Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2002212	09/17/2018
Name of Provider or Supplier	**Street Address, City, State**	
Valley Day And Night Clinic	1214 Dixieland Rd Ste 8, Harlingen, 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	Noted deficiencies and plans of correction were discussed with the laboratory representative at the entrance and exit conferences. The facility representatives were given an opportunity to provide evidence of compliance with the noted deficiency, and no such evidence was provided prior to survey exit. Based upon the onsite survey conducted 09/172018, this facility was found NOT to be in compliance with the CLIA regulations found at 42 CFR 493.1250 Analytic Systems 493.1441 Laboratory Director, (high complexity) 493.1487 Testing Personnel (high complexity) The laboratory's failure to be in compliance with these regulations was found to pose IMMEDIATE JEOPARDY to the patients served by the laboratory. NOTE: The laboratory was asked to cease glucose testing using the Quintet AC Blood Glucose Monitoring System on patients without a known history of diabetes. The laboratory voluntarily ceased glucose testing on patients without a history of diabetes. See letter dated 09/18/2018 and signed by the laboratory director. 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.
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions for the Quintet AC Blood Glucose Monitoring System, a random review of patient history test records, and staff

	interview, it was revealed the laboratory failed to follow manufacturer's instructions for 11 of 12 patients tested in 08/2018. Findings included: 1. The manufacturer's instructions (101-3GM550-0W3) for the Quintet AC Blood Glucose Monitoring System stated "The Quintet AC System is intended for self-testing or professional use. It should not be used to diagnose diabetes mellitus." 2. A random review of patient history and testing records from 08/2018 revealed the laboratory used the Quintet AC Blood Glucose Monitoring System for 11 of 12 patients who did NOT have a known history of diabetes. The following patients were tested using the Quintet AC system. a. Date: 08/21/2018; Patient#395962; Glucose=96 b. Date: 08/21/2018; Patient#309413; Glucose=108 c. Date: 08/21/2018; Patient#409807; Glucose=102 d. Date: 08/21/2018; Patient#353343; Glucose=89 e. Date: 08/22/2018; Patient#97490; Glucose=80 f. Date: 08/23/2018; Patient#323741; Glucose=96 g. Date: 08/23/2018; Patient#417494; Glucose=105 h. Date: 08/23/2018; Patient#308965; Glucose=113 i. Date: 08/24/2018; Patient #277073; Glucose=113 j. Date: 08/24/2018; Patient#305612; Glucose=88 k. Date: 08/27/2018; Patient#176770; Glucose=106 The laboratory failed to follow manufacturer's instructions and used the Quintet AC system to test patients with no known history of diabetes. 3. The above findings were confirmed by the technical consultant during an interview on 09/17/2018 at 1030 hours in Exam Room#6.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy, review of laboratory quality control (QC) records from 11/2017, 01/2018, 03/2018, and 06/2018 for the Cell-Dyn Emerald hematology analyzer, review of laboratory's Levey-Jennings reports generated by the Laboratory Information System (LIS) and confirmed in staff interview, it was revealed the laboratory failed to retain quality control data from the instrument database that would detect errors over time in hematology QC testing and ensure accurate and reliable test results. Findings included: 1. The laboratory policy titled "Control Policy" stated, "Control results shall be recorded and if controls are out of range a remedial action should be taken and recorded. All records are kept for at least two years. Patient testing must not be performed or reported when controls are out of range." 2. The laboratory policy titled "Quality Control Troubleshooting Guide" stated the following: "It is the policy of this laboratory to do the following when controls are out of range. 1. Ensure that controls are not expired then remix and rerun controls. If control fails then 2. Open a new vial of control and rerun, if it fails then 3. Verify control ranges then 4. Make sure that all reagents and controls are in the right temperature then 5. Evaluate maintenance schedule, ensure that all manufacturer's recommendations are followed on time for all maintenance procedures 6. Evaluate calibration-if necessary recalibrate and rerun control or 7. Call technical support for help 8. Ensure that all remedial action steps are documented Most importantly, no patient is reported if controls are out of range." 3. Review of Cell-Dyn Emerald quality control reports from 11/2017, 01/2018, 03/2018, and 06/2018 revealed days when control material was out of the established range and repeated. Review of the Laboratory Information System (LIS) Daily Control Report revealed only the run with all parameters within range was accepted into the LIS. A random sample of those

