

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D2003905	<b>(X3) Date Survey Completed</b>  07/16/2019
<b>Name of Provider or Supplier</b>  Valley Day And Night Clinic	<b>Street Address, City, State</b>  5502 North San Bernardo Ste 600, Laredo, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2009</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation, review of laboratory's procedure manual, American Association of Bioanalysts (AAB) General Instructions, AAB proficiency testing (PT) records, and in interview with staff, the laboratory failed to attest to the routine integration of proficiency samples into the patient workload for hematology PT samples in 2017 for 1 of 3 events (Q-3), 2018 for 2 of 3 events (Q-2, Q-3) and 2019 for 2 of 2 events (Q-1, Q-2). Findings: 1. Review of AAB GENERAL INTRUCTIONS revealed the following: "REPORTING RESULTS ... 7. Be sure to keep the attestation statements on the program instructions. We do not require these statements for grading. The attestation statements must be signed for each analyte by the analyst performing the procedure and kept in your files for inspection purposes ..." 2. Review of proficiency testing records from 2017, 2018 and 2019 all testing persons (TP) performing PT failed to sign the attestation forms for the following events: 2017 Q-3: PT was performed by 2 TP and the attestation form was only signed by 1 TP 2018 Q-2: PT was performed by 5 TP and the attestation form was only signed by 1 TP 2018 Q-3: PT was performed by 3 TP and the attestation form was only signed by 1 TP 2019 Q-1: PT was performed by 5 TP and the attestation form was only signed by 1 TP 2019 Q-2: PT was performed by 5 TP and the attestation form was only signed by 1 TP 3. During an interview on 07/16/2019 at 3:00 pm, the technical consultant stated that the PT attestation forms are signed electronically, and the electronic version only allows for one signature. She stated that the laboratory's</p>

practice to keep track of which TP performed PT was that all TP sign the instrument printouts for the PT that was performed by them. This confirmed the laboratory failed to ensure all attestation statements were signed by all TP.

**D2015**

**TESTING OF PROFICIENCY TESTING SAMPLES**  
CFR(s): 493.801(b)(5)(6)

(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.

This STANDARD is not met as evidenced by:  
Based on review of CMS 155 report, American Association of Bioanalysts (AAB) proficiency testing (PT) records and confirmed in staff interview, the laboratory failed to all retain hematology proficiency testing records for 2 of 3 testing events in 2018 (Q-2, Q-3) and 2 of 2 events in 2019 (Q-1, Q-2). Findings: 1. Review of CMS 155 report revealed the laboratory participated in hematology 2018 (Q-2, Q-3) and 2019 (Q-1, Q-2). The laboratory failed to maintain a copy of the following records: AAB report forms used to document PT results 2. During an interview on 07/16/2019 at 2:29 pm, the technical consultant stated that she did not know where the AAB report forms were located and that the staff "probably threw them away," confirming the above findings.

**D2121**

**HEMATOLOGY**  
CFR(s): 493.851(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 Centers for Medicare and Medicaid Services (CMS) 155 reports, American Association of Bioanalysts (AAB) proficiency testing (PT) records, and confirmed in interview, the laboratory failed to attain a score of at least 80 percent for the red blood cell (RBC), hematocrit (HCT), and platelets hematology analytes for 1 of 3 proficiency testing events in 2017 (2017 3rd Event). Findings included: 1. Review of CMS 155 report for PT 2017 (third event) revealed the following unsatisfactory scores: RBC 2019 3rd Event 0% HCT 2019 3rd Event 0% Platelets 2019 3rd Event 60% The laboratory failed to attain a score of at least 80% for RBC, HCT and platelet analytes. 2. Review of AAB report for PT 2017 (third event) revealed the following unsatisfactory scores: RBC 2019 3rd Event 0% HCT 2019 3rd Event 0% Platelets 2019 3rd Event 60% 3. During an interview on 07/16/2019 at 2:54 pm, the technical consultant confirmed the laboratory failed to attain a score of at least 80% for the above mentioned analytes.

