/19 under New Lot QC (Old lot to New lot Parallel Testing) revealed "upon receipt of a new lot of QC, testing personnel is required to perform parallel testing a minimum of 5 days before the expiration of the old lot. Determine if the new lot QC values are acceptable before new lot is put into use" 2. Review of the package insert for the Diatron Chemistry Control Level 1 (PI: DTMCL1-S042011 K.03, Rev: 2/28/19) revealed "As the results obtained will be dependent on a number of variables such as instrument, reagent and laboratory factors, it is strongly recommended that each laboratory verify the assigned values, or establish its own expected range, prior to introducing a new lot number." 3. Review of the package insert for the Diatron Chemistry Control Level 2 (PI: DTMCL2-S053012 K.03, Rev: 2/28/19) revealed "As the results obtained will be dependent on a number of variables such as instrument, reagent and laboratory factors, it is strongly recommended that each laboratory verify the assigned values, or establish its own expected range, prior to introducing a new lot number." 4. Review of the laboratory quality control records revealed no documentation that the laboratory established or verified the assigned values for the following quality control lot numbers: Diatron Chemistry Level 1 lot S042011B, exp 4/30/20 and Diatron Chemistry level 2 lot S053012B, Exp 5/31/20. 5. Review of the package insert for the Diatron Chemistry Control Level 1 (PI: DTMCL1-S042011 K.03, Rev: 2/28/19) revealed the following expected results for following lot number: Diatron Chemistry Level 1 lot S042011B, exp 4/30/20 Albumin: 2.4 +/- 0.3 Alkaline Phosphatase: 87 +/- 14 ALT: 46 +/- 6 AST: 47 +/- 7 Total Bilirubin: 0.8 +/- 0.4 Calcium: 9.8 +/- 1.6 Cholesterol: 140 +/- 17 Carbon Dioxide: 7 +/- 3 Creatinine: 1.1 +/- 0.3 Glucose: 88 +/- 11 Total Protein: 4.4 - 0.3 Triglyceride: 77 +/- 14 BUN: 15 +/- 2 6. Review of the package insert for the Diatron Chemistry Control Level 2 (PI: DTMCL2-S053012 K.03, Rev: 2/28/19) revealed the following expected results for the following lot number: Diatron Chemistry level 2 lot S053012B, Exp 5/31/20 Albumin: 4.3 +/- 0.3 Alkaline Phosphatase: 190 +/- 31 ALT: 111 +/- 13 AST: 183 +/- 12 Total Bilirubin: 5.1 +/- 1.2 Calcium: 13.8 +/- 0.6 Cholesterol: 285 +/- 25 Carbon Dioxide: 19 +/- 4 Creatinine: 4.9 +/- 0.5 Glucose: 311 +/- 28 Total Protein: 7.7 - 0.4 Triglyceride: 145 +/- 12 BUN: 50 +/- 4 7. Review of the laboratory quality control records from September 2019 to January 2020 revealed the laboratory used the above mean. Furthermore, the laboratory used the expected range as a standard deviation, making all acceptable ranges for both levels of chemistry controls +/- 4 SD. 8. The laboratory performed patient testing with the above quality control program from September 2019 to January 2020. See patient alias list. 9. An interview with the laboratory consultant on 1 /14/20 at 1650 hours confirmed the above findings. After another review of the

	monthly levey jennings (which were documented as reviewed previously by her) the laboratory consultant acknowledged that the SD used were too wide.
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 policies, laboratory quality control records, patient test records, and confirmed in interview, the laboratory failed to verify the acceptability of control materials for chemistry controls for the Diatron Pictus 500 chemistry analyzer. Findings were: 1. Review of the laboratory policy Quality Control Program (Policy #500), with an effective date 5/4/19 under New Lot QC (Old lot to New lot Parallel Testing) revealed "upon receipt of a new lot of QC, testing personnel is required to perform parallel testing a minimum of 5 days before the expiration of the old lot." 2. Review of the package insert for the Diatron Chemistry Control Level 1 (PI: DTMCL1-S042011 K.03, Rev: 2/28/19) revealed "As the results obtained will be dependent on a number of variables such as instrument, reagent and laboratory factors, it is strongly recommended that each laboratory verify the assigned values, or establish its own expected range, prior to introducing a new lot number." 3. Review of the package insert for the Diatron Chemistry Control Level 2 (PI: DTMCL2-S053012 K.03, Rev: 2/28/19) revealed "As the results obtained will be dependent on a number of variables such as instrument, reagent and laboratory factors, it is strongly recommended that each laboratory verify the assigned values, or establish its own expected range, prior to introducing a new lot number." 4.Review of the laboratory records revealed the laboratory put into use on 6/24/19 the following quality controls: Diatron Chemistry Level 1 lot S042011B, exp 4/30/20 and Diatron Chemistry level 2 lot S053012B, Exp 5/31/20. 5. Review of the laboratory quality control records revealed no documentation of establishing the acceptable ranges used in the laboratory for the above quality control lot numbers.
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 D6007, D6013, and D6020)
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 a review of laboratory preanalytic and analytic systems it was revealed that the laboratory director failed to ensure that testing systems performed in the laboratory provided quality laboratory services for all aspects of test performance in Hematology. Refer to D5421, D5439
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 verification records and confirmed in interview, the laboratory director failed to ensure the laboratory documented complete verification studies for the Diatron Abacus hematology analyzer prior to start of patient testing. Refer to D5421
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by:

