

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0862297	(X3) Date Survey Completed 07/29/2026
Name of Provider or Supplier Uc Davis Student Health Services	Street Address, City, State 930 Blue Ridge Road, Davis, CA	
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 onsite Validation survey was performed on 07/29/26. Standard-level deficiencies were cited.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. In addition, retain the following: This STANDARD is not met as evidenced by: Based on room temperature records and interview with the technical consultant, the laboratory failed to retain laboratory room temperatures records for one of three months. Findings included: 1. On 07/29/26 at 10:00 am, the technical consultant confirmed the following: a. The laboratory performed Complete Blood Count (CBC) on the Sysmex XN 430 analyzer. b. The laboratory performed Chemistry testing on the Horiba Pentra 400 analyzer. c. The laboratory performed Endocrinology testing on the TOSOH analyzer. d. The laboratory stored blood collection tubes for specimen collection for CBC, Chemistry, and Endocrinology testing. 2. A review of three months of laboratory room temperature records (September 2025, May 2026 and June 2026) revealed the laboratory failed to retain one (September 2025) of three months of laboratory room temperature records. 3. In an interview on 07/29/26 at 11:15 am, the technical consultant confirmed the findings above. 4. The laboratory performs approximately 15,605 CBC tests, 50,308 Chemistry tests, and 10,170 Endocrinology tests annually.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)

(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on room temperature records, manufacturer's instructions, and an interview with the technical consultant, the laboratory failed to ensure laboratory room temperatures fell within the laboratory's established acceptable temperature ranges for 31 of 41 days. Findings included: 1. On 07/29/26 at 10:00 am, the technical consultant confirmed the following: a. The laboratory performed Complete Blood Count (CBC) on the Sysmex XN 430 analyzer. b. The laboratory performed Chemistry testing on the Horiba Pentra 400 analyzer. c. The laboratory performed Endocrinology testing on the TOSOH analyzer. d. The laboratory stored blood collection tubes for specimen collection for CBC, Chemistry, and Endocrinology testing. 2. A review of the manufacturer's room temperature requirements revealed the following: a. Sysmex XN 430 - Required a room temperature of 15 - 30C. b. Horiba Pentra 400 - Required a room temperature of 18 - 32C. c. TOSOH - Required a room temperature of 15 - 30C. d. Vacutainer blood collection tubes - required a room temperature of 4 - 25C. 3. A record review of two months (May 2026 and June 2026) of the laboratory's room temperature logs titled, "Daily Temperature Recordings" specified an acceptable range of 20 - 25C. Further review of the log revealed room temperatures below the acceptable lower limit of 20C for 31 of 41 days as follows: 05/01/26 - room temperature documented as 18C 05/05/26- room temperature documented as 19C 05/06/26 - room temperature documented as 19C 05/08/26 - room temperature documented as 19C 05/13/26 - room temperature documented as 19C 05/15/26 - room temperature documented as 19C 05/19/26 - room temperature documented as 17C 05/20/26 - room temperature documented as 17C 05/21/26 - room temperature documented as 19C 05/22/26 - room temperature documented as 19C 05/26/26 - room temperature documented as 18C 05/27/26 - room temperature documented as 17C 05/28/26 - room temperature documented as 19C 05/29/26 - room temperature documented as 18C 06/01/26 - room temperature documented as 18C 06/02/26- room temperature documented as 19C 06/03/26 - room temperature documented as 19C 06/05/26 - room temperature documented as 19C 06/08/26 - room temperature documented as 18C 06/09/26 - room temperature documented as 18C 06/10/26 - room temperature documented as 18C 06/12/26 - room temperature documented as 18C 06/15/26 - room temperature documented as 18C 06/16/26 - room temperature documented as 19C 06/17/26 - room temperature documented as 19C 06/18/26 - room temperature documented as 19C 06/22/26 - room temperature documented as 18C 06/23/26 - room temperature documented as 18C 06/24/26 - room temperature documented as 17C 06/29/26 - room temperature documented as 18C 3. In an interview on 07/29/26 at 11:10 am, the technical consultant confirmed the findings above. 4. The laboratory performs approximately 15,605 CBC tests, 50,308 Chemistry tests, and 10,170 Endocrinology tests annually.

D5807

TEST REPORT
CFR(s): 493.1291(d)

(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's written procedure, patients' final reports, and interview with the general supervisor, the laboratory failed to ensure the accuracy of normal reference ranges for 3 of 26 analytes. Findings included: 1. On 07/29/26 at 10:00 am, the technical consultant confirmed the following: a. The laboratory performed Chemistry testing on the Horiba Pentra 400 analyzer. b. The laboratory performed Endocrinology testing on the TOSOH analyzer. 2. A review of the laboratory's written standard operating procedures for Chemistry and Endocrinology testing stated the following: a. "ABX PENTRA 400 NORMAL RANGES" Creatinine (CREAT) - female normal reference range of 0.6 - 1.1 mg/dL. High-Density Lipoprotein (HDL) - female normal reference range of 30-85 mg/dL. b. TOSOH "Reference Ranges" Thyroid Stimulating Hormone (TSH) - normal reference range of 0.5 -5.8 mIU/ml. 3. A review of three patient reports revealed a different normal reference range as follows: a. Patient #918352109 -Specimen collected and reported on 06/10/26 with a TSH normal reference range of 0.45-4.12 mIU/ml. b. Patient #924298435 - Specimen collected and reported on 07/28/26 with an HDL female normal reference of 40-132 mg/dL. c. Patient #921855839 - Specimen collected and reported on 07/29/26 with a CREAT female normal reference range of 0.5 - 0.9 mg/dL. 4. In an interview on 07/29/26 at 12:10 pm, the general supervisor confirmed the above findings. 5. The laboratory performs approximately 50,308 CREAT tests, 25,104 HDL tests, and 10,170 TSH tests annually.