	events are as follows: a. 11/25/2017 Control Lot Number L7268 First Run: 09:50AM RBC=2.51 (Acceptable range 2.03-2.43) HCT=19.6 (Acceptable range 15.4-19.4) Second Run: 10:00AM; All parameters within range Only QC values from the second run were in LIS b. 11/25/2017 Control Lot Number N7268 First Run: 09:55AM RBC=4.37 (Acceptable range 3.82-4.32) Second Run: 10:02AM RBC=4.38 (Acceptable range 3.82-4.32) Third Run: 10:06AM RBC=4.34 (Acceptable range 3.82-4.32) Third Run: 10:11AM; All parameters within range Only QC values from third run were in LIS. c. 11/27/2017 Control Lot Number N7268 First Run: 09:00AM RBC=4.38 (Acceptable range 3.82-4.32) Second Run: 09:05AM RBC=4.44 (Acceptable range 3.82-4.32) Third Run: 09:32AM RBC=4.46 (Acceptable range 3.82-4.32) Fourth Run: 09:40AM RBC=4.39 (Acceptable range 3.82-4.32) Fifth Run: 10:19AM RBC=4.46 (Acceptable range 3.82-4.32) Sixth Run: 11:47AM RBC=4.35 (Acceptable range 3.82-4.32) Sixth Run: 11:51AM; All parameters within range Only QC values from sixth run were in LIS d. 01/19/2018 Control Lot Number L7352 First Run: 09:08AM HGB=4.9 (Acceptable range 5.1-6.1) Second Run: 09:10AM HGB=5. 0 (Acceptable range 5.1-6.1) Third Run: 09:12AM; All parameters within range Only QC values from third run were in LIS e. 01/19/2018 Control Lot Number N7352 First Run: 09:15AM RBC=4.17 (Acceptable range 4.20-4.70) Second Run: 09:18AM RBC=4.00 (Acceptable range 4.20-4.70) HGB=10.9 (Acceptable range 11.4-12.8) Third Run: 09:26AM RBC=4.18 (Acceptable range 4.20-4.70) Fourth Run 09:28AM; All parameters within range Only QC values from fourth run were in LIS f. 03/03 /2018 Control Lot Number L7352 First Run: 10:07AM HGB=4.8 (Acceptable range 5.1-6.1) MCHC=28.4 (Acceptable range 28.5-34.5) Second Run: 10:32AM PLT=104 (Acceptable range 47-97) Third Run: 11:54AM PLT=98 (Acceptable range 47-97) Fourth Run: 11:58AM; All parameters within range Only QC values from fourth run were in LIS g. 06/12/2018 Control Lot Number L8071 First Run: 08:15AM MCH=21. 3 (Acceptable range 22.0-27.0) MCHC=27.1 (Acceptable range 29.3-35.3) Second Run: 08:17AM MCH=21.3 (Acceptable range 22.0-27.0) MCHC=27.4 (Acceptable range 29.3-35.3) Third Run: 08:26AM MCHC=28.4 (Acceptable range 29.3-35.3) Fourth Run: 08:59AM MCHC=28.4 (Acceptable range 29.3-35.3) Fifth Run: 09: 08AM MCHC=28.6 (Acceptable range 29.3-35.3) Sixth Run: 09:12AM MCHC=29.1 (Acceptable range 29.3-35.3) Seventh Run: 09:14AM MCHC=28.7 (Acceptable range 29.3-35.3) Eighth Run: 09:19AM; All parameters within range Only QC values from eighth run were in LIS h. 06/14/2018 Control Lot Number H8071 First Run: 08: 25AM MCHC=30.9 (Acceptable range 31.1-37.1) Second Run: 08:29AM; All parameters within range Only QC values from second run were in LIS 4. Review of laboratory's Levey-Jennings reports generated by the laboratory information system (LIS) from 11/2017 through 06/2018 revealed NO out of control values for any complete blood count analyte. The laboratory failed to ensure that ALL control results were recorded and to follow control procedures that detected error over time in hematology QC testing to ensure accurate and reliable test results. 5. The above findings were confirmed by the technical consultant in an interview on 09/17/2018 at 1027 hours in Exam Room#6. Word Key: WBC= White Blood Count RBC=Red Blood Count HCT=Hematocrit HGB=Hemoglobin MCV=Mean Corpuscular Volume MCHC= Mean Corpuscular Hemoglobin Concentration MCH= Mean Corpuscular Hemoglobin PLT=Platelet LYM=Lymphocyte GRA=Granulocyte
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 the manufacturer's instructions for the Cell-Dyn Emerald (9140847F-April 2012) hematology analyzer, Cell-Dyn Emerald analyzer test results from 03/2018 and 08/2018, patient complete blood count reports, and staff interview, it was revealed that the laboratory failed to establish a detailed, written Complete Blood Count (CBC) policy to ensure that results with flags are verified prior to being reported to the provider. Findings included: 1. The manufacturer's instructions for the Cell-Dyn Emerald hematology analyzer in the section titled "Instrument Alarms, Operational Alerts, and Measurand Data Flags" stated the following: a. "Test in Flags Box: L1 Action: Check the specimen for clots or agglutination. Follow your laboratory's review criteria or review a stained smear to confirm the differential results and verify the WBC count. Redraw and retest the specimen as required." b. "Test in Flags Box: L2 Action: Check the specimen for clots or agglutination. Follow your laboratory's review criteria or review a stained smear to confirm the differential results. Redraw and retest the specimen as required." c. "Test in Flags Box: L3 Action: Check the specimen for clots or agglutination. Follow your laboratory's review criteria or review a stained smear to confirm the differential results. Redraw and retest the specimen as required." 