| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 31D2033824 | 02/12/2020 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Fusion Diagnostics Laboratories, Llc | 210 Malapardis Road, Suite 103, Cedar Knolls, 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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| **D5209** | PERSONNEL COMPETENCY ASSESSMENT POLICIES<br>CFR(s): 493.1235<br><br>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 Technical Supervisor (TS) the laboratory failed to perform the CA correctly for four out of four Testing Personnel (TP) from 2/22/18 to the date of the survey. The findings include: 1. The laboratory did not assess test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples on four out of four TP. 2. "competent to perform the skill" column on the CA was not checked for four out of four TP for CA's performed in the calendar years 2018 and 2019. 3. The Laboratory failed to perform a CA on one out of four TP in the calendar years 2018 and 2019. 4. The TS confirmed on 2/11/20 at 11:00 am that the CA was not performed correctly. 35471 |
| **D5211** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(a)<br><br>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of the Proficiency Testing (PT) records and interview with the Technical Supervisor (TS), the laboratory failed to review and evaluate coded PT results obtained with the College of American Pathologists (CAP) in the calendar year |

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| | 2019. The findings include: 1. The laboratory did not evaluate Code 20 (No appropriate target/response; cannot be graded) for: a. Urine Drug Testing (screening) - Benzodiazepine Group samples UDS-12 and 15 in event 2 b. General Chemistry /Therapeutic Drugs - Triiodothyronine and Free Triiodothyronine for sample CHM-13 in event C. 2. The laboratory did not evaluate Code 26 (educational challenge) for: a. Diagnostic Immunology - Rheumatoid Factor screening titer samples RF-03, 04, 05 and Antistreptolysin O samples ASO 03- 05 in Event A b. Tick Transmitted Diseases - Borrelia burgdorferi Test 1 and 3 for sample TTD-01 and sample TTD-01 in event A c. Serology - Anti-iTG IgG, Qualitative for Celiac CES-04, 05, 06 in event A d. Diagnostic Immunology - Antistreptolysin O samples ASO-06, 08 in event B e. Hematology Auto Differentials - FH13 Blood Cell ID sample BCP-02 in event A f. Hematology Auto Differentials - FH13 Blood Cell ID samples BCP16-B20 in event B and samples BCP 26 -30 in event C g. Diagnostic Immunology - Rheumatoid Factor screening titer for samples RF-06, 07, 10 in event B h. Bacteriology Agar Diffusion samples D01 - D05 in event A-2019 i. Bacteriology Disk Differential samples D15-D20 in event C-2019 3. The laboratory did not evaluate Code 27 (lack of participant or Referee consensus) for: a. Hematology Auto Differentials - FH13 Blood Cell ID Ungraded for samples BCP-02 in event A. b. Special Immunology - Anti-gliadin IgG qual for samples CES 04- 06 in event B c. Special Immunology - Anti-ribonucleoprotein qualitative sample S2-20, Anti-Sjgren's-syndrome-related antigen A sample S2-20 in event C 4. The laboratory did not evaluate Code 28 (response qualified with a greater or less than sign; unable to quantitative) for Blood Lead - sample BL-5 event A, BL-10 event B and BL-11 event C. 5. The laboratory did not evaluate Code 30 (Scientific Committee decision) for General Chemistry/Therapeutic Drugs Samples serum Phosphorus samples CHM 06, 07 and 09 for event B. 6. The TS confirmed on 2/11/20 at 1:30 pm that the laboratory failed to evaluate coded results for PT events. 35471 |
| **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 Technical Supervisor (TS), the laboratory failed to follow the procedure to verify new lot numbers of Quality Control (QC) used in Hematology tests on the Coulter LH 750 from October 2019 to the date of the survey. The finding includes: 1. The PM stated new lots of QC "will be verified by the laboratory prior to being placed into use" but: a. Lot 865600 expired 10/20/19 - new lot was verified 10/21/19 b. Lot 866700 expired 1/12/20 - new lot was verified on 1/13/20 2. The TS confirmed 2/12/20 at 1:30 pm that the laboratory did not follow the PM. |
| **D5411** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(a)<br><br>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as |

