Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1047501	05/16/2024
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	An unannounced complaint investigation (TX00498723) was conducted on 05/16 /2024. The complaint was substantiated.
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 review of the laboratory's specimen collection procedures, review of patient test records for patient #147760, review of the laboratory's patient specimen logs from April 9, 2024, and staff interview, the laboratory failed to following its procedures for recording specimen receipt. The findings included: A. A review of the laboratory's specimen collection procedure under the section titled "Record of Specimen Receipt" determined: "Maintain a patient specimen log that includes the date, patient name, chart number, tests ordered, disposition of unacceptable samples and the identity of the personnel who performed the test." B. Further review under the section titled "Test Records" determined: "The laboratory will maintain test records which included a specimen log and a copy of the original patient report must be kept on file for two years. Reports and logs must be organized as to allow for ready access to reports. Test results must be reported promptly to providers and released only to authorized persons. Test Record Logs will provide the following information: The patient identification number, name and date of birth. The date and time of specimen collection. The condition and disposition of specimen that do not meet the laboratory's criteria for specimen acceptability. Records of patient testing, including instrument

	printouts must be retained for at least two years." C. A review of the test records for patient #147760 determined two samples - one for a complete blood count, one for a complete metabolic panel - were collected on 04/09/2024. D. A review of the patient specimen log from 04/09/2024 determined the information for patient #147760 was not documented on the log. E. The office manager confirmed the findings in an interview conducted on 05/16/2024 at 0945 hours in the laboratory.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(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 preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality assurance plan, review of the complete blood count orders in Labdaq for patient #147760, review of instrument results for patient #147760 tested on 04/09/024, and staff interview the laboratory failed to ensure the pending log was checked everyday. The findings included: A. A review of the laboratory's quality assurance plan revealed: "Supervisors for each location must:... 8. Check pending log at the end of the day." B. Further review of the laboratory's quality assurance plan revealed: "Procedure on how to clear the pending log everyday: 1. On the right side of the main Labdaq screen, Status (UA, microalbumin), Emerald (CBC), and Manual Entry (Fingerstick, Pregnancy Test, Strep, Flu AB, RSV, H.Pylori). 2. Click the icon and you can choose either pending by panel or pending by requisition. 3. Choose the date and location then press ok. the analyzer should be on default depending on location but there are instance where you see patients from other locations so just take care of you own patients. 4. Go to QQ and fix the problem like; duplicate entry when EMR is not transferring orders, patient did not submit a sample, was unable to draw patient, forgot to finalize a CBC flag." C. A review of the Labdaq records for patient #147760 determined the results for the complete blood count (CBC) on 05/16/2024 at 10:35 am were still pending in the information system. D. A review of patient test records on the Sysmex hematology analyzer on 05/16/2024 at 10:36 am determined the sample for patient #147760 was tested on 04/09/2024 at 9:54 am. The results were normal and had not transfered into the Labdaq information system. E. The complete blood cell results were released from the analyzer and sent to Labdaq at 10:38 am on 05/16/2024. F. The office manager confirmed the findings in an interview conducted at 10:38 am in the laboratory.