Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	38D0622888	09/29/2026
Name of Provider or Supplier	**Street Address, City, State**	
Physicians' Medical Center Lab	2435 Ne Cumulus Ave Suite A, Mcminnville, OR	

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
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) (d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the Individual Quality Control Plan (IQCP) for the detection of Syphilis antibodies and interview with the lab manager, the laboratory failed to ensure that all changes or updates to the IQCP were approved, signed and dated by the Laboratory Director (LD). Findings include: 1. Upon review of the IQCP for the detection of Syphilis antibodies, it was noted that the specimen source on the original IQCP risk assessment for specimen source said serum. A black line had been drawn through it and the words "venipuncture whole blood had been written in, without a date or initials of the editor. 2. Upon review of the Quality Assurance Plan (QAP) of the IQCP for detection of Syphilis antibodies, it was noted that the last line of the QAP on page 3, stating "IQCP will be evaluated at least annually for effectiveness and altered if needed" had a black line drawn through it and was initialed, but not dated by the Lab Manager. 3. Interview with the Lab manager at 2:30 pm verified that initials on the current IQCP for Syphilis antibodies were his and that he had also drawn the black line through the specimen source on page 1. 4. The laboratory reports performing 391 Syphilis serologies annually.
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.

	This STANDARD is not met as evidenced by: Based on review of laboratory Individual Quality Control Procedures (IQCP's) and interview with the Laboratory Director (LD) and the Lab Manager, the laboratory failed to follow the written Quality Assessment procedure (QAP) for the monitoring and review of the testing system and it's components for the detection of Syphilis antibodies, Chlamydia tracomatis infection and Neisseria gonorrhae infection (CT /NG). Findings include: 1. Upon review of the laboratory procedure manual containing the IQCP's for all three (3) analytes, it was noted that the last review for all three (3) of these was in 2022. 2. The last review for the Syphilis antibody assay IQCP was 04/05/2022. The last review for CT/NG infection IQCP was 06/05/2022. 3. The QAP portion of the IQCP's for both, states that review of the IQCP will occur annually. 4. Interview with the LD and Lab manager at 1:25 pm confirmed that they had not performed an annual review nor monitoring of outcomes for either IQCP's since the April and June 2022 dates. 5. The laboratory reports performing 391 Syphilis antibody screens and 596 CT/NG assays annually.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of the Individual Quality Control Procedures (IQCP's) and interview with the Lab Manager, the laboratory failed to implement and carry out the activities detailed in the Quality Assessment (QAP) portion of the IQCP and document in writing those activities. Findings include: 1. Upon review of the IQCP's for Syphilis antibody detection and Chlamydia trachomatis infection and Neisseria gonorrhea infection (CT/NG), the laboratory failed to document any changes or revisions to the IQCP, in writing. 2. Upon request for evidence of QAP monitors and findings associated with that IQCP, none could be produced. 3. Interview with the Lab Manager at 2:00 pm confirmed that there was no written evidence of corrective action when problems arose, no evidence of IQCP review since 2022 and no documented discussion of quality assessment with appropriate staff performing these assays. 4. The laboratory reports performing 391 Syphilis antibody detection assays and 596