2. The laboratory policy titled "Procedure for CBC" stated: "Rerun CBC's when results have flags (Section 3: Instrument Alarms, Operational Alerts, and Measurand Data Flags)." 3. The laboratory policy titled "CBC Flags" stated: "CBC results with flags need to be rerun. Remix the specimen and rerun. If results are the same, then add the comment verified by repeat analysis. Have the provider review the result immediately to decide when specimen needs to be sent to reference laboratory for confirmation." The laboratory's policies do NOT ensure that the results with flags are verified by a stained smear prior to reporting the results to the provider. 4. A review of Cell-Dyn Emerald test results from 03/2018 and 08/2018 revealed 11 patients results with the L1, L2, or L3 flags. Further review of the patient CBC final reports from the 11 flagged results from 03/2018 and 08/2018 revealed the laboratory failed to replace the WBC and differential results for 5 of 11 patient reports. Those patient reports are as follows: a. Date: 03/07/2018 Patient: 402964 Flag: L1, L2 b. Date: 03/14/2018 Patient: 340810 Flag: L1 c. Date: 03/15/2018 Patient: 319667 Flag: L3 d. Date: 08/03/2018 Patient: 415359 Flag: L1, L3 e. Date: 08/24/2018 Patient: 305612 Flag: L1, L3 5. In an interview on 09/17/2018 at 0930 hours in Exam Room #6, the technical consultant was asked how unresolved CBC flag results were reported to the provider. The technical consultant stated, "The lab replaces the WBC and differential results with 0's on the final report and the specimen is sent to a reference laboratory." The laboratory was asked to provide documentation of this policy. No documentation was provided. This confirmed the above findings.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on direct observation and staff interview, the laboratory failed to ensure

	reagents had not exceeded their expiration date. Findings included: 1. A tour of the laboratory on 09/17/2018 at 1139 hours revealed the following expired reagents in the refrigerator: a. 2 vials of Cell-Dyn 18 Plus controls; Lot number H8155; expiration date 08/13/2018 b. 2 vials of Cell-Dyn 18 Plus controls; Lot number H8155; expiration date 09/01/2018 The laboratory failed to ensure reagents had not exceeded their expiration date. 2. In an interview with the technical consultant on 09/17/2018 at 10:40 hours in the laboratory confirmed the above findings. The technical consultant stated, "I don't know why those controls are still in the refrigerator."
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 for the Quintet AC Blood Glucose Monitoring System, review of patient history and test records from 08/2018, review of laboratory records and staff interview, it was revealed the laboratory failed to have documentation of performing validation studies for a laboratory-modified test system. Findings included: 1. The manufacturer's instructions for the Quintet AC Blood Glucose Monitoring System stated "The Quintet AC System is intended for self-testing or professional use. It should not be used to diagnose diabetes mellitus." 2. A random review of patient history and testing records from 08/2018 revealed the laboratory used the Quintet AC Blood Glucose Monitoring System for glucose testing on the following patient who did NOT have a history of diabetes: a. Date: 08/21/2018; Patient#395962; Glucose=96 b. Date: 08/21/2018; Patient#309413; Glucose=108 c. Date: 08/21/2018; Patient#409807; Glucose=102 d. Date: 08/21/2018; Patient#353343; Glucose=89 e. Date: 08/22/2018; Patient#97490; Glucose=80 f. Date: 08/23/2018; Patient#323741; Glucose=96 g. Date: 08/23/2018; Patient#417494; Glucose=105 h. Date: 08/23/2018; Patient#308965; Glucose=113 i. Date: 08/24/2018; Patient #277073; Glucose=113 j. Date: 08/24/2018; Patient#305612; Glucose=88 k. Date: 08/27/2018; Patient#176770; Glucose=106 3. Since the laboratory had modified the instrument system approved by the Food and Drug Administration (FDA) as waived, the test system becomes high complexity and the test system performance specifications for sensitivity, specificity, accuracy, and precision could be affected. Establishment studies must be performed by the laboratory. 4. Review of laboratory records revealed the laboratory failed to have documentation of performance specifications for sensitivity, specificity, accuracy, and precision for the Quintet AC Blood Glucose Monitoring System. 5. During an interview on 09/17/2018 at 1030 hours in Exam Room#6, the technical consultant was asked to provide documentation of performing establishment studies for the Quintet AC Blood Glucose Monitoring System. No documentation was provided. This confirmed the above findings.

