Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2033824	02/22/2018
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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: a) Based on surveyor review of the Competency Assessment (CA) records and interview with the Laboartory Director (LD), the laboratory failed to perform CA correctly on four out of four testing personnel in 2016 and 2017. The findings include: 1. The laboratory did not document when testing personnel were observed, what records were reviewed and how assessment was done. 2. The LD confirmed on 2/21 /18 at 11:00 am that CA was not performed correctly. b) Based on surveyor review of CA and interview with the LD, the LD failed to ensure that qualified personnel performed CA in 2016 and 2017. The LD confirmed on 2/21/18 at 11:15 am that qualifed personnel did not perform CA.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) 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. This STANDARD is not met as evidenced by: a) Based on surveyor review of the Procedure Manual (PM) and interview with the Laboratory Director (LD), the laboratory failed to follow the Urine Culture (UC)

	procedure entitled "Rejection Criteria" from 5/7/15 to the date of survey. The finding includes: 1. The PM stated to reject the sample "when the collection time and method of collection have not been provided" but a review of five requisitions revealed five out of five had no collection method stated and the samples were not rejected. 2. The LD confirmed on 2/22/18 at 2:10 pm that the PM was not followed. b) Based on surveyor review of the PM and interview with the LD, the laboratory had an incorrect procedure for Quality Control (QC) of media from 5/7/15 to the date of survey. The finding includes: 1. The QC procedure in the PM stated "For each shipment or lot of media, the laboratory has documentation that the manufacturer's QC practices conform to the Clinical and Laboratory Standards Institute (CLSI) specifications" but CLSI guidelines were removed from the regulations. 2. The LD confirmed on 2/22/18 at 2:20 pm that the procedure in the PM was not the current QC procedure.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on surveyor review of the Individualized Quality Control Plan (IQCP) for Disk Diffusion Antimicrobial Susceptibility Testing and interview with the Laboratory Director (LD), the laboratory failed to have an approved, signed and dated IQCP Quality Control Plan procedure by the Laboratory Director (LD) from 1/4/16 to the date of the survey. The findings include: 1. A review of the IQCP plan revealed that there was no evidence of review, approval or signature of the LD on the Risk Management portion of the IQCP. 2. The IQCP did not include a Qualtiy Control Plan. 3. The LD confirmed on 2/22/18 at 1:45 pm that all portions of the IQCP were not signed.
D5409	PROCEDURE MANUAL CFR(s): 493.1251(e) The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2). This STANDARD is not met as evidenced by: Based on surveyor review of the Coagulation Procedure Manual (PM) and interview with the Laboratory Director (LD), the laboratory failed to record a discontinuance date on Coagulation procedure ceased on 4/30/17. The LD confirmed on 2/21/18 @ 12:00 pm that a discontinuance date was not recorded.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) 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. This STANDARD is not met as evidenced by:

	Based on surveyor review of the Quality Control (QC) records, Manufacture package insert (MPI), QC material, and interview with the Testing Personnel (TP), the laboratory used expired QC material for Hepatitis C Virus tests performed on the Architect analyzer from 10/24/17 to the date of survey. The findings include: 1.The MPI stated that QC material expires sixty days after opening. 2. Bio-Rad Virotrol I control Lot # 119650 was opened 9/1/17 expired 10/24/17. 3. Approximately 560 patients were run and reported to the date of survey. 4. The TP # 1 listed on CMS form 209 confirmed on 2/22/18 at 1:30 pm that the laboratory used expired QC material.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor review of the Individualized Quality Control Plan (IQCP) for Disk Diffusion Antimicrobial Susceptibility Testing and interview with the Laboratory Director (LD), the laboratory failed to establish and document the number, type and frequency of testing control material before implementing the IQCP from 1/4/16 to the date of the survey. The LD confirmed on 2/22/18 at 2::00 pm that the laboratory did not have a Quality Control procedure in the IQCP
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (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. This STANDARD is not met as evidenced by: Based on surveyor review of Quality Control (QC) records and interview with the Laboratory Director (LD), the laboratory failed to check the physical characteristics of each batch of media used in Bacteriology testing from 5/7/15 to the date of the survey. The LD listed confirmed on 2/22/18 at 2:20 pm that the laboratory did not perform the above mentioned QC check.
D5481	CONTROL PROCEDURES

	CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor review of the laboratory's Individualized Quality Control Plan (IQCP) for Disk Diffusion Antimicrobial Susceptibility Testing and interview with the Laboratory Director (LD) the laboratory failed to have documentation of data used to support their Risk Assessment (RA) for Disk Diffusion Antimicrobial Susceptibility Testing before reporting patient results from 1/4/16 to the date of the survey. The LD confirmed at 2:30 pm on 2/22/18 the laboratory did not have documentation of controls used to support their RA.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records and interview with Testing Personnel (TP), the laboratory failed to take corrective action when at least two out of three levels of controls were out of range for Carbon dioxide (CO2), total bilirubin (TBIL), Sodium (NA), Potassium (K), Chloride (CL), and Low-density Lipoprotein (LDL) tests performed on Beckman coulter AU480 analyzer from December 2017 through Feburary 2018. The findings include: 1.Bio-Rad Lyphocheck Liquid Assayed Multiqual control levels 1, 2 and 3 lot number 45780 for CO2, TBIL, NA, K, CL, LDL tests ran on AU480 analyzer were out of range on 2/6/18. 2.Bio-Rad Lyphocheck Liquid Assayed Multiqual control levels 1, and 2 lot number 45780 for CO2, TBIL test ran on AU480 analyzer were out of range on 2/11/18. 3. Approximately 45 patient samples were run and reported. 4. The TP # 1 listed on CMS form 209 confirmed on 2/22/18 at 11:00 am that no corrective action was taken for out of range QC on 11/22/17.
D5805	TEST REPORT CFR(s): 493.1291(c) 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. This STANDARD is not met as evidenced by: Based on surveyor review of Final Report (FR) and interview with the Laboratory Director (LD), the laboratory failed ensure that general immunology qualitative test results were reported correctly from January 2017 to the date of survey. The finding includes: 1. All qualitative tests performed on the Liaison XL and the DSX analyzers were reported quantitative with units of measurement on the FR. 2. The LD confirmed on 2/22/18 at 11:00 am that qualiative test results were not reported correctly.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: a) Based on the surveyor review of the Final Reports (FR) and interview with the Testing Personnel (TP), the laboratory failed to have a source of Reference Range (RR) used for Progesterone test performed on males from 11/18/15 to the date of the survey. The TP # 1 listed on CMS form 209 confirmed on 2/22/18 at 10:30 am that the laboratory does not have a source of RR used on FR. b) Based on surveyor review of the established RR, Manufacturer Range (MR), FR and interview with the (TP), the laboratory failed to ensure that the RR was accurate for Progesterone Follicular Phase for adult female performed on the Immulite analyzer from 11/18/15 to the date of survey. The findings include: 1.The RR for Progesterone Follicular Phase on the FR was 0.00 - 1.2 ng/mL but the MR had 0.33 - 1.2 ng/dL 2.There was no sourse for RR on the FR. 3. The TP # 1 listed on CMS form 209 confirmed on 2/22/18 at 11:30 am that the laboratory did not report correct RR on the FR.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on surveyor review of the laboratory's Individualized Quality Control Plan (IQCP) for Disk Diffusion Antimicrobial Susceptibility Testing and interview with the Laboratory Director (LD) the laboratory failed to maintain the Quality Assessment (QA) plan from 1/4/16 to the date of the survey. The LD confirmed on 2/22/18 at 2:35 pm the QA plan was not maintained.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) 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. This STANDARD is not met as evidenced by: Based on surveyor review of the Personnel Files (PF) and interview with Laboratory Director (LD), the LD failed to have foreign education evalutaion records for two out of four testing personnel performing patient testing from March 2017 to the date of survey. The LD confirmed on 2/21/18 at 10:50 am that foreign education evaluation was not in the PF.