

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D0886768	(X3) Date Survey Completed 04/19/2023
Name of Provider or Supplier South Davis Community Hospital	Street Address, City, State 485 East 500 South, Bountiful, UT	
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
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation and interview with testing personnel (TP), the laboratory failed to ensure the Lithium Heparin Separator tubes were not used past the expiration date. The laboratory performs approximately 5,000 tests per year. Findings include: 1. Direct observation of inventory storage on 4/19/2023 at 4:20 P.M. revealed 24 Lithium Heparin Separator tubes lot number B2212330 with an expiration date 2/03/2023. 2. Interview with TP18 and TP24 on 4/19/2023 at 4:25 P.M. confirmed the 24 Lithium Heparin Separator tubes were expired and the laboratory used the tubes to collect patient specimens.</p>
D5805	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.</p>

This STANDARD is not met as evidenced by:
Based on record review and interview with testing personnel (TP), the laboratory failed to list the address of the laboratory's location on the final test report. The laboratory performs approximately 5,000 iSTAT tests per year. Findings include: 1. Review of patient test reports on 4/19/2023 at 3:38 P.M. revealed no address listed on the final patient test report. 2. Interview with TP18 and TP25 on 4/19/2023 at 3:38 P. M. confirmed the laboratory failed to list the address of the laboratory in the final patient test report.

D6047

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)(i)

The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing.

This STANDARD is not met as evidenced by:
Based on testing personnel (TP) competency record review and interview with staff, the laboratory failed to include direct observation of performing the iSTAT procedure for 48 out of 48 testing personnel since the last survey 9/17/2020. The laboratory performs approximately 5,000 tests per year. Findings include: 1. Record review of testing personnel competencies revealed lack of direct observation for performing iSTAT procedure for 48 out of 48 testing personnel since last survey on 9/17/2020. 2. Interview with TP18 and TP24 on 4/19/2023 at 1:48 P.M. confirmed testing personnel competency records lacked direct observation of the iSTAT test procedure.