Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D1032610	02/10/2021
Name of Provider or Supplier	**Street Address, City, State**	
East Valley Endocrinology Diabetes & Metabolism Pc	9500 E Ironwood Square Rd, Ste 201, Scottsdale, 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
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on review of SARS-CoV-2 test results from patient testing and interview with the Technical Consultant, the Condition: Facility Administration was found to be not met. The laboratory failed to report SARS-CoV-2 (COVID-19) test results as required for 56 of 56 days reviewed from May 2020 through February 2021. Findings include: 1. The laboratory began SARS-CoV-2 (COVID-19) testing using the Architect i1000 analyzer on May 7, 2020. The laboratory performs the IgG COVID-19 test. 2. SARS-CoV-2 (COVID-19) test result from 11/06/20 (account# 19349) was reviewed during the survey conducted on February 10, 2021. 3. No evidence was presented for review during the survey to indicate the laboratory reported SARS-CoV-2 (COVID-19) test results (positive and negative) as required from patient testing performed by the laboratory on the following testing days: 4 days in May 2020, 10 days in June 2020, 10 days in July 2020, 6 days in August 2020, 7 days in September 2020, 1 day in October 2020, 4 days in November 2020, 6 days in December 2020, 6 days in January 2021 and 2 days in February 2021 (to the date of the survey). 4. 677 test results were not reported as required during the period of review. 5. The laboratory performed 677

	SARS-CoV-2 (COVID-19) tests during the period of review. 6. On February 10, 2021 at approximately 11:00 a.m. the Technical Consultant confirmed that the laboratory failed to report SARS-CoV-2 (COVID-19) test results as required.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the laboratory's SARS-CoV-2-IgG test procedure and interview with the Technical Consultant, the SARS-CoV-2-IgG procedure failed to include test reporting requirements for negative SARS-CoV-2-IgG test results . Findings include: 1. The laboratory began patient testing for SARS-CoV-2-IgG testing on the Architect i1000 analyzer on May 7, 2020. 2. The SARS-CoV-2-IgG test procedure submitted by the laboratory for review during the survey conducted on February 10, 2021 failed to include test reporting requirements for negative SARS-CoV-2-IgG test results. 3. The test procedure titled, "SARS-CoV-2-IgG" stated, "Patients testing positive for the IgG Antibody are to be reported in a timely manner to the Arizona Department of Health Services (ADHS) on the form provided on their website. The testing personnel will be responsible for gathering this information for submission to ADHS." 4. The Technical Consultant confirmed that the policy indicated above failed to include information for reporting negative SARS-CoV-2-IgG as required.
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 lack of reporting documentation for SARS-CoV-2-IgG test results and interview with the facility personnel, the laboratory failed to follow established

	procedures for reporting SARS-CoV-2-IgG test results as required. Findings include: 1. The laboratory began patient testing for SARS-CoV-2-IgG testing on the Architect i1000 analyzer on May 7, 2020. 2. The test procedure titled, "SARS-CoV-2-IgG" reviewed during the survey conducted on February 10, 2021 stated, "Patients testing positive for the IgG Antibody are to be reported in a timely manner to the Arizona Department of Health Services (ADHS) on the form provided on their website. The testing personnel will be responsible for gathering this information for submission to ADHS." 3. The laboratory failed to follow the established procedure and report positive SARS-CoV-2-IgG test results as required. The laboratory must report negative SARS-CoV-2-IgG test results as well (see D5403 for findings). 4. The laboratory performed 677 SARS-CoV-2-IgG tests from May 7, 2020 through the date of the survey. 5. The facility personnel confirmed that the laboratory failed to follow their established policy to report SARS-CoV-2-IgG test results as required.