Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0900897	03/07/2019
Name of Provider or Supplier	**Street Address, City, State**	
Valley Regional Diagnostics	502 South Closner, Edinburg, 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	A recertification survey was performed on March 7, 2019. The laboratory was found to be NOT IN COMPLIANCE with the CLIA regulations at: 42 CFR 493.1250 CONDITION: Analytic Systems
D5201	CONFIDENTIALITY OF PATIENT INFORMATION CFR(s): 493.1231 The laboratory must ensure confidentiality of patient information throughout all phases of the total testing process that are under the laboratory's control. This STANDARD is not met as evidenced by: Based on surveyor observation, review of patient final reports, and confirmed in interview of facility personnel, the laboratory failed to ensure confidentiality of patient information. The findings were: 1. Surveyor observation on March 7, 2019 at 13:00 hours revealed that while walking to the laboratory, the surveyor visualized a spiral notebook and loose sheets of paper sitting on the desk in a patient exam room. Upon entering the room, it was revealed the spiral notebook was a log book of notes and patient records with patient names and dates of birth. The loose sheets of paper contained patient names, dates of birth, and CPT codes. Information for Patient 1 (redacted): see patient alias report Information for Patient 2 (redacted): see patient alias report 2. Review of patient final reports for Patient 1 revealed the patient had laboratory testing performed on 05/04/2018, 07/10/2018, 09/13/2018, and 11/29/2018. 3. Review of patient final reports for Patient 2 revealed the patient had laboratory testing performed on 02/07/2017, 02/14/2019, and 02/28,2019. 4. Interview with testing personnel one (as listed on Form CMS 209) on March 7, 2019 at 15:45 hours in the referral office confirmed the findings. She provided laboratory results on each patient. She agreed the information that was found was for patients of the facility. Key: CPT - current procedural terminology CMS - Centers for Medicare and Medicaid Services

D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted test menu, proficiency testing records and confirmed in interview of facility personnel, the laboratory failed to perform twice annual accuracy for the non-regulated analyte Microalbumin (MAB). The findings were: 1. Review of the laboratory's submitted CMS 116 approved and signed by the laboraotry director on March 7, 2019, revealed the laboratory performs Microalbumin (MAB) testing on the Beckman Coulter AU 480 chemistry analyzer. The facility documented performing 125,000 chemistry tests annually. 2. The analyte of MAB is non-regulated. API provides two events per calendar year. 3. Review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records from 2017 (events 1 and 2) and 2018 (events 1 and 2) revealed the laboratory received the following scores: a. 2017 Chemistry (event 2) laboratory received an unsuccessful score of 0% b. 2018 Chemistry (event 2) laboratory received an unsuccessful score of 0% 4. Due to the unsuccessful scores, the laboratory failed to perform twice annual accuracy for MAB in 2017 and 2018. 5. An interview with the technical consultant on March 7, 2019 at 10:00 hours in the referral office confirmed the findings.
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 surveyor observations, review of manufacturer's instructions, review of patient results, and confirmed in interview of facility personnel, the laboratory failed to monitor and evaluate overall quality of its analytic systems as evidenced by: 1. The laboratory failed to resolve abnormal flags on CBC (complete blood count) patient results prior to their release to the healthcare provider (this is a repeat deficiency). Refer to D5411 2. The laboratory failed to ensure that expired laboratory supplies were not available for use. Refer to D5417 3. The laboratory failed to ensure calibration verification was performed every six months (this is a repeat deficiency). Refer to D5439
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 review of manufacturer's instructions, review of patient final reports, and confirmed in interview of facility personnel, the laboratory failed to resolve flags on CBC (complete blood count) results. The findings were: 1. This is a repeat deficiency from the survey dated December 8, 2016. 2. A review of the manufacturer's instructions for the Sysmex XP-300 hematology analyzer (Code No. AU553517, Revision July 2013) under the section titled "8.3 Histogram flags" revealed: "When histogram flags are displayed, perform analysis again. If afterwards the flags are still displayed, the sample is considered to correspond to one of the following." The manufacturer then identified histogram flags, probable causes, and corrective actions to perform to resolve the flag. An example is: Flag: AG Probable Causes: Presence of nucleated red blood cells, effects of fragmented red blood cells, increase of large platelets, platelet aggregation or agglutination, precipitation of fibrin, etc. Correction: Check smear, etc. 3. Review of patient results from February 28, 2019 to March 7, 2019 and March revealed the following patients had flags that were not resolved prior to being reported to the healthcare provider: Date: 02/28/2019 Account #: 306561 Flag: AG* Date: 03/02/2019 Account #: 306648 Flag: AG* Date: 03/04 /2019 Account #: 306709 Flag: AG* Date: 03/05/2019 Account #: 306787 Flag: AG* Date: 03/06/2019 Account #: 306850 Flag: AG* Date: 03/06/2019 Account #: 306826 Flag: AG* Date: 03/06/2019 Account #: 306866 Flag: AG* Date: 03/07/2019 Account #: 306927 Flag: AG* 4. An interview with testing personnel one (as listed on Form CMS-209) on March 7, 2019 at 15:30 hours in the referral office confirmed the findings. Key: CMS - Centers for Medicare and Medicaid Services