D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy, laboratory quality control (QC) records from 11/2017, 01/2018, 03/2018, and 06/2018 for the Cell-Dyn Emerald hematology analyzer and confirmed in staff interview, it was revealed the laboratory failed to document detailed correction actions taken for Cell-Dyn Emerald QC failures. Findings included: 1. The laboratory policy titled "Control Policy" stated, "Control results shall be recorded and if controls are out of range a remedial action should be taken and recorded. All records are kept for at least two years. Patient testing must not be performed or reported when controls are out of range." The laboratory policy titled "Quality Control Troubleshooting Guide" stated the following: "It is the policy of this laboratory to do the following when controls are out of range. 1. Ensure that controls are not expired then remix and rerun controls. If control fails then 2. Open a new vial of control and rerun, if it fails then 3. Verify control ranges then 4. Make sure that all reagents and controls are in the right temperature then 5. Evaluate maintenance schedule, ensure that all manufacturer's recommendations are followed on time for all maintenance procedures 6. Evaluate calibration-if necessary recalibrate and rerun control or 7. Call technical support for help 8. Ensure that all remedial action steps are documented Most importantly, no patient is reported if controls are out of range." 2. Review of Cell-Dyn Emerald quality control reports from 11/2017, 01/2018, 03/2018, and 06/2018 revealed days when control material was out of the established range and repeated. A random sample of those events are as follows: a. 11/25/2017 Control Lot Number L7268 First Run: 09:50AM RBC=2.51 (Acceptable range 2.03-2.43) HCT=19.6 (Acceptable range 15.4-19.4) Second Run: 10:00AM; All parameters within range b. 11/25/2017 Control Lot Number N7268 First Run: 09:55AM RBC=4.37 (Acceptable range 3.82-4.32) Second Run: 10:02AM RBC=4.38 (Acceptable range 3.82-4.32) Third Run: 10:06AM RBC=4.34 (Acceptable range 3.82-4.32) Third Run: 10:11AM; All parameters within range c. 11/27/2017 Control Lot Number N7268 First Run: 09:00AM RBC=4.38 (Acceptable range 3.82-4.32) Second Run: 09:05AM RBC=4.44 (Acceptable range 3.82-4.32) Third Run: 09:32AM RBC=4.46 (Acceptable range 3.82-4.32) Fourth Run: 09:40AM RBC=4.39 (Acceptable range 3.82-4.32) Fifth Run: 10:19AM RBC=4.46 (Acceptable range 3.82-4.32) Sixth Run: 11:47AM RBC=4.35 (Acceptable range 3.82-4.32) Sixth Run: 11:51AM; All parameters within range d. 01/19/2018 Control Lot Number L7352 First Run: 09:08AM HGB=4.9 (Acceptable range 5.1-6.1) Second Run: 09:10AM HGB=5.0 (Acceptable range 5.1-6.1) Third Run: 09:12AM; All parameters within range e. 01/19/2018 Control Lot Number N7352 First Run: 09:15AM RBC=4.17 (Acceptable range 4.20-4.70) Second Run: 09:18AM RBC=4.00 (Acceptable range 4.20-4.70) HGB=10.9 (Acceptable range 11.4-12.8) Third Run: 09:26AM RBC=4.18 (Acceptable range 4.20-4.70) Fourth Run 09:28AM; All parameters within range f. 03/03/2018 Control

	Lot Number L7352 First Run: 10:07AM HGB=4.8 (Acceptable range 5.1-6.1) MCHC=28.4 (Acceptable range 28.5-34.5) Second Run: 10:32AM PLT=104 (Acceptable range 47-97) Third Run: 11:54AM PLT=98 (Acceptable range 47-97) Fourth Run: 11:58AM; All parameters within range g. 06/12/2018 Control Lot Number L8071 First Run: 08:15AM MCH=21.3 (Acceptable range 22.0-27.0) MCHC=27.1 (Acceptable range 29.3-35.3) Second Run: 08:17AM MCH=21.3 (Acceptable range 22.0-27.0) MCHC=27.4 (Acceptable range 29.3-35.3) Third Run: 08:26AM MCHC=28.4 (Acceptable range 29.3-35.3) Fourth Run: 08:59AM MCHC=28.4 (Acceptable range 29.3-35.3) Fifth Run: 09:08AM MCHC=28.6 (Acceptable range 