

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0687360	(X3) Date Survey Completed 08/29/2024
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Review of the CMS 209 form, lack of documentation and interviews with laboratory staff, determined the laboratory failed to assess employee competency as directed in personnel requirements. Survey findings follow: A) Review of the CMS 209 form submitted by the laboratory revealed that the Technical Consultant (TC) #1 on the CMS 209 form was also listed as the General Supervisor (GS). B) Review of personnel records for TC #1 on the CMS 209 form, revealed that no competency evaluation for the position of General Supervisor was present. C) Upon request, the laboratory was unable to provide documentation of competency determinations for calendar year 2023 or 2024 for the position of General Supervisor for the personnel identified above. D) In an interview at 11:25 a.m. on 8/27/2024, the technical consultant #1 on the form CMS 209, confirmed that competency determinations have not been performed on the personnel designated as general supervisor.</p>
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.</p>

This STANDARD is not met as evidenced by:
 Based on a review of the manufacturer's instruction, the laboratory's procedure manual, patient test records, and interview with staff the laboratory failed to ensure 10 of 24 examined patient ammonia samples were centrifuged within 15 minutes of collection and 5 of 56 examined lactic acid samples were centrifuged within 30 minutes of collection from June through July of 2024. 1- A) A review of the manufacturer's instructions ("Ammonia Ultra" from Abbott, REF 6K89-30, 307237/RO4, rev.-7/2017) for the ammonia analysis performed in the laboratory, stated: "Rapid separation of plasma from blood cells is critical for obtaining reliable results. The standard recommendation is no more than 15 minutes from sample collection to start of centrifugation." B) The Laboratory's Quality Control (QC) Policy manual did not contain specific policies for ammonia, but stated "Unity Health Newport will follow the testing procedures set forth by Abbott, the manufacturers of the c4000, and ci4100 analyzers in the published IFU, SOP and Package inserts." C) A sampling of ammonia patient test records from June and July revealed: Sample ID 705238; Collected : 6/12/24 14:12, Analyzed: 6/12/24 15:21 Sample ID 718101; Collected : 6/20/24 09:42, Analyzed: 6/20/24 11:02 Sample ID 758356; Collected : 7/16/24 17:40, Analyzed: 7/16/24 22:13 Sample ID 771382; Collected : 7/25/24 04:10, Analyzed: 7/25/24 05:34 Sample ID 781200; Collected : 7/31/24 10:15, Analyzed: 7/31/24 11:04 D) During interview, the Technical Consultant (as listed on the CMS-209 form) confirmed that the lab documented collection times and report times; but not centrifuge times for ammonia testing. 2- A) A review of the manufacturer's instructions ("Lactic Acid2" from Abbott, REF 04T3020, H06713R02, rev.-9/2022) for the Lactic acid analysis performed in the laboratory, stated: "Separate the plasma by centrifugation within 30 minutes of sample collection." B) The Laboratory's QC Policy manual did not contain specific policies for lactic acid, but stated "Unity Health Newport will follow the testing procedures set forth by Abbott, the manufacturers of the c4000, and ci4100 analyzers in the published IFU, SOP and Package inserts." C) A sampling of lactic acid patient test records from June and July revealed: Sample ID 687521; Collected : 6/2/24 04:45, Analyzed: 6/2/24 05:26 Sample ID 690547; Collected : 6/4/24 00:04, Analyzed: 6/4/24 01:08 Sample ID 708760; Collected : 6/14/24 12:00, Analyzed: 6/14/24 13:29 Sample ID 711547; Collected : 6/17/24 00:27, Analyzed: 6/17/24 01:41 Sample ID 749031; Collected : 7/10/24 16:30, Analyzed: 7/10/24 18:42 D) During interview, the Technical Consultant (as listed on the CMS-209 form) confirmed that the lab documented collection times and report times; but not centrifuge times for lactic acid testing.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT
 CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:
 Through review of the laboratory's policy and procedure for "Quality Control" (QC), review of quality control Levy-Jennings charts for March through July 2024, review of QA review notes, lack of documentation and interview it was determined that the laboratory failed to recognize or take corrective action on six of six months data

reviewed when the standard deviation for albumin was 10 times the actual calculated value. Findings follow: A) Review of the laboratory's policy and procedure for QC revealed that "the lab will establish ranges based on historical data". B) Review of QC reports from March through July 2024 for Albumin assays performed on the Architect 4000 showed the standard deviation was set at 1.0 when 0.1 was the appropriate historical standard deviation. C) Upon request, the laboratory was unable to provide documentation that the range identified above had been identified and corrective action taken. D) Review of the Technical Consultants QA review notes for all of 2024 revealed there was no mention of range correction for Albumin assays and no corrective action in regard to Albumin assays was identified. E) In an interview on 8/28/24 at 2:35pm the technical consultant confirmed that the standard deviation ranges were too wide from March through July 2024 and no corrective actions were taken or documented.