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| | determined under 493.1253.<br><br>This STANDARD is not met as evidenced by:<br>a. Based on surveyor observation, review of the Manufacturer's Package Insert (MPI) and interview with the Technical Supervisor (TS), the laboratory failed to follow the manufacturer's instruction for storage of Analytical Profile Index (API) media on the date of survey. The finding includes: 1. The MPI stated to store API reagent from 2 to 8 degrees Celsius (C) but the laboratory stored an unopened box in the freezer. 2. The TS confirmed on 2/12/2020 at 1:10 pm that the laboratory did not follow the MPI. b. Based on surveyor review of the MPI, Microbiology Quality Control (QC) records and interview with the TS, the laboratory failed to follow the MPI for BD BBL Sensi-Disc Antimicrobial Susceptibility Test Discs for Urine Culture Sensitivity tests from 2 /22/18 to the date of the survey. The findings include: 1. The MPI for Zone Size Interpertation stated: a. Zone size for Staphylococcus aureus with Levofloxin had an assigned value of 25-30 but 29-37 was on the QC record in the laboratory. b. Zone size for Pseudomonas aeruginosa with Cefepime had an assigned value of 23-29 in the MPI but 24 -30 was on the QC record in the laboratory. 2. The TS confirmed on 2/12 /20 at 2:10 pm the laboratory did not follow the MPI. |
| **D5413** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(b)<br><br>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of the Temperature Logs and interview with the Technical Supervisor, the laboratory failed to monitor and document the Freezer Temperature where sensitivity discs for Bacteriology tests were stored from 2/3/20 to the date of survey. The TS confirmed on 2/11/20 at 10:20 am that the laboratory did not document freezer temperature. |
| **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>Based on surveyor review of Manufactures Package Insert, observation of the Quality Control material, and interview with the Technical Supervisor (TS), the laboratory failed to put a new expiration date on Hematology, Chemistry, Immunology and |

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| | Endocrinology Control material on the date of the survey. The TS confirmed on 2/12 /20 at 1:10 pm the laboratory failed to put a new expiration date on the control material. |
| **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.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor observation of reagents and interview with the Technical Supervisor (TS), the laboratory failed to discard expired reagents from 11/2/19 to the date of the survey. The findings include: 1. Expired reagents were found as below: a. Herpes Simplex 1- Specific Immunoglobulin G (HVS-1 Specific IgG) used on the Liasion Diasorin XL b. Lipase - used on the Beckman Coulter AU480 c. Creatine Kinase used on the Beckman Coulter AU480 2. The TS confirmed on 2/12/20 at 1:10 pm that the laboratory did not discard expired reagent. |
| **D5419** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(e)<br><br>Components of reagent kits of different lot numbers must not be interchanged unless otherwise specified by the manufacturer.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor observation of Reagent Kits (RK) and interview with the Technical Supervisor (TS), the laboratory failed to ensure all components of RK used on the Diasorin and DSX analyzers for Immunology Tests of different lot numbers were not interchanged from 2/22/18 to the date of the survey. The findings include: 1. Mixed RK were found as follows: a. Tissue transglutaminase (tTG) Immunoglobin A (IgA) Elisa kit 050432 contained 8 unpackaged and unsealed microcuvettes, (lot number unknown). HRF sample diluents 045902, 057435, 0554419 b. Gladian IgA contained two kits of unsealed microcuvettes in opened unsealed bag. Lot numbers not known. c. Anti-cyclic citrullinated peptide (CCP 3.3) Immunoglobulin G (IgG)/IgA Kit 053873 contained: i. HRP IgG/IgA Conjugate 503871, 053871, 2 vials 051687 ii. TMB Chromogen 055554 - 057050 iii. HRP Stop Solution 005526, 057429, 052910 iv. Negative QC 057531 - 040428 v. Low Positive 055716 - 05168 vi. Sample Diluents - 2 -TMP Stop Solution - Poured off lot number or expiration date not recorded d. Sjgren's-syndrome-related antigen B (SS-B) IgG lot 052098 contained i. HRP wash concentrate 049104, 3 - 053057, 051868 ii. HRP sample diluents 3 - 053058, 052537, 053267 iii. TMB Chromogen 2 - 052449, 049549 iv. HRP Stop Solution 050025, 052221 v. HRP IgG Conjugate 047994 2. Approximately 20 tests are run per week with RK. 3. The TS confirmed on 2/12/20 at 12:10 pm the laboratory interchanged components of the RK. |
| **D5429** | MAINTENANCE AND FUNCTION CHECKS<br>CFR(s): 493.1254(a)(1)<br><br>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory |

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| | must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor observation of Incubator 3 and interview with the Technical Supervisor (TS), the laboratory failed to perform and document maintenance as specified by the manufacturer on Incubator 3 used in Bacteriology testing at the time of the survey. The finding includes: 1. Observation of Incubator 3 revealed a red warning "Alarm Replace Hepa Filter". 2. Testing Personnel on site at the time of the survey stated the laboratory does not replace the Hepa Filter. 3. The TS confirmed on 2 /12/20 at 2:05 pm that maintenance as specified by the manufacturer was not performed. |
| **D5451** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(3)(iii)(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-- Test procedures producing graded or titered results include a negative control material and a control material with graded or titered reactivity, respectively; 493.1256 (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 Technical Supervisor (TS), the laboratory failed to titer a positive control for Syphilis, Mononucleosis, Antistreptolysin O and Rheumatoid Factor tests from 2/22/18 to the date of survey. The finding includes: 1. There was no documented evidence a positive control was titered further than 1:2 when a patient result was titered beyond 1:2. 2. The TS confirmed on 2/12/20 at 10:00 am that a positive titered control was not titered every time a patient was tittered. |
| **D5477** | CONTROL PROCEDURES<br>CFR(s): 493.1256(e)(4)(g)<br><br>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on the surveyor review of the Quality Control (QC) records and interview with the Testing Personnel (TP), the laboratory failed to check each new lot number and shipment of media for its ability to support growth and select or inhibit organisms from 2/22/18 to the date of the survey. The findings include: 1. There was no documented evidence ability to support growth and select or inhibit organisms was checked on any lot number of the Agar listed below: a. BBL Trypticase Soy b. |

