

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0468990	(X3) Date Survey Completed 03/16/2022
Name of Provider or Supplier Millard Henry Clinic	Street Address, City, State 101 Skyline Dr, Russellville, 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
D5791	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p> <p>(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.</p> <p>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 January 2021 and May 2021, review of the technical consultants QA review notes, lack of documentation and interview it was determined that the laboratory failed to recognize or take corrective action on two of two months data reviewed when quality control for Total Cholesterol assays demonstrated a shift in values. Findings follow: A) Review of the laboratory's policy and procedure for QC revealed that QC will be "evaluated for acceptability by applying the Westgard Multi-rule formula" and "Levy-Jennings charts and/or electronic graphs or other records will be reviewed each week to observe for shifts and /or trends". B) Review of QC reports for Total Cholesterol assays performed with Biorad Liquid Assay Multiquel QC material level 1 and level 3 lot # 45821 revealed that results for level 1 were shifted below the target mean 23 of 23 days of testing and results for level 3 were shifted below the target mean on 22 of 23 days of testing in January 2021. C) Review of QC reports for Total Cholesterol assays performed with Biorad Liquid Assay Multiquel QC material level 1 and level 3 lot # 45821 revealed that results for level 1 were shifted below the target mean 22 of 23 days of testing and results for level 3 were shifted below the target mean on 22 of 23 days of testing in May 2021. D) Upon request, the laboratory was unable to provide documentation that the shifts identified above had been identified and corrective action taken. E) Review of the Technical Consultants QC review notes revealed there was no mention of shifts or trends for Total Cholesterol assays were and no corrective action in regard to Total</p>

Cholesterol assays was identified. F) In an interview on 3/16/22 at 02:15 PM the laboratory staff members, identified as numbers two and three on the CMS 209 form, confirmed that the QC values for Total Cholesterol were shifted below the target mean in January and May 2021, the shift was not noted on the Technical Consultants QA notes and no corrective action was implemented, and the QC values in January and May of 2021 represented a shift according to the Westgaard Multi-rule formula.