29.3-35.3) Sixth Run: 09:12AM MCHC=29.1 (Acceptable range 29.3-35.3) Seventh Run: 09:14AM MCHC=28.7 (Acceptable range 29.3-35.3) Eighth Run: 09:19AM; All parameters within range h. 06/14/2018 Control Lot Number H8071 First Run: 08:25AM MCHC=30.9 (Acceptable range 31.1-37.1) Second Run: 08:29AM; All parameters within range 3. Review of the laboratory corrective action forms for 11/2017, 01/2018, 03/2018, and 06/2018 in the section titled "Corrective Action" revealed the following was written for corrective action. a. 11/25/2017 Corrective Action "All controls passed. Reran low" b. 11/27/2017 Corrective Action "All controls passed. Reran normal" c. 01/19/2018 Corrective Action "All controls passed" d. 03/03/2018 Corrective Action "All controls passed" e. 06/12/2018 Corrective Action "All controls passed. Reran all controls" f. 06/14/2018 Corrective Action "All controls passed. Reran low & high control" The laboratory failed to document detailed correction actions taken for Cell-Dyn Emerald QC failures. 4. The above findings were confirmed by the technical consultant in an interview on 09/17 /2018 at 1027 hours in Exam Room#6.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of Cell Dyn Emerald hematology analyzer Quality Control records for 09/2018, laboratory daily control reports, laboratory's quality assurance (QA) records and staff interview, the laboratory failed to have an effective QA system in place to ensure that Cell-Dyn 18 Plus control values entered into the Cell-Dyn Emerald hematology analyzer corresponded to Cell-Dyn 18 Plus control values entered into the Laboratory Information System (LIS). Findings included: 1. Random review of Cell Dyn Emerald hematology analyzer quality control printouts from 09 /2018 and the laboratory's daily control reports generated from the LIS revealed the following: a. Lot number L8239; Expiration date 2018-12-14; Date of QC run 09/11 /2018 Analyte: LYM=1.2 Expected Values (Cell-Dyn)=0.5-1.7 Expected Values(LIS) =0.6-1.8 MID=0.1 Expected Values (Cell-Dyn)=0.0-0.4 Expected Values(LIS)=-0.1-0.3 GRA=1.0 Expected Values (Cell-Dyn)=0.2-1.8 Expected Values(LIS)=0.0-2.0 LYM%=51.8 Expected Values (Cell-Dyn)=40.8-60.8 Expected Values(LIS)=41.8-61.8 MID%=4.3 Expected Values (Cell-Dyn)=0.0-12.0 Expected Values(LIS)=-1.0-9.0 GRA%=43.9 Expected Values (Cell-Dyn)=35.6-55.6 Expected Values(LIS)=34.2-54.2 RBC=2.23 Expected Values (Cell-Dyn)=1.96-2.36 Expected Values(LIS)=2.08-2.48 HCT=17.1 Expected Values (Cell-Dyn)=14.4-18.4 Expected Values(LIS)=15.6-19.6 MCV=76.5 Expected Values (Cell-Dyn)=72.0-80.0 Expected Values(LIS)=73.1-

81.1 MCH=23.3 Expected Values (Cell-Dyn)=22.0-27.0 Expected Values(LIS)=20.9-25.9 MCHC=30.4 Expected Values (Cell-Dyn)=29.3-35.3 Expected Values(LIS)=27.3-33.3 PLT=48 Expected Values (Cell-Dyn)=39 -89 Expected Values(LIS)=32-82 b. Lot number N8239; Expiration date 2018-12-14; Date of QC run 09/11/2018 Analyte: WBC=7.9 Expected Values (Cell-Dyn)=7.4-9.4 Expected Values(LIS)=7.0-9.0 LYM=2.1 Expected Values (Cell-Dyn)=1.0-3.4 Expected Values(LIS)=0.8-3.2 GRA=5.4 Expected Values (Cell-Dyn)=3.9-7.9 Expected Values(LIS)=3.6-7.6 LYM%=26.0 Expected Values (Cell-Dyn)=16.7-34.7 Expected Values(LIS)=15.9-33.9 MID%=6.2 Expected Values (Cell-Dyn)=0.0 - 10.0 Expected Values(LIS)= -0.2-9.8 GRA%=67.8 Expected Values (Cell-Dyn)=61.8-79.8 Expected Values(LIS)=61.3-79.3 RBC=4.15 Expected Values (Cell-Dyn)=3.85 - 4.35 Expected Values(LIS)=3.95-4.45 HGB=11.0 Expected Values (Cell-Dyn)=10.5 - 11.9 Expected Values(LIS)=10.6-12.0 HCT=35.6 Expected Values (Cell-Dyn)=30.5-37.5 Expected Values(LIS)=32.7-39.7 MCV=85.8 Expected Values (Cell-Dyn)=78.0-88.0 Expected Values(LIS)=81.2-91.2 MCH=26.5 Expected Values (Cell-Dyn)=24.8-29.8 Expected Values(LIS)=24.3-29.3 