| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 05D2087903 | 09/13/2018 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Advanced Diagnostics Lab | 23275 S Pointe Dr, Ste 150, Laguna Hills, CA | |

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 review and the lack of documentation of the Quality Control (QC) being performed for the analytes tested (See D5447), laboratory's policy and procedure and interview with the technical consultant, it was determined that the laboratory failed to 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. The finding included: a. The laboratory's policy and procedure manual for record retention policy stated: "Advanced Diagnostic labs shall keep and maintain records for a minimum period of three (3) years." b. For eleven (11) out of eleven (11) random patient test results reviewed covering period from 1/15/2016 to 5/25/2018, the laboratory has no documentation to show QC materials being performed for each of the requested random patient test results. c. The technical consultant confirmed (9/13/2018, 1400), that the laboratory has no documentation to show for the QC performance for the period the surveyor requested. |
| **D5300** | PREANALYTIC SYSTEMS<br>CFR(s): 493.1240<br><br>Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as specified in 493. |

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| | 1249 for each specialty and subspecialty of testing performed.<br><br>This CONDITION is not met as evidenced by:<br>Based on review of the laboratory's policy, procedure, random patient sampling test results, and interview with the technical consultant, it was determined that the laboratory failed to monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as specified in 493.1249 for each specialty and subspecialty of testing performed. See D 5311 |
| **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) 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 the laboratory's policy, procedure, random patient sampling test results, and interview with the technical consultant, it was determined that the laboratory failed to establish and follow written policies and procedures. The findings included: a. The laboratory's policy and procedure for Complete Blood Count (CBC) acceptability for analysis stated: "All CBC's must be run within 2 days of collection, not receipt. CBC's received after 2 days of draw will be rejected, and a new sample will be requested. All clients will receive a letter explaining this." b. For eight (8) out of eleven (11) random patient sampling test results reviewed covering period from 1 /15/2016 to 5/25/2018, eight (8) were analyzed and reported even though the specimens were more than 2 days old of collection date and time. c. The following are examples. Pt#: Collection Test Age of Date: Date: Spec.: Pt2 1/29/2016 2/3/2016 5 days Pt3 3/11/2016 3/16/2016 5 days Pt4 9/21/2016 10/5/2016 14 days Pt5 12/21 /2016 1/11/2017 21 days Pt6 3/21/2017 3/24/2017 3days Pt7 6/20/2017 6/23/2017 3 days Pt8 10/4/2017 10/18/2017 14 days Pt9 12/20/2017 1/12/2018 22 days d. The technical consultant submitted and confirmed (9/13/2018, 1400) random patient test results. Based on review above patient test results cannot be assured due to the age of the specimens. |
| **D5400** | ANALYTIC SYSTEMS<br>CFR(s): 493.1250<br><br>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.<br><br>This CONDITION is not met as evidenced by:<br>Based on review and the lack of documentation of the quality control (QC) print outs, |

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| | random patient sampling test results and interview with the technical consultant /testing personnel, it was determined that the laboratory failed to monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. See D5447. |
| **D5447** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(3)(i)(g)<br><br>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the quality control (QC) print outs, random patient sampling test results and interview with the technical consultant/testing personnel, it was determined that the laboratory failed to least once a day patient specimens are assayed or examined perform the (QC) each quantitative procedure, include two control materials of different concentrations. The findings included: a, For eleven (11) out of eleven (11) random patient sampling test results for Routine Chemistry, Endocrinology, and Hematology tests, no documentation of the QC materials being performed for the following analytes. b. 2016 Routine Chemistry Pt: Date of test: Analyte: #1 1/15/2016 Alb, #1 1/18/2016 PSA #2 2/4/2016 Alb, PSA #3 3/16/2016 Alb #3 3/17/2016 PSA #4 9/28/2016 Alb, PSA 2016 Hematology Pt: Date of test: Analyte: #1 1/15/2016 CBC #2 2/3/2016 CBC #3 3/16/2016 CBC #4 10/5/2016 CBC 2016 Endocrinology Pt: Date of test: Analyze: #1 1/18/2016 E2, LH #2 2/4/2016 E2, LH #3 3/17/2016 E2, LH #4 9/28/2016 LH #4 10/5/2016 E2 2017 Routine Chemistry Pt: Date of test: Analyte: #5 1/11/2017 Alb, PSA #6 3/24/2017 Alb, PSA #7 6/23 /2017 Alb, PSA #8 10/18/2017 Alb, PSA #9 12/22/2017 Alb, PSA 2017 Hematology Pt: Date of test: Analyte: #5 1/11/2017 CBC #6 3/24/2017 CBC #7 6/23/2017 CBC #8 10/18/207 CBC #9 1/12/2018 CBC 2017 Endocrinology Pt: Date of test: Analyte: #5 1 /11/2017 E2, LH #6 3/24/2017 E2, LH #7 6/23/2017 E2, LH #8 10/18/2017 E2, LH #9 12/22/2017 E2, LH 2018 Routine Chemistry Pt: Date of test: Analyte: #10 3/27 /2018 Alb, PSA #11 5/26/2018 Alb, PSA 2018 Endocrinology Pt: Date of test: Analyte: #10 3/27/2018 E2, LH #11 5/26/2018 E2, LH 2018 Hematology Pt: Date of test: Analyte: #10 3/27/2018 CBC #11 5/26/2018 CBC c. The technical consultant submitted and confirmed (9/13/2018, 1400) that the above analytes lack the documentation for QC materials being performed by the laboratory. Note: Abbreviations Pt: Patient Alb: Albumin CBC: Complete Blood Count E2: Estradiol LH: Luteinizing Hormone PSA: Prostate-Specific Antigen |
| **D6082** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(1)<br><br>The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing.<br><br>This STANDARD is not met as evidenced by: |

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| | Based on review and the lack of documentation of the Quality Control (QC) not being performed for the analytes tested (See D5447), review of the laboratory's policy, procedure for specimen acceptability and rejection criteria (See D5311), and review of the laboratory's record retention policy and procedure (See D 3031), it was determined that the laboratory director failed to ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. |