| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 03D1032610 | 07/12/2018 |
| **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 |
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| **D3031** | RETENTION REQUIREMENTS<br>CFR(s): 493.1105(a)(3)<br><br>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.<br><br>This STANDARD is not met as evidenced by:<br>Based on lack of quality control (QC) documentation for review and interview with the facility personnel, the laboratory failed to retain documentation of the Quality Control (QC) that is performed on the Sysmex XP300 hematology analyzer and the Axcel Chemistry analyzer, each day patient specimens are tested. Findings include: 1. The laboratory performs Complete Blood Count (CBC) testing on the Sysmex XP-300 analyzer, with an approximate annual test volume of 14,544 and the laboratory performs patient testing on the Axcel Chemistry analyzer, with an approximate annual test volume of 62,928. 2. The laboratory was using a Laboratory Information System (LIS), LabDaq, to store test records, including QC records for testing performed on the analyzers indicated above. On December 12, 2017 the LIS became inoperable and all QC records stored in the LIS prior to that date were no longer accessible to the laboratory. 3. No QC documentation was presented for review during the survey for patient testing that occurred on 12/02/2016 and 4/03/2017. 4. The facility personnel confirmed that the laboratory did not have documentation of daily QC performance for the testing dates mentioned above. |
| **D5311** | SPECIMEN SUBMISSION, HANDLING, AND REFERRAL<br>CFR(s): 493.1242(a)<br><br>The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) |

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| | Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of established policies and procedures for specimen rejections, review of laboratory records and interview with the facility personnel, the laboratory failed to follow established policies and procedures for rejected specimens. Findings include: 1. The laboratory performs patient testing in the specialties of Diagnostic Immunology, Chemistry and Hematology with an approximate annual test volume of 78,516. 2. The laboratory's established policy titled, Specimen Rejection, states, "... Record the reason for rejection in the Specimen Rejection Log". 3. No documentation was presented for review during the survey conducted on July 12, 2018 to indicate the laboratory had followed the established policy indicated above and documented rejected specimens in the Specimen Rejection Log. The last documented entry in the log was dated 11/03/2016. 4. The facility personnel confirmed that the laboratory did not follow the established policy and document rejected specimens in the Specimen Rejection log from November 2016 through the date of the survey. |
| **D5431** | MAINTENANCE AND FUNCTION CHECKS<br>CFR(s): 493.1254(a)(2)<br><br>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of hematology test records and interview with the facility personnel, the laboratory failed to document the background count that is performed each day of patient testing on the Sysmex XP-300 hematology analyzer. Findings include: 1. The laboratory performs patient testing on the Sysmex XP-300 hematology analyzer, with an approximate annual test volume of 14,544. At the time of the survey conducted on July 12, 2018 it was the practice of the laboratory to perform the background count on the hematology analyzer each day prior to testing patient specimens. The background count documentation is stored in a binder in the laboratory for a period of two years. 2. No evidence was presented for review during the survey to indicate the laboratory performed and retained the documentation of the background count for patient testing that occurred on 12/02/2016. 3. The facility personnel confirmed that the laboratory could not produce evidence that a background count was performed on the patient testing date indicated above. 4. The number of patients tested on the Sysmex XP-300 hematology analyzer on 12/02/2016 could not be determined during the survey. |
| **D5787** | TEST RECORDS<br>CFR(s): 493.1283(a)<br><br>The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) |

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| | The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).<br><br>This STANDARD is not met as evidenced by:<br>Based on review of patient test reports, review of the laboratory's record system and interview with the facility personnel, the laboratory failed to maintain a record system that includes the date of specimen testing and the identity of the personnel who performed each patient test. Findings include: 1. The laboratory performs testing in the specialties of General Immunology, Chemistry and Hematology, with an approximate annual test volume of 78,516. 2. The laboratory utilizes an electronic medical record (EMR) system to maintain patient test reports and was using a Laboratory Information System (LIS), LabDaq, to store patient test records, which included the test date and identity of the person who performed each test. On December 12, 2017 the LIS became inoperable and all patient test records stored in the LIS prior to that date were no longer accessible to the laboratory. 3. Patient test records (ID# 20790 from 12/02/2016 and ID# 24235 from 4/03/2017) presented for review during the survey failed to include the date of specimen testing and the identity of the testing personnel who performed the test. 4. The facility personnel confirmed that the laboratory did not have documentation of the testing date and the identity of the testing personnel who performed each test for the patient test reports indicated above. |
| **D5801** | TEST REPORT<br>CFR(s): 493.1291(a)<br><br>The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of patient test reports maintained in the electronic medical record (EMR) system and interview with the facility personnel, the laboratory failed to have a system in place to ensure the accurate and reliable entry of test results that are recorded on a test result form found in the EMR. Findings include: 1. The laboratory performs patient testing in the specialties of Diagnostic Immunology, Chemistry and Hematology with an approximate annual test volume of 78,516. The laboratory utilizes an electronic medical record (EMR) system to maintain patient test reports. It was the practice of the laboratory to electronically interface patient test results from the analyzer to the LIS and then from the LIS to the EMR. 2. Review of patient test reports in the EMR during the survey revealed that the laboratory is utilizing a form titled, "Procedure Log" to manually record test results, in addition to the interfaced test results. 3. The Procedure Log reviewed during the survey for patient# 20790 from testing that occurred on 12/02/2016 included the test name, test date and test result but lacked the laboratory name and address where the testing occurred, the reference range for each test, and the appropriate units of measure for each test result. 4. No documentation was presented for review to indicate the laboratory had a system in |

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| | place at the time of the survey to ensure that test results manually entered on the Procedure Log form found in the EMR were accurate. 5. The facility personnel confirmed that the laboratory does not have a system in place to check the accuracy of test results that are manually entered onto the Procedure Log form found in the EMR. |
| **D6093** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(5)<br><br>The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.<br><br>This STANDARD is not met as evidenced by:<br>Based on lack of quality control records for review, the laboratory director failed to ensure that quality control programs are maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. See D3031 and D5431 for findings. |