

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0687360	(X3) Date Survey Completed 05/07/2026
Name of Provider or Supplier Unity Health Newport	Street Address, City, State 1205 Mclain, Newport, 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
D5783	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2)</p> <p>(b)(2) Results of control or calibration materials, or 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.</p> <p>This STANDARD is not met as evidenced by: Based upon review of Laboratory Policy and Procedure number 570.7.1 "Quality Control Program, Levey-Jennings graphs for quality control (QC) detail reports for total bilirubin (Tbil) testing performed on the Architect Plus 4100, "corrective action log", "Results List By Analyzer" report, and interview with laboratory staff, the laboratory failed to evaluate patient results back to the last successful QC performance when QC for Tbil testing failed to meet the laboratory's criteria for acceptability on one of four occasions reviewed. Findings follow A) Review of the laboratory policy and procedure 570.7.1 "Quality Control Program" revealed "the lab will validate a random sample of patient's since the last acceptable QC run in the event of failure", and "the lab will utilize appropriate Westgard rules for determining acceptable QC runs, 2-2S failure, 1-3S failure". B) Review of the Tbil QC Statistic Report Levey-Jennings graphs for control level 2 lot# 46040 performed on the Architect Plus 4100 chemistry analyzer revealed that on 1/13/26 the level 2 control with an acceptable range of (2.35 to 2.87) was unacceptable on four successive runs with a result of 2.90 flagged 2-2S at 01:35 a.m., with a result of 3.02 flagged 1-3S at 01:46 a.m., with a result of 3.05 flagged 1-3S at 02:21 a.m., and a result of 2.92 flagged 2-2S at 03:25 a.m. before being acceptable at 03:45 a.m. The previous acceptable result was 1/12/26 at 01:35 a.m. C) Review of the Tbil QC Statistic Report Levey-Jennings graphs for control level 3 lot# 45980 performed on the Architect Plus 4100 chemistry analyzer</p>

on 1/13/26 revealed that the level 3 control with an acceptable range of (5.9 to 7.5) was unacceptable on three successive runs with a result of 7.67 flagged 2-2S at 01:49 a.m., with a result of 7.83 flagged 2-2S at 02:21 a.m., with a result of 7.88 flagged 2-2S at 07:26 a.m., before being acceptable at 07:46 a.m. The previous acceptable result was 1/12/26 at 01:38 a.m. D) Review of statements of corrective action revealed that the corrective action for the Architect Plus 4100 on 1/13/26 was listed as calibration of Tbil assays. Calibration of Tbil on 1/13/26 represented a change in the testing system. E) Review of the "Results List by Analyzer" report revealed that Tbil assays were performed and reported on twenty-seven patients (identified as numbers 1 through 27 on a separate patient identification list) on 1/12/26 from 03:22 a.m. until 1/12/26 at 14:26 p.m. F) Upon request the laboratory was unable to provide evidence that results were evaluated for Tbil assays performed on 1/12/26. G) In an interview on 5/7/26 at 10:33 a.m., the laboratory staff member (# 3 on the form CMS 209) confirmed that Tbil assays performed and reported on 1/12/26 had not been evaluated.