Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2003905	09/08/2021
Name of Provider or Supplier	**Street Address, City, State**	
Valley Day And Night Clinic	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.

(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 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 Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on surveyor's observations on 09/08/2021 at 1230 hours in the laboratory, review of manufacturer Operating Manual for the HemoCue Glucose 201 with Plasma Conversion, review of the Consult Diagnostics Urine Analysis Controls, Dropper Style package insert, and interview with the staff it was determined the laboratory failed to document opened or amended expiration dates on the opened/in use laboratory products as per manufacturer requirements for 3 of 3 products reviewed. The findings were: 1. Surveyor's observations on 09/08/2021 at 1230 hours in the laboratory revealed the following opened/in use products were stored in the refrigerator: HemoCue Glucose 201 Microcuvettes Lot 2105415 Exp. 2022-03-19

	Consult Diagnostics Urine Analysis Control 1, Dropper Style Lot 73241 Exp. 2022-04-30 Consult Diagnostics Urine Analysis Control 2, Dropper Style Lot 73242 Exp. 2022-04-30 Note: The above vials did not have an opened date or revised expiration date documented. 2. Review of the manufacturer's Operating Manual (version 900751 140726 US Bergstens, HBG) for the HemoCue Glucose 201 with Plasma Conversion revealed "Microcuvettes stored in an opened vial are stable for 30 days when stored in a refrigerator at 35-46F (2-8C)." 3. Review of the Consult Diagnostics Urine Analysis Controls, Dropper Style package insert contained: "Once opened, bottles of control are stable for 18 months when stored tightly capped at 2-8C (35.6-46.4F) or for 30 days at 20-25C (68-77F)." 4. In an interview on 09/08/2021 at 1230 hours in the laboratory the Technical Consultant (as stated on Form 209 signed by Laboratory Director on 09/08/2021) stated that the products should have had opened dates documented but could not state when the vials were opened. This confirmed the findings.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) 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. This STANDARD is not met as evidenced by: Based on review of the laboratory's Proficiency Testing (PT) records for 2020 and 2021, review of the American Association of Bioanalysts (AAB) PT agency's attestation requirements, and interview with the staff it was determined the laboratory director/designee failed to sign 3 of 5 attestation records as required. The findings were: 1. Review of the laboratory's PT attestation statement revealed: "In addition to the analysts' signature one of the following must sign once for all analytes reported on this form: Director, or Technical Consultant, or Technical Supervisor" 2. Review of the laboratory's AAB PT records for 2020 (Nonchemistry Q1, Q2, and Q3) and 2021 (Nonchemistry Q1, Q2) revealed 3 of 5 PT attestation forms did not have either the Director or the Technical Consultant signatures. They were: 2020 Nonchemistry Q2 2020 Nonchemistry Q3 2021 Nonchemistry Q1 3. In an interview on 09/08/2021 at 1000 hours in the conference room the Technical Consultant (as stated on Form 209 signed by Laboratory Director on 09/08/2021) confirmed the above PT attestation forms did not have the required signatures.
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 laboratory's Cell-Dyn hematology analyzer's Principles of Operation manual, review of the Cell-Dyn analyzer's patient test instrument printouts for July and August of 2021, review of the laboratory's patient reports, review of the laboratory's policies and staff interview it was determined the laboratory failed to