MCHC=30.9 Expected Values (Cell-Dyn)=29.9-35.9 Expected Values(LIS)=28.1-34.1 PLT=178 Expected Values (Cell-Dyn)=174-244 Expected Values(LIS)=155-225 c. Lot number H8239; Expiration date 2018-12-14; Date of QC run 09/11/2018 Analyte: WBC=18.3 Expected Values (Cell-Dyn)=15.8-20.8 Expected Values(LIS)=16.0-21.0 LYM=2.4 Expected Values (Cell-Dyn)=0.3-4.3 Expected Values(LIS)=0.5-4.5 MID=0.6 Expected Values (Cell-Dyn)=0.0-2.4 Expected Values(LIS)=-0.4 - 2.0 GRA=15.2 Expected Values (Cell-Dyn)=11.9-18.9 Expected Values(LIS)=11.8-18.8 LYM%=13.2 Expected Values (Cell-Dyn)=6.6-18.6 Expected Values(LIS)-7.6-19.6 MID%=3.5 Expected Values (Cell-Dyn)=0.0-10.0 Expected Values (LIS=-0.9 - 9.1 GRA%=83.3 Expected Values (Cell-Dyn)=76.4-92.4 Expected Values(LIS)=74.3-90.3 RBC=5.20 Expected Values (Cell-Dyn)=4.91-5.51 Expected Values(LIS)=4.95-5.55 HGB=15.0 Expected Values (Cell-Dyn)=14.8 - 16.8 Expected Values(LIS)=14.3-16.3 HCT=46.9 Expected Values (Cell-Dyn)=42.9-49.9 Expected Values(LIS)=44.3-51.3 MCV=90.2 Expected Values (Cell-Dyn)=840 - 94.0 Expected Values(LIS)=85.9-95.9 MCH=28.8 Expected Values (Cell-Dyn)=27.8-32.8 Expected Values(LIS)=26.6-31.6 MCHC=32.0 Expected Values (Cell-Dyn)=31.1-37.1 Expected Values(LIS)=29.0-35.0 PLT=377 Expected Values (Cell-Dyn)=359-529 Expected Values(LIS)=313-483 d. Lot number L8239; Expiration date 2018-12-14; Date of QC run 09/12/2018 Analyte: LYM=1.1 Expected Values (Cell-Dyn)=0.5-1.7 Expected Values(LIS)=0.6-1.8 MID=0.1 Expected Values (Cell-Dyn)=0.0-0.4 Expected Values(LIS)=-0.1-0.3 GRA=0.9 Expected Values (Cell-Dyn)=0.2-1.8 Expected Values(LIS)=0.0-2.0 LYM%=52.5 Expected Values (Cell-Dyn)=40.8-60.8 Expected Values(LIS)=41.8-61.8 MID%=4.8 Expected Values (Cell-Dyn)=0.0-12.0 Expected Values(LIS)=-1.0-9.0 GRA%=42.7 Expected Values (Cell-Dyn)=35.6-55.6 Expected Values(LIS)=34.2-54.2 RBC=2.24 Expected Values (Cell-Dyn)=1.96-2.36 Expected Values(LIS)=2.08-2.48 HCT=17.4 Expected Values (Cell-Dyn)=14.4-18.4 Expected Values(LIS)=15.6-19.6 MCV=77.8 Expected Values (Cell-Dyn)=72.0-80.0 Expected Values(LIS)=73.1-81.1 MCH=22.8 Expected Values (Cell-Dyn)=22.0-27.0 Expected Values(LIS)=20.9-25.9 MCHC=29.3 Expected Values (Cell-Dyn)=29.3-35.3 Expected Values(LIS)=27.3-33.3 PLT=49 Expected Values (Cell-Dyn)=39 -89 Expected Values(LIS)=32-82 e. Lot number N8239; Expiration date 2018-12-14; Date of QC run 09/12/2018 Analyte: WBC=7.8 Expected Values (Cell-Dyn)=7.4-9.4 Expected Values(LIS)=7.0-9.0 LYM=2.0 Expected Values (Cell-Dyn)=1.0-3.4 Expected Values(LIS)=0.8-3.2 GRA=5.0 Expected Values (Cell-Dyn)=3.9-7.9 Expected Values(LIS)=3.6-7.6 LYM%=26.0 Expected Values (Cell-Dyn)=16.7-34.7 Expected Values(LIS)=15.9-33.9 MID%=9.5 Expected Values (Cell-Dyn)=0.0 - 10.0 Expected Values(LIS)= -0.2-9.8 GRA%=64.5 Expected Values (Cell-Dyn)=61.8-79.8 Expected Values(LIS)=61.3-79.3 RBC=4.18 Expected Values (Cell-Dyn)=3.85 - 4.35 Expected Values(LIS)=3.95-

	4.45 HGB=11.1 Expected Values (Cell-Dyn)=10.5 - 11.9 Expected Values(LIS)=10.6-12.0 HCT=36.2 Expected Values (Cell-Dyn)=30.5-37.5 Expected Values(LIS)=32.7-39.7 MCV=86.7 Expected Values (Cell-Dyn)=78.0-88.0 Expected Values(LIS)=81.2-91.2 MCH=26.6 Expected Values (Cell-Dyn)=24.8-29.8 Expected Values(LIS)=24.3-29.3 MCHC=30.7 Expected Values (Cell-Dyn)=29.9-35.9 Expected Values(LIS)=28.1-34.1 PLT=178 Expected Values (Cell-Dyn)=174-244 Expected Values(LIS)=155-225 f. Lot number H8239; Expiration date 2018-12-14; Date of QC run 09/12/2018 Analyte: WBC=18.3 Expected Values (Cell-Dyn)=15.8-20.8 Expected Values(LIS)=16.0-21.0 LYM=2.4 Expected Values (Cell-Dyn)=0.3-4.3 Expected Values(LIS)=0.5-4.5 MID=0.6 Expected Values (Cell-Dyn)=0.0-2.4 Expected Values(LIS)=-0.4 - 2.0 GRA=15.3 Expected Values (Cell-Dyn)=11.9-18.9 Expected