	Based on review of the laboratory quality control (QC) records and confirmed in interview, the laboratory director failed to ensure the laboratory established and maintained a quality control program. Refer to D5469
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on review of the laboratory policies, verification studies, calibration records, and confirmed in interview, the technical consultant failed to provide technical oversight of the laboratory. (Refer to D6040, D6042, and D6053)
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Review of policies and procedures, quality control records, calibration records, and patient test records revealed that the technical consultant failed to ensure the laboratory documented complete verification studies for the Diatron Abacus hematology analyzer. (See D5421)
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: The technical consultant failed to ensure that the quality control program had been established and maintained for the Diatron Abacus hematology analyzer. (See D5469)
D6053	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 semiannually during the first year the individual tests patient specimens.

	This STANDARD is not met as evidenced by: Based on review of the CMS form 209, personnel records and verified by interview, the Technical Consultant failed to perform the initial competency evaluations in the first year for 1 of 1 testing personnel for the moderately complex testing in the specialties of hematology. Findings were: 1. Review of the laboratory's CMS 209 signed by the laboratory director on 1/31/20 revealed 1 testing personnel for the laboratory. 2. Review of the laboratory records available revealed the laboratory consultant, who is not qualified to be a technical consultant, performed the competency for TP#1. The laboratory consultant has an associates degree. 3. An interview with the laboratory consultant on 1/14/20 at 1020 hours in the conference room confirmed the above findings. She was unaware she could not perform the competency.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on a review of the laboratory's quality control records, facility procedures, record review and staff interview, it was revealed that the laboratory director failed to provide overall management and direction of the laboratory services (refer to D6079, D6086, D6093)
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) 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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on a review of laboratory preanalytic and analytic systems it was revealed that the laboratory director failed to ensure that testing systems performed in the laboratory provided quality laboratory services for all aspects of test performance in Chemistry. Refer to 5311, D5411, D5415, D5423
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that 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 for the non FDA-approved chemistry tests using the Diatron Pictus 500 chemistry analyzer, and confirmed in interview, the laboratory director failed to ensure the studies were complete prior to performing patient testing (refer to D5423-A, B, C).
D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Review of the laboratory policy, American Proficiency Institute (API) proficiency testing (PT) records, and confirmed in interview, the laboratory director failed to ensure a corrective action plan was followed for any unacceptable or unsatisfactory PT. Refer to D5211, D5291
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control records and staff interview, it was revealed the laboratory director failed to ensure a quality control plan was established and followed for high complexity testing in chemistry. Refer to D5441, D5469
D8100	INSPECTION REQUIREMENTS CFR(s): 493.1771 Each laboratory issued a CLIA certificate must meet the requirements in 493.1773 and the specific requirements for its certificate type, as specified in 493.1775 through 493.1780. All CLIA-exempt laboratories must comply with the inspection requirements in 493.1773 and 493.1780, when applicable. This CONDITION is not met as evidenced by: Based on review of the laboratory CMS116, surveyor observations, and confirmed in interview, the laboratory failed to meet the requirements in 493.1773. Refer to D8103
D8103	BASIC INSPECTION REQUIREMENTS CFR(s): 493.1773(b)(c)(d) (b) General Requirements. As part of the inspection process, CMS or a CMS agent may require the laboratory to do the following: (b)(1) Test samples, including

	proficiency testing samples, or perform procedures. (b)(2) Permit interviews of all personnel concerning the laboratory's compliance with the applicable requirements of this part. (b)(3) Permit laboratory personnel to be observed performing all phases of the total testing process preanalytic, analytic, and postanalytic). (b)(4) Permit CMS or a CMS agent access to all areas encompassed under the certificate including, but not limited to, the following: (b)(4)(i) Specimen procurement and processing areas. (b)(4)(ii) Storage facilities for specimens, reagents, supplies, records, and reports. (b)(4)(iii) Testing and reporting areas. (b)(5) Provide CMS or a CMS agent with copies or exact duplicates of all records and data it requires. (c) Accessible records and data. A laboratory must have all records and data accessible and retrievable within a reasonable time frame during the course of the inspection. (d) Requirement to provide information and data. A laboratory must provide, upon request, all information and data needed by CMS or a CMS agent to make a determination of the laboratory's compliance with the applicable requirements of this part. This STANDARD is not met as evidenced by: Based on review of the laboratory CMS116, surveyor observations, and confirmed in interview, the laboratory failed to permit surveyor to observe all phases of the total testing process (preanalytic, analytic). Findings were: 1. Review of the CMS116 revealed the laboratory hours of operation as 8:00 AM to 5:00 PM, Monday through Friday. Initial survey performed on 1/14/2020 during regular hours of operation. 2. An interview with the laboratory consultant on 1/14/2020 at 1000 hours in the laboratory revealed she instructed the facility to send out all specimens for the day. No non-waived patient testing were observed throughout the day. No patient specimens were observed for collection nor any testing performed. 3. Review of the CMS116 revealed the laboratory performed 26500 testing annually. 4. An interview with the laboratory consultant on 1/14/2020 at 1710 hours in the conference room confirmed the above findings. She was unaware the laboratory should maintain their usual operation during the inspection. She stated that the inspection should be "all hands on deck."