

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D0872266	(X3) Date Survey Completed 11/29/2023
Name of Provider or Supplier East Valley Internal Medicine Pc	Street Address, City, State 2081 W Frye Rd, Ste 200, Chandler, AZ	
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
D5433	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.</p> <p>This STANDARD is not met as evidenced by: Based on lack of function check documentation for the three centrifuges maintained by the laboratory, review of policies and procedures, and interview with the testing personnel (TP-1), the laboratory failed to perform function checks on the three centrifuges which are used as peripheral equipment involved in patient testing. Findings include: 1. The laboratory maintains three centrifuges (two Drucker Diagnostics Model 642E and one UNICO Powerspin Hx Centrifuge). 2. The laboratory's established policy titled, "General Maintenance Program" states, "Centrifuges: RPM and timer check biannually (If speed or time dependent specimens are obtained)." 3. The laboratory failed to provide evidence that function checks were performed on the three centrifuges listed above biannually during 2021, 2022, and 2023 as required per laboratory policy. 4. The TP-1 interviewed on 11/29/23 at 3:15 PM confirmed that the required function checks for the three centrifuges listed above were not performed during 2021, 2022, and 2023. 5. The laboratory's annual test volume in the specialty of Chemistry is 45,000.</p>