Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 45D1103871	**(X3) Date Survey Completed** 08/01/2019
Name of Provider or Supplier Valley's Kids And Teens Clinic	**Street Address, City, State** 1110 South Stewart Rd, Suite F, San Juan, 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(s) at the exit conference. The facility representative(s) were 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.
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 Beckman Coulter AcT Diff 2 hematology analyzer, review of patient test records from June 2019- July 2019, and staff interview, it was revealed the laboratory failed to following the manufacturer's instructions for resolving "*" flags on CBC (complete blood count) results. Findings include: 1. A review of the manufacturer's instructions for the Beckman Coulter AcT Diff 2 hematology analyzer (PN 4237495B, June 2003) under the section titled "What Flags and Codes Mean" revealed the manufacturer provided actions to take when specific flags were identified on CBC results. For the flag of "*" the manufacturer

	stated: "* "Possible sample handling problem. Possible dual RBC population. Possible interference with WBC count. Platelet distribution failure. Possible sample interference or instrument problem. See instructions for +++++, +, or -----." "---- Thoroughly mix and rerun the sample. If flag repeats then Zap the machine and do bleach bath. ++++ Zap and rerun samples. If flag is still present after the rerun Call tech support. XXXX Mix the sample with a wooden applicator and rerun. If repeats ZAP and do bleach bath. If continues call tech support. 2. A review of the laboratory's patient test records from June 2019- July 2019 revealed the following patients with "*" flags present on the report: Patient ID: 000003410 Reported: 6/18/19 Patient ID: 000003482 Reported: 7/19/19 Patient ID: 000003508 Reported: 7/31/19 3. An interview with the technical consultant (as indicated on the CMS 209 form, signed by the laboratory director on 7/29/19) on 8/1/19 at 11:35 in the conference room, after review of the records, confirmed the above findings. Key: RBC= Red Blood Cell WBC= White Blood Cell
D5789	TEST RECORDS CFR(s): 493.1283(b) Records of patient testing including, if applicable, instrument printouts, must be retained. This STANDARD is not met as evidenced by: Based on a review of the laboratory's patient test records from June 2019- July 2019 and staff interview, it was revealed the laboratory failed to retain records of patient testing on the Beckman Coulter AcT Diff 2 hematology analyzer. Findings include: 1. The laboratory was asked to provide test records on 12 patient's specimens run on the Beckman Coulter AcT Diff 2 hematology analyzer from 6/3/19 to 7/31/19. 2. The laboratory was only able to provide test records on 9 of those patient's specimens. The 3 test records that were not retained in the laboratory were: Patient ID: 000003398 Run Date: 6/7/19 Patient ID: 000003419 Run Date: 6/21/19 Patient ID: 000003494 Run Date: 7/25/19 3. An interview with the technical consultant and testing person #2 (as indicated on the CMS 209 form, signed by the laboratory director on 7/29/19) on 8 /1/19 at 12:05 in the conference room, revealed the test records could not be retrieved for the above patients. This confirmed the above 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 control policy, manufacturer's instructions for the Beckman Coulter 4C-ES Cell Control, review of the laboratory's quality control records from December 2017- July 2019, and staff interview, it was revealed the laboratory failed to ensure the quality assessments identified problems in the analytic systems. Findings include: 1. A review of the laboratory's policy titled 'Controls' revealed the following statement: "For 'Cleared' methods, the Lab must: Follow the manufacturer's instructions." 2. Review of the manufacturer's instructions

	for the Beckman Coulter 4C-ES Cell Control- Abnormal High control stated: "*" flags for platelet, MONO% and MONO # parameters confirm that distribution criteria are not met. 3. A random review of the laboratory's quality control records from December 2017- July 2019 revealed the following days where the Abnormal High control was receiving "*" flags for MONO% and MONO#, however the laboratory failed to perform remedial action to correct the problem: -Abnormal High Lot # 088000 Lot in use with flags present from 12/19/17 to 3/27/18 -Abnormal High Lot # 089200 Lot in use with flags present from 4/3/18 to 4/30/18 -Abnormal High Lot # 087800 Lot in use with flags present from 7/9/19 to 7/31/19 4. Quality assessment reports reviewed from December 2017- July 2019 revealed no documentation that the above issue was identified. 5. An interview with the technical consultant (as indicated on the CMS 209 form signed by the laboratory director on 7/29/19) on 8/1/19 at 10:00 in the conference room revealed the manufacturer told the laboratory that flags on the MONO# and MONO% were normal and it was ok to accept this quality control as acceptable. The laboratory was asked to provide documentation of the manufacturer's claims, no documentation was provided. This confirmed the above findings.
D6024	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) 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)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, the laboratory's quality assessment report for January 2019, and patient test results, the laboratory director failed to ensure remedial actions were taken and documented when significant deviations from the laboratory's established and acceptable performance specifications were identified. Findings include: 1. A review of the laboratory's policy titled, 'Corrective Action Program' states the following: Document Corrective actions for Unexpected Results in: Failed controls Corrective Action/ Remedial Action Program: Document the date, what the corrective action was, and the signature or initials of the person performing the corrective action. Document... investigations Document...who, what, where, when Document...for the record. You might not remember tow years later Document...for someone else There is never too much documentation 2. A review of the laboratory's quality assessment report for January 2019 (signed by the laboratory director on 2/28 /19) revealed the following: Hematology: Coulter: On 01/10/19, WBC analyte was out for the Normal and High controls; 2 patients were run. On 01/14/19, RBC analyte was out for the Normal and High controls; 1 patient was run. Please consider reported patient tests to be invalid for procedures that had controls out of limits. And: a) Retrieve patient record and indicate that the test result was invalid. b)Make the correction, but don't white out or erase the previous result. You may make one line through it, but don't erase. c)Notify the requesting physician of the error and request permission to repeat the test. d)Keep a record in lab of what happened. 3. A review of patient test results for the following patients revealed the following: Patient ID: 000003090 Reported Date: 1/10/19 WBC result was erased with black marker Patient ID: 000003091 Reported Date: 1/10/19 WBC result was erased with black marker

	Patient ID: 000003094 Reported Date: 1/14/19 RBC result was erased with black marker 4. The laboratory was asked to provide documentation of the required remedial /corrective action. No documentation was provided. 5. An interview with testing person #2 (as indicated on the CMS 209 form, signed by the laboratory director on 7 /29/19) on 8/1/19 at 11:30 in the conference room, revealed the results were erased after the provider had already seen the patient report and no other corrective action was performed. This confirmed the above findings. Key: WBC= White blood cell RBC= Red blood cell
D6051	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(v) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. This STANDARD is not met as evidenced by: Based on review of the laboratory's competency assessments performed for 2017-2019, and staff interview, it was revealed the technical consultant failed to include the review of previously analyzed specimens or proficiency testing samples as part of the laboratory's competency assessments for 1 of 3 testing personnel. Findings include: 1. A review of the CMS 209 form, signed by the laboratory director on 7/29/19, indicated the laboratory identified three testing personnel who perform moderate complexity testing. 2. A review of the laboratory's competency assessments for testing person #3 (as indicated on the CMS 209 form) revealed the technical consultant performed competency assessments for testing person #3 on the following dates: 4 /2017 4/2018 4/2019 3. Further review of the competency assessments revealed the technical consultant failed to include the review of previously analyzed specimens or proficiency testing samples as part of the competency assessments. 4. An interview with the technical consultant (as indicated on the CMS 209 form) on 8/1/19 at 09:45 in the conference room, after review of the records, confirmed the above findings.