

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0672809	(X3) Date Survey Completed 11/03/2021
Name of Provider or Supplier Sam Houston State University	Street Address, City, State 1608 Avenue J, Huntsville, 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.
D3007	<p>FACILITIES CFR(s): 493.1101(b)</p> <p>The laboratory must have appropriate and sufficient equipment, instruments, reagents, materials, and supplies for the type and volume of testing it performs.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory reference manual, observation of available centrifugation equipment and confirmed in interview, the laboratory failed to have appropriate equipment (centrifuge) for one of two tests: microscopic urines. Findings were: 1. A review of the laboratory reference manual, Ames Modern Urine Chemistry Manual, (Revised 1991) revealed the following statement: "To obtain sediment, 10 to 15 milliliters of urine should be taken and centrifuged at a standard speed, usually 1500 to 2000 rpm for 5 minutes." 2. Surveyor observation in the laboratory on 11/3/21 at 0910 hours revealed that the centrifuge used to spin urines for microscopic examination was a single speed, Drucker 642E Centrifuge, SN 200713FP004. Review of the laboratory work order for the centrifuge revealed documentation of a maintenance check on 3/18/21 that documented speed of the centrifuge at 3321, 3318 rpm (revolutions per minute). 3. Review of the CMS116 signed by the laboratory director on 11/3/21 revealed the laboratory performed 124 microscopic urines annually. 4. An interview with the laboratory director on 11/3/21 at 1045 hours in the laboratory confirmed the above findings.</p>

<p>D5413</p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observations, manufacturer's instructions, and confirmed in interview, the laboratory failed to monitor storage temperature for two of two BD Vacutainers tubes stored in the phlebotomy room. Findings included: 1. Surveyor observations on 11/3/21 at 1010 hours revealed the laboratory stored two containers of BD Vacutainer tubes used for reference testing stored in the phlebotomy room. BD Vacutainer SST Ref 367988, lot 1076257, exp 3/31/2022 BD Vacutainer K2EDTA Ref 367861, lot 1137392, exp 9/30/22 2. Review of the BD Vacutainer package insert (03/2018 500030670) under Storage revealed "Store tubes at 4-25C (39-77F), unless otherwise noted on the package label." 3. Surveyor observations on 11/3/21 at 1015 hours revealed no mechanism to monitor the temperature in the phlebotomy room. 4. An interview with the laboratory director on 11/3/21 at 1030 hours in the lab confirmed the above findings.</p>
<p>D5415</p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observations, laboratory test records from 11/3/21, and confirmed in interview, the laboratory failed to label the identity and expiration date of the reagents of one of two nonwaived tests. (wet prep) Findings included: 1. Surveyor observations on 11/3/21 at 1020 hours revealed tubes of saline prepared for wet preps with no label of the identity and/or expiration date of the saline. lot T21CO3, exp 3/1/23 2. An interview with the laboratory director on 11/3/21 at 1025 hours in the lab revealed that the laboratory prepared the tubes with saline for wet prep. She confirmed that the laboratory did not document the saline transferred onto the tubes. 3. Surveyor observations on 11/3/21 at 1030 hours revealed the laboratory performed a wet prep test with no label of the saline used. Patient ID 852365 4. An interview with the laboratory director on 11/3/21 at 1115 hours in the lab confirmed the above findings. She acknowledged that the laboratory should label the saline solution.</p>
<p>D5805</p>	<p>TEST REPORT CFR(s): 493.1291(c)</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.

This STANDARD is not met as evidenced by:

Based on review of the laboratory and patient records from 2021 and confirmed in interview, the laboratory failed to document the reference ranges on two of two nonwaived testing: wet prep and microscopic urinalysis. Findings included: 1. Random review of patient final reports from May 2021 to November 2021 revealed the following 14 patient final reports with no documentation of the reference range. 6/7/21: Patient ID 167305 Wet prep 7/2/21: Patient ID 172348 Wet prep 8/4/21: Patient ID 172222 Wet prep 9/8/21: Patient ID 192977 Wet prep 10/6/21: Patient ID 237488 Wet prep 11/3/21: Patient ID 220966 Wet prep 5/26/21: Patient ID 752807 UA micro 6/7/21: Patient ID 653572 UA micro 6/25/21: Patient ID 793861 UA micro 7/19/21: Patient ID 764858 UA micro 7/27/21: Patient ID 827512 UA micro 9/24/21: Patient ID 803702 UA micro 10/11/21: Patient ID 854296 UA micro 10/7/21: Patient ID 871374 UA micro 2. An interview with the laboratory director on 11/3/21 at 1040 hours in the laboratory confirmed the above findings.