Values(LIS)=11.8-18.8 LYM%=13.1 Expected Values (Cell-Dyn)=6.6-18.6 Expected Values(LIS)-7.6-19.6 MID%=3.2 Expected Values (Cell-Dyn)=0.0-10.0 Expected Values (LIS=-0.9 - 9.1 GRA%=83.7 Expected Values (Cell-Dyn)=76.4-92.4 Expected Values(LIS)=74.3-90.3 RBC=5.24 Expected Values (Cell-Dyn)=4.91-5.51 Expected Values(LIS)=4.95-5.55 HGB=15.0 Expected Values (Cell-Dyn)=14.8 - 16.8 Expected Values(LIS)=14.3-16.3 HCT=47.7 Expected Values (Cell-Dyn)=42.9-49.9 Expected Values(LIS)=44.3-51.3 MCV=91.1 Expected Values (Cell-Dyn)=840 - 94.0 Expected Values(LIS)=85.9-95.9 MCH=28.6 Expected Values (Cell-Dyn)=27.8-32.8 Expected Values(LIS)=26.6-31.6 MCHC=31.4 Expected Values (Cell-Dyn)=31.1-37.1 Expected Values(LIS)=29.0-35.0 PLT=392 Expected Values (Cell-Dyn)=359-529 Expected Values(LIS)=313-483 The laboratory failed to ensure that Cell-Dyn 18 Plus control values entered into the Cell-Dyn Emerald hematology analyzer corresponded to Cell-Dyn 18 Plus control values entered into the Laboratory Information System (LIS). NOTE: The laboratory utilized the LIS to access quality control acceptability. 2. The above findings were confirmed in an interview with the technical consultant on 09/17/2018 at 1027 hours in Exam Room#6. Word Key: WBC= White Blood Count RBC=Red Blood Count HCT=Hematocrit HGB=Hemoglobin MCV=Mean Corpuscular Volume MCHC= Mean Corpuscular Hemoglobin Concentration MCH= Mean Corpuscular Hemoglobin PLT=Platelet LYM=Lymphocyte GRA=Granulocyte LYM%=Lymphocyte Percent GRA%=Granulocyte Percent MID%=Mid Cell Percent
D5813	TEST REPORT CFR(s): 493.1291(g) The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values. This STANDARD is not met as evidenced by: Based on review of laboratory policy, Cell-Dyn Emerald (Serial Number 030113-003572) hematology analyzer test results from 03/2018 and 08/2018, patient final reports, and staff interview, it was revealed that the laboratory failed to follow its own written policy for reporting complete blood count (CBC) panic values for 4 of 5 patients. Findings included: 1. Review of the laboratory policies revealed the following: a. The laboratory policy titled "Reporting Panic Values" stated, "All panic values must be verified by the testing personnel by re-running the test and then notify the provider as soon as possible for panic results." b. The laboratory policy titled "Reporting Laboratory Results" stated, "The laboratory staff will immediately notify the provider of any test result found to be in the PANIC RANGE." c. The laboratory policy titled "Panic Values" stated the following panic values for CBC results: 1. WBC Under 2,000 Over 20,000 2. HGB Under 7.5 Over 18 3. HCT Under 25 Over 55

	4. PLT Under 50,000 Over 800,000 2. Review of Cell-Dyn Emerald hematology analyzer test results from 03/2018 and 08/2018 revealed the laboratory failed to document provider notification for 4 of 5 patients with panic values. Those patients /values are as following: a. Date: 03/08/2018 Patient: 353981 HGB=22.3 HCT=66.5 b. Date:03/10//2018 Patient: 403236 HGB=18.5 HCT=55.2 c. Date: 03/15/2018 Patient: 319667 HGB=19.9 HCT=59.1 d. Date: 08/07/2018 Patient: 292485 HGB=18. 4 HCT=59.4 3. The above findings were confirmed in an interview with the technical consultant on 09/17/2018 at 0930 hours in Exam Room #6. WORD KEY: WBC=White Blood Count HGB=Hemoglobin HCT=Hematocrit PLT=Platelet
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 review of the laboratory's modified Quintet AC blood glucose monitoring test system, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory director failed to have documentation to qualify as a laboratory director overseeing high complexity testing (refer to D6078) and failed to provide oversight for high complexity testing (refer to D6086).
