Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0705327	10/22/2020
Name of Provider or Supplier	**Street Address, City, State**	
General John J Pershing Memorial Hospital	130 E Lockling, Brookfield, MO	

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
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on review of 2020 chemistry proficiency testing (PT) during on-site recertification survey and interview with the technical supervisor (TS), the laboratory failed to achieve satisfactory performance for Total Cholesterol for the second and third PT testing event in 2020. See D-tag 2096.
D2096	ROUTINE CHEMISTRY CFR(s): 493.841(f) Failure to achieve satisfactory performance for the same analyte or test in two

	consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on review of 2020 proficiency testing (PT) results during on site recertification survey and interview with the technical supervisor (TS), the laboratory failed to achieve satisfactory performance for Total Cholesterol for two consecutive PT testing events in 2020. Findings: 1. The laboratory obtained an unsatisfactory score of zero percent for Total Cholesterol analyte in the second PT event for 2020. 2. The laboratory obtained an unsatisfactory score of zero percent for Total Cholesterol analyte in the third PT event for 2020. 3. Interview with the TS on October 20, 2020 at 11:00 AM confirmed the laboratory failed to achieve satisfactory performance for the Total Cholesterol analyte in the second and third PT events of 2020.
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: Based on review of the quality assessment (QA) policy, instrument comparisons, quality control (QC) policies, QC records in 2020 and interview with technical supervisor (TS), the laboratory failed to establish and follow written policies and procedures for ongoing mechanism to monitor, assess and correct problems identified in the analytic systems. Findings: 1. Review of the QA policy revealed the laboratory's QA policy failed to identify acceptable ranges for instrument comparisons for the following instruments: Poch 1000i and Cell-Dyn Ruby hematology analyzer, and two Vitros 350's chemistry analyzers for 2019 and 2020. 2. Review of the chemistry, hematology and coagulation QA and QC policies showed the laboratory failed to have a procedure to address shifts and trends in QC. 3. Review of the Vitros 350 chemistry QC showed Cholesterol was trending low for August and September in 2020. 4. Review of the Vitros 350 total cholesterol proficiency testing showed the laboratory failed total cholesterol for second and third events in 2020. 5. Review of the Cell-Dyn hematology QC procedure and QC records revealed the laboratory performed three levels of QC daily and failed to define a method to assess the three daily hematology controls tested for acceptability. 6. Interview with the TS on November 20, 2020 at 11:30 AM confirmed the laboratory failed to establish effective QA and QC policies to monitor and access QC failures, shifts, trends, and instrument comparisons.