| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 31D1048389 | 11/07/2019 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Excell Clinical Laboratory | 95 Dermody Street, Cranford, NJ | |

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 Urinalysis Calibartion Printouts and interview with the General Supervisor (GS), the laboratory failed to retain calibartion records for Urinalysis test performed on Clinitek Advantus from August 2019 to the date of survey. The GS confirmed on 11/6//19 at 1:15 pm calibration printouts were not retained. |
| **D3033** | RETENTION REQUIREMENTS<br>CFR(s): 493.1105(a)(3)(i)<br><br>In addition, the laboratory must retain records of test system performance specifications that the laboratory establishes or verifies under 493.1253 for the period of time the laboratory uses the test system but no less than 2 years.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyors observation of lack of Performance Analyzer (PA) data and interview with the Laboratory Director (LD), the laboratory failed to retain PA raw data for the Shimadzu used to perform confirmatory Drug Testing from July 2018 to the date of survey. The LD confirmed on 11/7/19 at 2:15 pm that PA raw data was not retained. |
| **D5209** | PERSONNEL COMPETENCY ASSESSMENT POLICIES<br>CFR(s): 493.1235 |

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| | As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of the Competency Assessment (CA) records and interview with the Laboratory Director (LD), the laboratory failed to perform a CA on two who performed interpretation of Urine Confirmatory tests out of seven TP from Novmber 2018 to the date of survey. The LD confirmed on 11/7/19 at 11:00 am that CA was not performed on two TP. |
| **D5315** | SPECIMEN SUBMISSION, HANDLING, AND REFERRAL<br>CFR(s): 493.1242(c)<br><br>The laboratory must refer a specimen for testing only to a CLIA-certified laboratory or a laboratory meeting equivalent requirements as determined by CMS.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of Toxicology Records, Final Reports and interview with the Laboratory Director (LD), the laboratory failed to refer the interpretation of chromatography for Urine Toxicology confirmation testing to a non-CLIA-certified laboratory from July 2018 to the date of survey. The LD confirmed on 11/7/19 at 2:45 pm that toxicology tests were reviewed and resulted from a non-CLIA-certified laboratory. |
| **D5401** | PROCEDURE MANUAL<br>CFR(s): 493.1251(a)<br><br>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of the Procedure Manual (PM) and interview with the General Supervisor (GS), the laboratory failed to follow the procedure to verify new lot numbers of Quality Control" (QC) used in Coagulation tests on the date of the survey. The finding includes: 1. The PM stated new lots of QC will be run five times prior to use but there was no documented evidence QC Level 1- Lot NO193167 was verified. 2. The GS confirmed 11/7/19 at 1:30 pm that the laboratory did not follow the PM. |
| **D5403** | PROCEDURE MANUAL<br>CFR(s): 493.1251(b)<br><br>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 |

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| | 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.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of the Procedure Manual (PM) and interview with the Laboratory Director (LD), the laboratory failed to have all procedures needed for Urine Toxicology confirmation tests run on the Shimadzu from July 2018 to the date of the survey. The finding includes: 1. The laboratory failed to have a procedure for verification of new lots of reagents, prepared mobile phases and standards before they were put in use. 2. The LD confirmed on 11/7/19 at 1:50 pm that the laboratory did not have the above procedure. |
| **D5415** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(c)<br><br>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.<br><br>This STANDARD is not met as evidenced by:<br>a. Based on surveyor review of Manufactures Package Insert (MPI), observation of the Quality Control material, and interview with the General Supervisor (GS), the laboratory failed to put a new expiration date on Hematology and Coagulation Control material used on the Beckman Coulter LH 500 and Instrumentation Laboratory ACL 1000 as per the MPI respectively on the date of the survey. The GS confirmed on 11/7 /19 at 10:20 am the laboratory failed to put a new expiration dates on the control material. b. Based on surveyor review of MPI, observation of testing kits, and interview with the GS, the laboratory failed to put expiration dates on the reagents and strips used for tests performed on the Dynex analyzer on the date of the survey. The GS confirmed on 11/7/19 at 1:20 pm the laboratory failed to put new expiration dates on the materials in test kits. |
| **D5417** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(d)<br><br>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. |