D6078	LABORATORY DIRECTOR QUALIFICATIONS CFR(s): 493.1443 The laboratory director must be qualified to manage and direct the laboratory personnel and performance of high complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b) (1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2) Be a doctor of medicine, a doctor of osteopathy or doctor of podiatric medicine licensed to practice medicine, osteopathy or podiatry in the State in which the laboratory is located; and (b)(2)(i) Have at least one year of laboratory training during medical residency (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(2)(ii) Have at least 2 years of experience directing or supervising high complexity testing; or (b)(3) Hold an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution and-- (b)(3)(i) Be certified and continue to be certified by a board approved by HHS; or (b)(3)(ii) Before February 24, 2003, must have served or be serving as director of a laboratory performing high complexity testing and must have at least-- (b)(3)(ii)(A) Two years of laboratory training or experience, or both; and (b)(3)(ii)(B) Two years of laboratory experience directing or supervising high complexity testing. (b)(4) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under regulations at 42 CFR 493.1415, published March 14, 1990 at 55 FR

	9538, on or before February 28, 1992; or (b)(5) On or before February 28, 1992, be qualified under State law to direct a laboratory in the State in which the laboratory is located; or (b)(6) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, the American Osteopathic Board of Pathology, or possess qualifications that are equivalent to those required for certification. This STANDARD is not met as evidenced by: Based on review of the laboratory's blood glucose monitoring system, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory director failed to have documentation to qualify as a laboratory director overseeing high complexity testing. The findings were: 1. A review of the laboratory's glucose monitoring system revealed the laboratory had modified an FDA-approved test by utilizing the Quintet AC Blood Glucose Monitoring system to test patients with no history of diabetes. 2. A review of the laboratory's personnel records revealed the laboratory director was licensed in the state of Texas, however failed to have documentation of: a) at least 1 year of laboratory training during medical residency, or b) at least 2 years directing or supervising high complexity testing. 3. In interview on 09/17/2018 at 1030 hours in Exam Room#6, the technical consultant was asked to provide documentation of the additional experience to qualify as a director over a high complexity lab. No documentation was provided. This confirmed the findings.
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 manufacturer's instructions for the Quintet AC Blood Glucose Monitoring system, review of patient test records from September 2018, and staff interview, it was revealed the laboratory director failed to ensure establishment studies were performed prior to testing patient samples for a laboratory-modified test system (refer to D5423).
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on review of the CMS-209 form and personnel records, it was revealed the laboratory failed to have documentation that 11 of 11 testing persons (TP#1 through TP #11) met the qualifications required to perform high complexity testing. (Refer to D6171)
D6171	TESTING PERSONNEL QUALIFICATIONS

CFR(s): 493.1489(b)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

	This STANDARD is not met as evidenced by: Based on review of the CMS-209 form, review of the laboratory's Quintet AC Blood Glucose Monitoring System, and review of the laboratory's personnel records revealed the laboratory failed to have documentation that 11 of 11 testing persons (TP#1 - TP#11) met the qualifications required to perform high complexity testing. Findings included: 1. Review of the CMS-209 form included Testing Person #1 through Testing Person #11 listed to perform moderated complexity testing. 2. A review of the laboratory's glucose monitoring system revealed the laboratory had modified an FDA-approved test by utilizing the Quintet AC Blood Glucose Monitoring system to test patients with no history of diabetes 3. Review of personnel records revealed a high school diploma as the highest documented education for Testing Person #1 through Testing Person #11. Testing Person #1 through Testing Person #11 were NOT qualified to perform high complexity testing. 4. The above findings were confirmed by the technical consultant in an interview on 09/17/2018 at 1030 hours in Exam Room#6.