Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1047501	10/30/2019
Name of Provider or Supplier	**Street Address, City, State**	
Valley Day And Night Clinic	1755 W Price Rd, Brownsville, 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 representative was given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. 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.
D3033	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)(i) In addition, the laboratory must retain records of test system performance specifications that the laboratory establishes or verifies under 493.1253 for the period of time the laboratory uses the test system but no less than 2 years. This STANDARD is not met as evidenced by: Based on the laboratory policy, instrument printouts for test results, and staff interview, it was revealed the laboratory failed to have documentation of retaining instrument printouts for Sysmex hematology analyzer verification study. The findings were: 1. Review of the laboratory policy "Test Records" it stated "Records of patient testing, including instrument printouts must be retained for at least two years. 2. Review of Sysmex verification study from July 02 and July 03 2018 revealed 2 out of 20 sample ID records were not retained. Sample ID # 000380401 07/03/2019 Sample

	ID # 000380408 07/03/2018 3. An interview with the technical consultant on 10/30 /2019 at 11:45 hours confirmed the laboratory did not retain the instrument printouts. Key: ID - Identification
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 made in the laboratory on October 30, 2019 at 14:48 hours found an unlabeled urine sample located in a bucket with 15 other patient samples. 2. Review of the laboratory's policy for "Specimen Identification" stated, "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." 3. The laboratory did not follow its own policy for specimen labeling. 4. An interview with the technical consultant on October 30, 2019 at 14:48 hours in the laboratory confirmed the findings. She agreed it was not labeled with any patient information.
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: A. Based on review of laboratory policies, review of manufacturer's instructions, review of calibration records, and confirmed in interview of facility personnel, the laboratory failed to follow the manufacturer's instructions to run quality control in duplicate after a calibration. The findings were: 1. Review of the laboratory's policy titled, "Instrument Operation and Maintenance" approved by the laboratory director on January 30, 2006 stated, "This laboratory will follow procedures as the manufacturer describes for testing, reporting, calibrating, controls, specialty protocols, and for performing/documenting and remedial action." 2. Review of the manufacturer's instructions for Vitros 350/250/250AT Chemistry Systems Operator's Manual (2016-03-01), under "Verifying a Calibration" it stated, "...Run quality control samples in duplicate." 3. Review of the laboratory's quality control records found the following days when calibrations were performed, but quality control was not performed in duplicate to verify the calibration as required by the manufacturer: 02-27-2018 07-27-2018 08-28-2018 12-07-2018 02-09-2019 4. An interview with the technical consultant on October 30, 2019 at 12:30 hours in the conference room

	confirmed the findings. 42141 B. Based on review of the manufacturer's instructions for the Sysmex XN-L hematology analyzer, review of the laboratory's verification studies, and staff interview, it was revealed the laboratory failed to follow the manufacturer's instructions when performing verification studies. The findings were: 1. A review of the Sysmex XN- Series XN-L Method Verification Manual under "Correlation Studies" it stated "Complete blood count samples should be analyzed within 4 hours of collection and on both analyzers within 2 hours of each other." 2. Review of laboratory's verification studies revealed the 8 out of 20 samples did not follow manufacturer's instruction for analyzing samples. Sample ID 000380335 Cell-Dyn tested 07/03/2018 @ 09:55 am Sysmex XN-L tested 07//03/2018 @18:18 pm (8 hrs, 23 minutes later) Sample ID 000380322 Cell-Dyn tested 07/03/2018 @ 09:49 am Sysmex XN-L tested 07/03/2018 @ 18:23 pm (8 hrs, 32 minutes later) Sample ID 000380212 Cell-Dyn tested 07/02/2018 @ 04:52 pm Sysmex XN-L tested 07/03/2018 @ 18:47 pm (25 hrs, 3 minutes later) Sample ID 000380107 Cell-Dyn tested 07/02 /2018 @ 09:32 am Sysmex XN-L tested 07/03/2018 @ 18:57 pm (33 hrs, 25 minutes later) Sample ID 000380129 Cell-Dyn tested 07/02/2018 @ 11:18 am Sysmex XN-L tested 07/03/2018 @ 19:00 pm (30 hrs, 42 minutes later) Sample ID 000380098 Cell-Dyn tested 07/02/2018 @ 09:11 am Sysmex XN-L tested 07/03/2018 @ 19:02 pm (34 hrs, 9 minutes later) Sample ID 0003800265 Cell- Dyn tested 07/02/2018 @ 07:49 am Sysmex XN-L tested 07/03/2018 @ 18:13 pm (35 hrs, 24 minutes later) 3. An interview with the technical consultant on 10/30/2019 at 13:30 hours in the conference room , the above findings were confirmed. Key: hrs - Hours
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the laboratory's verification records for the Sysmex XN-L hematology analyzer performed in July 2018, and staff interview, it was revealed the laboratory failed to have documentation of complete verification studies prior to performing patient testing. The findings were: 1. A review of the laboratory's verification studies for the Sysmex XN- L hematology analyzer performed in July 2018 revealed the laboratory failed to have documentation of evaluating its patient normal ranges. 2. The laboratory was asked to provide documentation of evaluating its patient normal ranges and the results of its comparison studies. No documentation was provided. 3. An interview with the technical consultant on 10/30/2019 at 11:15 hours in the conference room confirmed the laboratory did not perform a verification for normal patient ranges on the Sysmex. It was confirmed that the laboratory utilized the patient normal ranges from the previous analyzer.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of

	the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on review of the laboratory's verification records, and staff interview, it was revealed the laboratory director failed to ensure verification studies were complete prior to patient testing (refer to D5421).
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: Based on a review of the laboratory's verification records and staff interview, it was revealed the technical consultant failed to ensure verification studies of the Sysmex XN-L hematology analyzer were complete for normal patient ranges. (refer to D5421).
D6055	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing whenever test methodology or instrumentation changes. The individual's performance must be reevaluated to include the use of the new test methodology or instrumentation prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of laboratory QA policy, review of the laboratory's submitted form CMS 209, review of the laboratory's personnel records, and staff interview, it was revealed the technical consultant failed to have documentation of performing competency assessments on testing personnel prior to performing patient testing when a new test system was introduced. The findings were: 1. A review of laboratory QA policy under "Quality Assurance Plan" under " Personnel Assessment" it stated "Twice a year the first year and at least annually thereafter, the Technical Consultant will review performance of each employee working in the laboratory to assure employee competency. This will be accomplished by direct observation of testing skills and by continuing education seminars. The written review will be filed in the employee's personnel file." The laboratory's policy failed to include competency assessment procedures when a new instrument or methodology is introduced. 2. A review of the laboratory's submitted Form CMS 209 revealed 4 out 19 testing personnel did not have competency assessments for the Sysmex XN-L hematology analyzer prior to performing patient samples. a) Testing personnel 2 competency

	performed 08/10/18 (1 month after installation of Sysmex) b) Testing personnel 3 competency performed 12/18/18 (5 months after installation of Sysmex) c) Testing personnel 8 competency performed 06/10/18 (no competencies performed after installation) d) Testing personnel 17 competency performed 10/05/2018 (3 months after installation of Sysmex) 3. An interview with the technical consultant on 10/30 /2019 at 10:48 hours in the conference room revealed she did not perform competency assessments after new instrumentation was introduced to the laboratory these personnel. Key: QA - Quality Assurance