Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0503800	07/10/2018
Name of Provider or Supplier	**Street Address, City, State**	
Valley Day And Night Clinic	305 E Expressway 83, Mission, 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 surveyed on July 10, 2018 and found to be in compliance with the CLIA regulations and recertification is recommended.
D2128	HEMATOLOGY CFR(s): 493.851(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on a review of laboratory policy, review of the laboratory's American Association of Bioanalysts (AAB) proficiency testing records, and confirmed in interview of facility personnel, the laboratory failed to document remedial action for unacceptable analytes or testing event scores. The findings included: 1. Review of the laboratory's policy titled, "Proficiency Testing" (no laboratory director approval date), stated, " ...The laboratory should document all steps taken in PT performance. All records and reports will be maintained for two years." 2. Review of the laboratory's AAB proficiency testing records from 2016 (event 3), 2017 (events 1, 2, and 3), and 2018 (events 1 and 2) revealed the following unacceptable scores: 2017 (event 3) Erythrocytes = 60% Hematocrit = 60% 3. Review of the laboratory's corrective action for the failed analytes approved by the laboratory director on December 26, 2017 stated, "All failed analytes were reran and results are within the expected range. Providers were notified to review past results. The machine was calibrated and all periodic maintenance are up to date." 4. On July 10, 2018, the laboratory was asked for documentation of the patient remediation that was performed. No documentation

	was provided. 5. An interview with the technical consultant on 07/10/2018 at 1000 hours in the conference room confirmed the above findings. She agreed no patient remediation was documented.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of laboratory policy, review of quality control records, and confirmed in interview of facility personnel, the laboratory failed to follow its own quality control troubleshooting policy. The findings were: 1. Review of the laboratory's "Control Policy" (no laboratory director approval date) under, "Quality Control Troubleshooting Guide" stated, "It is the policy of this laboratory to do the following when controls are out of range." -Ensure that controls are not expired then remix and return controls. If control fails then -Open a new vial of control and rerun, if it fails, then -Verify control ranges then -Make sure that all reagents and controls are in the right temperature then -Evaluate maintenance schedule, ensure that all manufacturer's recommendations are followed on time for all maintenance procedures -Evaluate calibration- if necessary recalibrate and return control or -Call technical support for help -Ensure that all remedial action steps are documented 2. Review of the laboratory's quality control records from October 2017 to February 2018 revealed the following dates when quality control was run multiple times and remedial action steps were not documented: Lot L7268 Date: 11/09/2017 Run 1 @ 08:18 Run 2 @ 08: 19 Run 3 @ 08:27 Lot H7268 Date: 11/27/2017 Run 1 @ 08:49 Run 2 @ 08:51 Run 3 @ 09:01 Run 4 @ 09:14 Run 5 @ 09:17 Run 6 @ 09:25 Lot H7268 Date: 12/01/2017 Run 1 @ 08:41 Run 2 @ 08:42 Run 3 @ 08:49 Run 4 @ 09:04 Run 5 @ 09:06 Run 6 @ 09:32 Run 7 @ 09:36 Lot N7268 Date: 12/20/2017 Run 1 @ 0831 Run 2 @ 08:33 Run 3 @ 08:41 Run 4 @ 08:46 Run 5 @ 08:47 Run 6 @ 08:49 Run 7 @ 08:50 Run 8 @ 09:31 Run 9 @ 09:33 Lot L7268 Date: 01/02/2018 Run 1 @ 09:02 Run 2 @ 09:10 Run 3 @ 09:12 Run 4 @ 09:14 Run 5 @ 09:16 Run 6 @ 09:17 Lot L7268 Date: 01/03 /2018 Run 1 @ 08:22 Run 2 @ 08:25 Run 3 @ 08:34 Run 4 @ 08:40 Run 5 @ 08:41 3. The laboratory was asked to provide documentation of following its own policy to document remedial action steps for repeat testing. No documentation was provided. 4. An interview with the technical consultant on 07/10/2018 at 1100 hours in the conference room confirmed the findings.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by:

	A. Based on review of laboratory policy, review of the laboratory's QC (quality control) records, and staff interview, the laboratory failed to ensure an effective QA (quality assessment) system was in place to monitor, assess, and correct problems identified in the analytic systems as evidenced by: 1. The laboratory failed to follow its own policy to document remedial action steps for repeat quality control test runs. (refer to D5401) B. Based on review of laboratory policy, and confirmed in interview of facility personnel, the laboratory failed to provide documentation of any quality assurance reports in 2017 up to the date of the survey, July 10, 2018. The findings were: 1. Review of the laboratory's policy titled, "Quality Assurance Plan" (no laboratory director approval date) stated, "Valley Day and Night Clinic has established a Quality Assurance Plan to" -Evaluate the effectiveness of our written policies and procedures -Identify problems in our laboratory and apply corrective actions -Assure that accurate and reliable test results are obtained and reposted to the physicians in a timely manner -Revise our laboratory policies and procedures whenever necessary. Periodically, one of the following systems in our laboratory will be evaluated to be sure that it meets our quality goals. If a problem is identified we will design and implement a solution that is approved by the Laboratory Director. To determine if the plan has worked the system is re-evaluated in 3 months. All written records of reviews, findings and actions will be kept. 2. On July 10, 2018 at 1130 hours in the conference room, the technical consultant was asked to provide quality assurance records. The document provided was from December 2016. She confirmed that was the only QA record available for review because (QA) was done verbally.