Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2068211	03/15/2019
Name of Provider or Supplier	**Street Address, City, State**	
Infinity Diagnostic Laboratories	370 North Street, Teterboro, 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: Based on surveyor review of the Competency Assessment (CA) records and interview with the Quality Assurance Personnel (QAP), the laboratory failed to perform CA correctly on 13 of 13 Testing Personnel (TP) in the calendar years 2017 and 2018. The findings include: 1. The CA was not performed on each test method performed by TP. 2. Tool # 5, 'Required Competency' column on CA record was not assessed by blind samples testing if PT was performed by TP. 3. All tools listed on 'Required Competency' column on CA record did not include how assessment was done and what records were reviewed. 4. The QAP confirmed on 3/13/19 at 10:30 am that CA was not done correctly.
D5315	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(c) The laboratory must refer a specimen for testing only to a CLIA-certified laboratory or a laboratory meeting equivalent requirements as determined by CMS. This STANDARD is not met as evidenced by: Based on surveyor review of Work Records, Final Reports and interview with the Testing Personnel (TP), the laboratory referred Urine Toxiciology Confirmation testing to a non-CLIA-certified laboratory from March 2018 to the date of survey. The finding includes. 1. The TP #10 listed on CMS form 209 reviewed, verified and

	resulted toxicology results from a non-CLIA-certified laboratory. 2. The TP # 10 listed on the CMS form 209 stated, "I read from home". 3. The General Supervisor confirmed on 3/15/19 at 2 pm that toxicology tests were reviewed and resulted from a non-CLIA-certified laboratory.
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 Quality Control (QC) records, Procedure manual (PM) and interview with the General Supervisor (GS), the laboratory failed use their established form for documenting of QC verification for Apolipoprotein from 5/24/18 to the date of survey. The GS confirmed on 3/15/19 at 12:00 pm that the procedure was not followed. b) Based on surveyor review of the Final Report (FR), Procedure Manual (PM) and interview with the GS, the laboratory failed to follow their procedure for reporting Triglycerides from 10/26/17 to the date of survey. The findings include: 1. The Reference Interval (RI) on the FR had borderline high 150 - 199 mg/mL. but the PM had 150 - 500 mg/mL. 2. The RI on the FR had 200 - 499 mg /dL but the PM had >500 mg/dL. 3. The GS confirmed on 3/15/19 at 1:00 pm that the laboratory did not follow the PM. 35471 c. Based on surveyor review of the PM and interview with the Testing Personnel (TP), the laboratory failed to establish a procedure to verify new lots of reagents used on the Shimadzu LCMS 8045 prior to patient testing from March 2018 to the date of survey. The TP #10 listed on CMS form 209 confirmed on 3/13/19 at 11:00 am that the laboratory did not establish the above procedure. d. Based on surveyor review of the PM and interview with the TP, the laboratory failed to establish a procedure for manual integration of chromatography peaks on the Shimadzu LCMS 8045 prior to patient testing from March 2018 to the date of survey. The TP #10 listed on CMS form 209 confirmed on 3 /13/19 at 11:10 am that the laboratory did not establish the above procedure.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) 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 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. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual and interview with the Testing Personnel (TP), the laboratory failed to establish a procedure for Yeast identification from 10/26/17 to the date of the survey. The TP #3 confirmed on 3/14/19 at 2:10 pm that the laboratory did not establish the above procedure.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) 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 determined under 493.1253. This STANDARD is not met as evidenced by: a. Based on surveyor review of the Manufacturers Package Insert (MPI), Microbiology work records and interview with the Testing Personnel (TP), the laboratory failed to follow the MPI for BD BBL Sensi-Disc Antimicrobial Susceptibility Test Discs for Urine Culture Sensitivity tests from 10/26/17 to the date of the survey. The finding includes: 1. The MPI stated to perform a Gram Stain but there was no documented evidence Gram Stains were performed. 2. The TP #3 listed on CMS form 209 confirmed on 3/14/19 at 2:10 pm the laboratory did not follow the MPI. b. Based on surveyor review of the MPI, Sample Requisitions (SR) and interview with the General Supervisor (GS), the laboratory failed to follow the manufacturer's instruction for Pro B-type Natriuretic Peptide (pBNP) tests run on the Stratus CS from 10/26/17 to the date of the survey. The findings include: 1. The MPI stated the whole blood sample must be analyzed within two hours. 2. A review of the SR reveled five out of five samples were received more than two hours after blood was drawn. 3. Approximately ten samples are run and reported each week. 4. The GS confirmed on 3/15/19 at 2:40 pm that the laboratory did not follow the MPI.
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 observation of Quality Control (QC) material in use, review of the Triage B-type Natriuretic Peptide (BNP) Control Kit Manufacture Package Insert (MPI) and interview with the General Supervisor (GS), the laboratory used expired BNP QC material for the Access 2 analyzer from 1/11/19 to the date of survey. The findings include: 1. The MPI stated open vial stability was for 30 days. 2. BNP QC

