

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 38D0627472	(X3) Date Survey Completed 08/23/2023
Name of Provider or Supplier Willamette Valley Dermatology	Street Address, City, State 1605 G St, Springfield, 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
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>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 general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory records and discussion with the Office Manager / Medical Assistant (MA #1), the laboratory failed to ensure that a current Quality Assurance (QA) plan was written and being followed with QA activities being documented in writing at least twice per year. Findings include: 1. Upon request for a copy of the laboratory's QA plan, none could be provided in writing or digitally. 2. Upon request for written documentation of QA activities for the years 2021, 2022 and 2023 to date, none could be produced. 3. The Office Manager / MA#1 confirmed that neither a written QA plan or written evidence of QA activities at least twice per year for 2021, 2022, and 2023 to date could be produced during interview at 2:30 pm on 08/23/2023.</p>
D5293	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c)</p> <p>(b) The general laboratory 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 general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.</p>

This STANDARD is not met as evidenced by:

Based on the lack of written Quality Assurance (QA) activity records since the last Clinical Laboratory Improvement Amendments (CLIA) survey and interview with the Office Manager / Medical Assistant (MA#1) during survey 08/23/2023, the laboratory failed to conduct QA monitoring and document in writing any QA activities since the last CLIA survey. Findings include: 1. The last CLIA survey was conducted on 07/26/2023. 2. Upon request of written records of QA activities and Corrective actions (CA) for 2021, 2022, 2023 to date, none could be produced. 3. Upon request of written records demonstrating discussion of laboratory QA plan findings with appropriate staff for 2021, 2022, 2023 to date, none could be produced. 4. Interview with the Office Manager / MA#1 at 2:30 pm on 08/23/2023 confirmed that there was no written record of any QA activities for 2021, 2022, 2023 to date. 5. Also see D5291