	follow manufacturer instructions for addressing flagged results. The findings were: 1. Review of the laboratory's Cell-Dyn hematology analyzer's Principles of Operation manual under section 3, Table 3.4 revealed: "Measurand: WBC Result Flag: 3 Text in Flag Box: L3 Result Displayed: xxxxx Cause: May indicate presence of eosinophils or myelocytes. Action: Check the specimen for clots and agglutination. Follow the laboratory's review criteria or review a stained smear to confirm the differential results. Redraw and retest the specimen as required." 2. Review of the Cell-Dyn analyzer's patient test instrument printouts for August and July of 2021 revealed the following patient sample results contained the L3 Flag: Patient 506904 - sample tested on 07/26/2021 Patient 602281 - sample tested on 08/03/2021 Patient 492228 - sample tested on 08/22/2021 3. Review of the laboratory's reports for the above patient revealed: Patient 506904 - no laboratory test report was found, the instrument printout was attached to the patient chart directly. - Sample was repeated with persisting Flag 3, no indication of further review or confirmation by stained smear was found for the sample. Patient 602281 - laboratory test report contained "Flag 3" as a result. - Sample was repeated with persisting Flag 3, no indication of further review or confirmation by stained smear was found for the sample. Patient 492228 - laboratory test report contained "Flag 3" as a result. - Sample was repeated with persisting Flag 3, no indication of further review or confirmation by stained smear was found for the sample. 4. Review of the laboratory's policies for hematology testing revealed there wasn't a written policy for resolving flags. 5. In an interview on 09/08/2021 at 1310 hours in the conference room the Technical Consultant (as stated on Form 209 signed by Laboratory Director on 09/08/2021) stated that the techs are supposed to blank-out the instrument results, repeat the test, and if repeat results were the same to confirm with manual differential. This confirmed the findings.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on surveyor's observations on 09/08/2021 at 1230 hours in the laboratory, review of manufacturer package inserts and assay sheets for the Cell-Dyn hematology analyzer controls and interview with the staff it was determined the laboratory failed to document opened or amended expiration dates on opened/in use laboratory products as per manufacturer requirements for 3 of 3 products reviewed. The findings were: 1. Surveyor's observations on 09/08/2021 at 1230 hours in the laboratory revealed the following opened/in use products were stored in the refrigerator: Cell-Dyn hematology analyzer control Lot H1179 Exp. 2021-10-15 Cell-Dyn hematology analyzer control Lot N1179 Exp. 2021-10-15 Cell-Dyn hematology analyzer control Lot L1179 Exp. 2021-10-15 Note: None of these products had opened dates or amended expiration dates documented. 2. Review of manufacturer package inserts and assay sheet for the Cell-Dyn hematology analyzer controls revealed: Cell-Dyn Controls package insert contained: "Once opened, containers can be used only for the number of days stated on the assay sheet ..." And Cell-Dyn Controls assay sheet for Controls' Lot 1179 Exp 2021-10-15 contained: "8 Consecutive-Day Open Tube Stability" 3. In an interview on 09/08/2021 at 1230 hours in the laboratory the

	Technical Consultant (as stated on Form 209 signed by Laboratory Director on 09/08 /2021) stated that the products should have had opened dates documented, but could not state when the vials were opened. This confirmed the findings.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on review of the laboratory's Instrument Operation and Maintenance policy, review of the laboratory's instrument calibration records for Cell-Dyn hematology analyzer for 2019, 2020 and 2021, and interview with the staff it was determined the laboratory failed to follow laboratory's procedure for frequency of calibration for 3 of 5 intervals reviewed. The findings were: 1. Review of the laboratory's Instrument Operation and Maintenance policy revealed: "Calibration of all laboratory instruments is every 6 months and every time there's a change of lot numbers or there's a major repair on the instrument." 2. Review of the laboratory's instrument calibration records for Cell-Dyn hematology analyzer for 2019, 2020 and 2021 revealed 3 of 5 calibrations exceeded the 6 months interval as follows: First Calibration on 05/06 /2019 Next Calibration on 12/14/2019 -elapsed interval of 7 months and 14 days Next Calibration on 06/06/2020 -elapsed interval of 5 months and 21 days Next Calibration on 01/21/2021 -elapsed interval of 6 months and 14 days Next Calibration on 02/12 /2021 -elapsed interval of 22 days Next Calibration on 08/29/2021 -elapsed interval of 6 months and 17 days 3. In an interview on 09/08/2021 at 1000 hours in the conference room the Technical Consultant (as stated on Form 209 signed by Laboratory Director on 09/08/2021) confirmed the intervals exceeded 6 months between calibrations on the above 3 of the 5 records reviewed.
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 Assurance (QA) Plan, random review of the laboratory's QA documents/records for September 2020 to August 2021, and interview with the staff it was determined the laboratory failed to document Laboratory Director and Technical Consultant review of its monthly quality assurance

	processes as per its policy for 12 of 12 months reviewed. The findings were: 1. Review of the laboratory's Quality Assurance (QA) Plan revealed: "We will perform a quality perform a quality(sic) review at least monthly and review the results with the laboratory Director or technical consultant for their approval," And "The Laboratory Director or the Technical Consultant will initial and date our written reviews and actions." And "The records of our quality assurance reviews are filed with this plan and are available for review by the Laboratory Director, Consultant, Staff and laboratory Surveyors. All records are dated and initialed by the staff performing the review, by the Technical Consultant and by the Laboratory Director." 2. Review of the laboratory's QA documents/records for September 2020 to August 2021 revealed there was no documentation of QA processes' review by the Laboratory Director or Technical Consultant. 3. In an interview on 09/08/2021 at 1150 hours in the conference room the Technical Consultant (as stated on Form 209 signed by Laboratory Director on 09/08/2021) stated that the monthly review of QA processes was not followed as written in the policy. This confirmed the findings.