**D2122**

**HEMATOLOGY**

CFR(s): 493.851(b)

Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

This STANDARD is not met as evidenced by:

Based on review of Centers for Medicare and Medicaid Services (CMS) 155 reports, American Association of Bioanalysts (AAB) proficiency testing (PT) records, and confirmed in interview, the laboratory failed to attain a score of at least 80 percent for each testing event in the specialty of hematology. Findings: 1. Review of CMS 155 report for PT 2017 (third event) revealed the laboratory received an overall score of 60% for the specialty of hematology. This constitutes unsatisfactory performance in hematology for the third testing event of 2017. 2. Review of AAB PT records revealed PT 2017 (third event) the laboratory received an overall score of 60% for the specialty of hematology. This constitutes unsatisfactory performance in hematology for the third testing event of 2017. 3. During an interview on 07/16/2019 at 2:54 pm, the technical consultant confirmed the laboratory failed to attain a score of at least 80% for the specialty of hematology third testing event in 2017.

**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 surveyor observation, review of laboratory policy, and confirmed in interview of facility personnel, the laboratory failed to follow its own policy for specimen labeling. The findings were: 1. Surveyor observation 1: made on July 16, 2019 at 16:30 hours in the laboratory revealed a patient's urine specimen in process on the analyzer. The specimen was not labeled with any identifying information. Further observations revealed a CBC (complete blood count) collected in a purple top with only the patient's first and last name. 2. Surveyor observation 2: during a tour of the laboratory on 07/16/2019 at 1:07 pm, the surveyor observed an unlabeled urine specimen in the refrigerator used for the storage of vaccinations. The laboratory failed to follow its own written policy for labeling specimens using unique patient identifiers. 3. Review of the laboratory's policies revealed a policy approved and signed by the laboratory director on November 20, 2013 that stated, "Specimen Identification: Each specimen must have unique identifiers such as name and date of birth. These identifiers will be used throughout the testing process so that results can be confidently used in patient care. This can be done by using LIS labels for tubes." 4. The laboratory did not follow its own policy for specimen labeling 5. The above findings were confirmed in interview with the technical consultant on July 16, 2019 at 16:45 hours in the laboratory when she told the testing person that all specimens must be labeled even if they are for worker's compensation.

**D5403**

**PROCEDURE MANUAL**

CFR(s): 493.1251(b)

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on review of laboratory policy, manufacturer's instructions, corrective action logs, and staff interview, the laboratory failed to include a policy for troubleshooting instrument failures for the CELL-DYN hematology analyzer. Findings: 1. Review of laboratory policy for the CELL-DYN hematology analyzer revealed there was no policy for troubleshooting instrument failures. 2. Review of an update from the manufacturer Abbott, dated February 2019 stated: "Changes included in v3.2.0 are the following: Software v3.2.0 improves fluidics cycles, including: enhanced Backflush, Auto Clean, Shutdown, Auto Rinse and System Clean, and fluidic cycles to reduce "CYCLE: PRESSURE DEFAULT" errors ..." 3. Review of corrective action logs in 2018 and 2019 (random review) revealed the following: Corrective action was documented as "machine not working" for the following dates: 03/01/2018 03/17/2018 03/18/2018 03/19/2018 3/22/2018 03/25-03/30/2018 04/05/2018 04/08/2018 04/09/2018 There was no documentation of further troubleshooting to fix the CBC analyzer. Corrective action was documented as "CBC not working" for the following dates: 05/12/2019 05/29/2019 06/06/2019 06/08/2019 06/13/2019 07/07/2019 07/14/2019 There was no documentation of further troubleshooting to fix the CBC analyzer. 4. During an interview on 07/16/2019 at 5:32 pm, the technical consultant (TC) stated that when the staff documented on the corrective action log that the CBC analyzer was not working it was due to a "pressure default" error upon startup. The TC stated that the staff do not troubleshoot the analyzer and just do not run the analyzer until the next day or someone may attempt to turn it on and run it later in the day. She also stated that the software update will be performed once they schedule service by the manufacturer.