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 surveyor observation, review of manufacturer's instructions, and confirmed in interview of facility personnel the laboratory failed to ensure expired items were not available for use in patient testing. The findings were: 1. Surveyor observation on March 7, 2019 at 08:10 hours during the initial tour of the facility revealed the following expired items: EDTA microtainers Lot 7102699 Expiration date: 09-30-2018 35 tubes Amber microtainers Lot 7093868 Expiration date: 06-30-2018 39 tubes 2. Review of the manufacturer's instructions for BD Vacutainer (04/2018, VDP40161-WEB-08) stated, "Do not use tubes after their expiration date. Tubes expire on the last day of the month and year indicated." 3. Interview with testing personnel one (as listed on Form CMS-209) on March 7, 2019 at 08:10 hours confirmed the findings. She stated the items were, "Not in use." Key: BC - Becton Dickinson EDTA - ethylenediaminetetraacetic acid CMS - Centers for Medicare and Medicaid Services
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's test menu, review of the laboratory's calibration verification records from 2017 and 2018, and confirmed in interview of facility personnnel, the laboratory failed to have documentation of performing calibration verifications every six months for analytes on the Beckman Coulter AU480 and the Beckman Coulter Access 2 chemistry analzyers. The findings were: 1. A review of the laboratory's test menu revealed the following analytes which were tested on the Beckman Coulter AU480 analyzer: Albumin Alkaline phosphatase Alanine aminotransferase Aspartate aminotransferase Blood urea nitrogen Calcium Cholesterol Chloride Carbon dioxide Creatinine Direct bilirubin Glucose High density lipoprotein Potassium Low density lipoprotein Magnesium Sodium Phosphorus Total Bilirubin Total Protein Triglyceride Urine Microalbumin Uric Acid 2. A review of the laboratory's test menu revealed the following analyte was tested on the Beckman Coulter Access 2 chemistry analyzer: T3 Uptake 3. Each test utilized less than 3 calibrators, and the facility tested three levels of quality control once per day. The analytes required calibration verification every six months. 4. A review of the laboratory's calibration verification records for analytes tested on the Beckman Coulter AU480 from January 2017 to December 2018 revealed the laboratory performed calibration verifications as follows: April 24, 2017 June 6, 2017 (1 month, 13 days later) December 9, 2017 (6 months later) April 3, 2018 (3 months, 25 days later) November 27, 2018 (7 months, 28 days later) 5. Review of the laboratory's calibration verification records from 2017 and 2018 revealed the laboratory performed calibration verification on the Beckman Coulter Access 2 chemistry analyzer for T3 Uptake as follows: March 10, 2017 September 13, 2017 (6 months, 3 days later) June 27, 2018 (9 months, 14 days later) November 29, 2018 (5 months, 2 days later) 6. Interview with testing personnel one (as listed on Form CMS 209) on March 7, 2019 at 13:15 hours in the referral office confirmed the findings. Key: CMS - Centers for Medicare and Medicaid Services
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from

	the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on a review of patient CBC (complete blood count) instrument printouts from February 28, 2019 to March 7, 2019, review of patient CBC results provided to providers, and staff interview, it was revealed the laboratory failed to ensure flags on CBC (complete blood count) results were transmitted into the laboratory's information system. The findings were: 1. This is a repeat deficiency from the survey conducted on December 8, 2016. 2. A review of Sysmex XP-300 analyzer instrument printouts from February 28, 2019 to March 7, 2019 identified the following CBC results with flags: Date: 02/28/2019 Account #: 306561 Flag: AG* Date: 03/02/2019 Account #: 306648 Flag: AG* Date: 03/04/2019 Account #: 306709 Flag: AG* Date: 03/05/2019 Account #: 306787 Flag: AG* Date: 03/06/2019 Account #: 306850 Flag: AG* Date: 03/06/2019 Account #: 306826 Flag: AG* Date: 03/06/2019 Account #: 306866 Flag: AG* Date: 03/07/2019 Account #: 306927 Flag: AG* The results were interfaced into the laboratory's information system. 3. A review of patient results as reported to the provider for the identified patients revealed 8 of 8 results did not have documentation of the AG flag. 4. An interview with testing personnel one (as listed on Form CMS 209) on March 7, 2019 at 15:30 hours in the referral office confirmed the findings. Key: CMS - Centers for Medicare and Medicaid Services
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 review of manufacturer's instructions, review of laboratory records, surveyor observation of patient samples, and staff interview, it was revealed the laboratory director failed to ensure laboratory services provided quality testing. The findings were: 1. The laboratory director failed to ensure the manufacturer's instructions were followed for resolving flags on CBC (complete blood count) results (refer to D5411). 2. The laboratory director failed to ensure calibration verifications were performed as required (refer to D5439).