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| | This STANDARD is not met as evidenced by:<br>Based on surveyor observation of Analyzer printout and interview with the General Supervisor (GS), the laboratory used expired reagent for Follicle-Stimulating Hormone (FSH) tests ran on the Vitros 3600 analyzer on 11/4/19. The findings include: 1) FSH patient results were flagged with "RE" Reagent Expired code. 2) 4 Patients were run and reported. 3) The GS confirmed on 11/6/19 at 12:10 pm that the laboratory used an expired reagent. 35471 b. Based on surveyor observation of the coagulation Quality Control (QC) material in use, review of the Hemosil Level 1 & 2 QC Manufacture's Package Insert (MPI) and interview with the GS, the laboratory used expired QC material for the Coagulation testing performed on the Instrumentation Laboratory (IL) ACL 1000 analyzer on the date of survey. The findings include: 1. The MPI stated QC expired eight hours after it was reconstituted. 2. The open date on the QC material was 11/4/19. 3. Approximately 50 patients were run and reported with expired QC. 4. The GS confirmed on 11/7/19 at 11:00 am that the laboratory used expired QC material. |
| **D5421** | ESTABLISHMENT AND VERIFICATION OF PERFORMANCE<br>CFR(s): 493.1253(b)(1)<br><br>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of the Performance Specification (PS) records and interview with the General Supervisor (GS), the laboratory failed to ensure that all PS procedures were performed on the Premier 9210 analyzer from February 2019 to the date of survey. The finding includes: 1. The laboratory did not verify Patient Normal Range (PNR) study. 2. The GS confirmed on 11/7/19 at 11:15 am that PNR study was not performed. |
| **D5423** | ESTABLISHMENT AND VERIFICATION OF PERFORMANCE<br>CFR(s): 493.1253(b)(2)<br><br>Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. |

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| | This STANDARD is not met as evidenced by:<br>Based on surveyor review of the manufacturer's package insert and interview with the Laboratory Director (LD) and General Supervisor (GS), the laboratory failed to follow 'Intended Use' instruction for Quantitative Serum Human Chorionic Gonadotropin test from 1/11/18 to the date of survey. The findings include: 1. The laboratory modified "Intended Use" of the test so it was off label test. 2. The laboratory did not perform any performance specification for off label test. 3. The laboratory reported around 91 qualitative results from 1/2/19 to 11/7/19 on the basis of quantitative test values. 4. The LD and GS confirmed on 11/7/19 at 1:30 pm that the laboratory did not follow Intended Use of the procedure. 35471 b. Based on surveyor review of the PS and interview with the Laboratory Director (LD), the laboratory failed to have complete PS for Urine Drug tests performed on the Shimadzu analyzer from July 2018 to the day of the survey. The findings include: 1. A review of the PS revealed the laboratory did not establish performance characteristics as follows: a. The validation of the hydrolysis control did not include validation of: i. Optimal Enzyme Concentration ii. Temperature of the Heat Block iii. Time on the Heat Block b. Method comparison studies were not performed. c. Analytical Sensitivity was not established for all parameters at 20% per Clinical Scientific Literature. 2. The LD confirmed on 11/7/19 at 1:20 PM that the LD did not ensure that all PS were established. |
| **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 surveyor review of the Quality Control (QC) records and interview with the Laboratory Director (LD), the laboratory failed to perform and document two levels of Glucuronide control on each day of patient testing for Urine Drug Confirmation (UDT) testing performed on the Shimadzu analyzer from July 2018 to the date of the survey. The finding includes: 1. A review of the work records for UDC revealed the laboratory failed to include a negative Glucuronide control when patient samples were run. 2. Approximately 50 patients were run per day. 3. The LD confirmed on 11/7/19 at 2:40 pm that two levels of QC were not performed every day of patient testing. |
| **D5467** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(9)(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-- When using calibration material as a control material, use calibration material from a different lot number than that used to establish a cut-off value or to calibrate the test system. (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of the Procedure Manual, Calibrators, Controls and interview with the Laboratory Director (LD), the laboratory failed to prepare control |