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| | Columbia CNA c. BBL Mac Conkey d. BBL Mueller Hinton II e. BBL Mueller Hinton f. BBL Heckton Enteric g. CDC Anaerobic Blood Agar 2. The TP #4 listed on CMS form 209 confirmed on 2/11/20 at 10:00 am the laboratory did not perform the above QC. |
| **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 the Levy Jennings (LJ) charts, Quality Control records, and interview with the Technical Supervisor (TS), the laboratory failed to perform corrective action when the Beckman Coulter AU480 had QC running below the mean for three months from 11/1/19 to the date of the survey. The findings include: 1. A review of the LJ charts revealed QC was consistently running below the mean for Alkaline Phosphatase, Calcium, Amylase, Aspartate Aminotransferase (AST), Creatine Kinase (CK), Creatinine, Lactate Dehydrogenase (LDH), Blood Urea Nitrogen (BUN), Uric Acid, Complement (C4), Chloride, and Glucose. 2. There was no documented evidence corrective action was performed. 3. The TS confirmed on 2/12/20 at 2:10 pm that corrective action was not performed. |
| **D5891** | POSTANALYTIC SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1299(a)<br><br>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 postanalytic systems specified in 493.1291.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of the Procedure Manual (PM) and interview with the Technical Supervisor (TS), the laboratory failed to establish a procedure for verifying manually entered and calculated results from 2/22/18 to the date of survey. The TS confirmed on 2/12/20 at 11:30 am that the laboratory did not have the procedure mentioned above. |
| **D6022** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(5)<br><br>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory |

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| | director must-- (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur.<br><br>This STANDARD is not met as evidenced by: |
| **D6051** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(8)(v)<br><br>The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.<br><br>This STANDARD is not met as evidenced by: |
| **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 interview with the Technical Supervisor (TS), the Laboratory Director (LD) failed to ensure that PS procedures for Hemoglobin A1C tests performed on the Variant II Turbo analyzer were adequate from July 2019 to the date of survey. The findings include: 1. There was no documented evidence that the LD approved the accuracy and linearity. 3. The TS confirmed on 2/12/20 at 12:30 pm that PS procedures were not adequate. |
| **D6091** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(4)(iii)<br><br>The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of the Proficiency Testing (PT) records and interview with the Technical Supervisor (TS), the Laboratory Director (LD) failed to ensure that PT performed with the College of American Pathologists (CAP) was reviewed and evaluated by the appropriate staff in the calendar year 2019. The TS confirmed on 2/11 /20 at 10:45 am that the LD did not ensure all PT reports were reviewed. |
| **D6094** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(5)<br><br>The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to |

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| | identify failures in quality as they occur.<br><br>This STANDARD is not met as evidenced by:<br>a. Based on surveyor review of the laboratory's Individualized Quality Control Plan (IQCP) for Disk Diffusion Antimicrobial Susceptibility Testing and Media QC and interview with the Laboratory Director (LD) via telephone the laboratory failed to maintain the Quality Assessment (QA) plan from 1/4/16 to the date of the survey. The LD confirmed on 2/12/20 at 2:35 pm the QA portion of the IQCP was not maintained. Note: This was cited on the 2/22/18 survey. Plan of Correction stated "This assessment will be completed annually". b. Based on surveyor review of the Quality Assurance (QA) procedure and interview with the Laboratory Director (LD) via telephone the LD failed to ensure that the QA program was maintained to assure quality of laboratory services from 2/22/18 to the date of the survey. The finding includes: : 1. The QA procedure stated quarterly an internal audit and tracer would be performed for self inspection. 2. The laboratory did not have any documented evidence a tracer or internal audit was performed. 3. The LD confirmed on 2/12/20 at 1:45 pm that the QA procedure was not maintained. |
| **D6102** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(12)<br><br>The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of Personnel Records (PR) and interview with the Technical Supervisor (TS), the Laboratory Director failed to ensure that the education record for one of four testing personnel was available on the date of the survey. The TS confirmed 2/11/20 at 10:00 am that all education records were not available. |