**D5413**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**

CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's

instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on direct observation, manufacturer's instructions, and confirmed in interview, the laboratory failed to ensure quality control (QC) was stored according to manufacturer's instructions. Findings: 1. Review of the CELL-DYN Quality Control package insert revealed the following: "STORAGE AND STABILITY CELL-DYN 18 Plus Control should be tightly capped and stored, at 2-10C (36-50F). Protect containers from overheating and freezing." 2. During a tour of the laboratory on 07/16/2019 at 1:07 pm, the surveyor observed the thermometer reading of the temperature in the reagent refrigerator to be 24C. The following reagents were stored in the refrigerator: 2 (unopened) boxes of CELL-DYN Quality Control, Lot# 9154, expiration date: 09/20/2019 1 opened box of CELL-DYN Quality Control, Lot# 9154, expiration date: 09/20/2019 Note: this was the control that was currently in use by the laboratory and was used to run the morning QC. Low control was tested at 09:47 am. Normal control was tested at 10:27 am. High control was tested at 10:30 am. The following patient was run using QC that had been compromised: ID 452607 tested on 07/16/2019 at 4:41 pm. 3. During an interview on 07/16/2019 at 1:07 pm, the technical consultant stated that when the staff came in in the morning the reagent refrigerator was not working. The staff moved the CELL-DYN QC reagent to the vaccination refrigerator. The TC stated that at 10:00 am she told the staff to move the QC back to the non-working refrigerator because it could not be in the same refrigerator as the vaccination refrigerator.

**D5785**

**CORRECTIVE ACTIONS**

CFR(s): 493.1282(b)(3)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.

This STANDARD is not met as evidenced by:

Based on review of laboratory policy, review of environmental records, review of patient results, and confirmed in interview of facility personnel, the laboratory failed to document corrective action on days when patients were tested and the temperature of the laboratory was documented out of the laboratory's acceptable range. The findings were: 1. Review of the laboratory's policy titled, "Instrument Operation and Maintenance" (no approval date) stated, "Temperature readings must be done daily and documented." The policy failed to include directions for testing personnel to follow in the event the temperature was outside of the acceptable range of the laboratory. 2. Review of the laboratory's environmental logs revealed the laboratory had defined its acceptable room temperature as 20 to 25 degrees Celsius. 3. Review of the laboratory's environmental records from July 2018 and July 2019 found the random review of dates when the temperature of the laboratory was documented outside of the laboratory's documented acceptable range. Date Temperature 07-26-2018 26 07-27-2018 29 07-28-2018 30 07-29-2018 31 07-30-2018 32 07-31-2018 33 10-20-2018 26 01-24-2019 32 01-25-2019 32 4. Review of patient test records revealed that on 3 of the 9 days when the laboratory's temperature was documented

out of range, patients were tested as follows for CBC (complete blood count):  
Account # 384228 Date: 07-26-2018 Account # 398791 Date: 10-20-2018 Account:  
417181 Date: 01-24-2019 5. Interview of the technical consultant on July 16, 2019 at  
16:30 hours in the conference room confirmed the findings.

**D5791**

**ANALYTIC SYSTEMS QUALITY ASSESSMENT**

CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's Quality Assessment (QA) policy, corrective action logs, quality control (QC) logs and confirmed in interview, it was revealed the laboratory failed to have an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in analytic systems. Findings: 1. The laboratory failed to include a policy for troubleshooting instrument failures for the CELL-DYN hematology analyzer. Refer to D5403. 2. The laboratory failed to ensure quality control (QC) was stored according to manufacturer's instructions. Refer to D5413.