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| | and calibrator material from different lot numbers of standards for Urine Toxicology confirmation tests from July 2018 to the date of the survey. The LD confirmed on 11/7 /19 at 2:10 pm the laboratory did not use different lot numbers to prepare calibrators and controls. |
| **D5469** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(10)(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-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of Quality Control (QC) records and interview with the General Supervisor (GS), the laboratory failed to verify last three lot of QC material used for Hemoglobin A1C test performed on the Premier 9210 analyzer from Febraury 2019 to the date of survey. The GS confirmed on 11/7/19/19 at 10:15 am that the assayed values of QC material were not verified before putting in use. |
| **D5781** | CORRECTIVE ACTIONS<br>CFR(s): 493.1282(b)(1)<br><br>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of Quality Control (QC) Work Records (WR), Corrective Action Log (CAL) and interview with the General Supervisor (GS), the laboratory failed to document Corrective Action (CA) when QC had error codes "RE" Reagent expired, "ME" Mechanical Error and "OR" Out of dynamic Range on the Vitros 3600 analyzer from 11/6/18 to the date of survey. The GS confirmed on 11/7/19 at 10:45 am the laboratory did not document CA. |
| **D5791** | ANALYTIC SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1289(a)(c) |

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| | (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.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of the Quality Control material, Levy Jennings (LJ) charts and interview with the General Supervisor (GS), the laboratory failed to assess and correct problems in the analytic system when the LJ charts had the incorrect control lot number and ranges for Coagulation tests run on the Instrumentation Laboratory (IL) ACL 1000 on the date of survey. The findings include: 1. The Level 1 Prothrombin Time (PT) and Activated Thromboplastin Time (APTT) QC lot number listed on the LJ chart was not the lot number of the QC in use. 2. There was no documented evidence as to what the expected QC values were. 3. There was no documented evidence as to when the QC was put into use. 4. The GS confirmed on 11 /7/19 at 11:45 am that the laboratory did not assess and correct problem in the analytic system. |
| **D5805** | TEST REPORT<br>CFR(s): 493.1291(c)<br><br>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of the Final Report (FR) and interview with the Laboratory Director (LD), the laboratory failed to report Urine Drug confirmation test results accurately from July 2108 to the date of survey. The finding includes: 1. The laboratory performed non Food and Drug Administration cleared tests and there was no statement stating the test had not been cleared or approved by the U.S. Food and Drug Administration" on the FR. 2. The laboratory failed to include the name and address of the laboratory where the peaks were read. 3. The LD confirmed on 11/7/19 at 2:45 pm that Urine Drug confirmation tests were not reported accurately. |
| **D6086** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(3)(ii)<br><br>The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of the Performance Specification (PS) records and |

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| | interview with the Laboratory Director (LD), the LD failed to ensure that PS were adequate to perform Urine Toxicology tests on the Shimadzu system from July 2018 to the date of survey. The findings include: 1. There was no validation performed to establish the expiration date of reagents, working solutions, Internal Standard, controls and calibrators used. 2. Sample stability studies were not performed beyond four days and on all storage conditions. 3. There was no criteria for acceptance of the "Quality Assurance Split Sample" analysis. 4. A review of UR-144 method validation for % recovery revealed a 45% recovery but the established confidence range was 50% or above. 5. The laboratory did not have criteria to review chromatography. 6. The LD confirmed on 11/7/19 at 2:20 pm that the LD did not ensure the PS were adequate. |