

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0466751	(X3) Date Survey Completed 06/13/2018
Name of Provider or Supplier Unity Health Specialty Care	Street Address, City, State 1200 South Main Street, Searcy, AR	
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
D5435	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.</p> <p>This STANDARD is not met as evidenced by: Through a review of the laboratory policy titled "Routine Urinalysis by CHEMSTRIP Urine Test Strips", observations made during a tour of the laboratory, and interviews with laboratory staff, it was determined the laboratory failed to ensure the urinalysis centrifuge speed is within the laboratory's established limits. Survey findings follow: A. The "Routine Urinalysis by CHEMSTRIP Urine Test Strips" policy states, "For microscopic analysis, centrifuge urine for 3 - 5 minutes at 1500 - 1700 rpm. B. During a tour of the laboratory (9:29 a.m. on 6/13/2018) the surveyor observed the sticker on the centrifuge which had the centrifuge speed recorded as 3412 rpm on 4/11/2018. C. Laboratory employee #6 (as listed on the form CMS-209) confirmed, at the time of the tour, that the speed of the centrifuge was outside of the speed required by the policy.</p>
D5783	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or</p>

both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:

Through a review of the policy titled "Chemistry Quality Control", a review of November 2017 Levey - Jennings Reports for ALT (Alanine Aminotransferase), a review of the corrective action log book, and interviews with laboratory staff, it was determined the laboratory failed to take corrective action necessary to ensure accurate patient results. Survey findings follow: A. The policy titled "Chemistry Quality Control" lists the following corrective actions to take for unacceptable quality control values: 1. Repeat the control; 2. Make up new controls or reagents if applicable; 3. Rerun the control; 4. Recalibrate the assay if applicable and rerun the control; 5. Notify the Medical Technologist in charge of Chemistry or Laboratory Manager; 6. Perform preventative maintenance on instrument as needed; 7. Follow troubleshooting guide for the instrument. (Refer to Operators Manual); 8. Call service engineer; 9. Patient results: Do not report any patient results until problem has been corrected. Send all specimens to appropriate site; 10. If instrument requires major maintenance or calibration, 10% of specimens run since last successful QC must be retested and checked for clinical significant changes. B. The policy titled "Chemistry Quality Control" states, "DOCUMENTATION OF CORRECTIVE ACTION: 1. All rule violations must be documented in corrective action log book. 2. All repeats are listed in corrective action log book. 3. All steps in corrective action process for unacceptable controls must be documented in the appropriate corrective action log book." C. Through a review of the November 2017 Levey - Jennings Reports for ALT it was determined the Level 2 Control was unacceptable on 11/27/2017. On 11/27/2017 the Levey - Jennings Report includes three results for ALT Level 2 Control. All three results for 11/27/2017 are flagged as unacceptable. D. A review of the corrective action log book revealed that on 11/27/2017 the laboratory documented that the Level 2 Control was out of acceptable range. The only documented corrective action was adjustment of the mean to make the result appear in although the result was never changed by a corrective action. The laboratory failed to document the corrective actions listed in the "Chemistry Quality Control" policy.