	material in use was dated with an open date of 1/11/19. 3. Approximately 200 patients were run and reported with expired QC . 4. The GS confirmed on 3/15/19 at 3:00 pm that the laboratory used expired QC material.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) 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. This STANDARD is not met as evidenced by: a. Based on review of the Performance Specification (PS) records and interview with the General Supervisor (GS), the laboratory failed to verify Reference Interval (RI) for Hemoglobin A1c (HBA1c) test performed on the Premier Hb 9210 analyzer from October 2018 to the date of survey. The GS confirmed on 3/14/19 at 12:00 pm that the laboratory did not perform RI verification for HBA1c test. 20464 b. Based on review of the PS records and interview with the GS, the laboratory failed to verify Reference Interval (RI) for Vitamin B12, and Insulin-Like Growth Factor 1 performed on the Immulite 2000 analyzer from July 2018 to the date of survey. The GS confirmed on 3 /14/19 at 12:00 pm that the laboratory did not perform RI verification. 35471 c. Based on surveyor review of the PS records and interview with the GS, the laboratory failed to verify Accuracy for tests performed on the Diasorin 2 analyzer before testing patients from July 2018 to the date of survey. The GS confirmed on 3/15/19 at 2:00 pm that accuracy was not performed.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) 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--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records and interview with the Testing Personnel (TP), the laboratory failed to perform and document quality control on each day of patient testing for Ova and Parasite test from 10/26/17 to the date of the survey. The TP #3 listed on CMS form 209 confirmed on 3/14/19 at 1:20 pm that the laboratory did not perform QC each day of patient testing.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g)

	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 qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: a. Based on lack of the Quality Control (QC) records and interview with the General Supervisor (GS), the laboratory failed to perform and document quality control for QuantiFERON-TB Gold Plus test from January 2019 to the date of the survey. The finding includes: 1. The laboratory did not perform positive and negative QC on each day of patient testing. 2. The laboratory ran and reported around 15 patient results a week. 3. The GS confirmed on 3/14/19 at 1:15 pm that the laboratory did not perform and document quality control on each day of patient testing. 35471 b. Based on surveyor review of the QC records and interview with the GS, the laboratory failed to perform and document negative and positive controls on each day of patient testing for Glenmark ePLEX and Cephid Gene Xpert tests from 10/26/17 to the date of survey. The findings include: 1. The laboratory did not perform positive and negative QC on each day of patient testing. 2. QC was being done once a month for the Cephid Gene Xpert and weekly for the Glenmark ePLEX. 3. Approximately 15 patients were run per day on the Cephid Gene Xpert and 5 per week on the Glenmark ePLEX. 4. The GS confirmed on 3/14/19 at 1:40 pm that the laboratory did not perform and document QC on each day of patient testing.
D5467	CONTROL PROCEDURES CFR(s): 493.1256(d)(9)(g) 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. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual, Calibrators, Controls and interview with the Testing Personnel (TP), the laboratory failed to use different lot numbers of standards to make the calibrator and controls for Urine Toxicology confirmation tests from March 2018 to the date of the survey. The TP #10 listed on CMS form 209 confirmed on 3/13/19 at 10:10 am the laboratory did not use different lot numbers.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) 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. This STANDARD is not met as evidenced by: Based on surveyor review of Quality Control (QC) records, Manufacture's Package Insert (MPI) and interview with the General Supervisor (GS), the laboratory failed to verify commercially assayed QC material with each new lot and/or shipment for Urine Toxicology testing performed on the Advia 1800 analyzer from 10/26//18 on the date of survey. The GS confirmed on 3/15/2019 at 12:00 pm that the QC materials were not verified before putting in use.
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 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 10/26/17 to the date of the survey. The TP #3 listed on CMS form 209 confirmed on 3/13/19 at 2:30 pm the laboratory did not perform the above QC.
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: a. Based on surveyor review of the Final Report (FR) and interview with the Testing Personnel (TP), the laboratory failed to report Urine Drug confirmation test results accurately from March 2018 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 performance characteristics of this test were determined by (Laboratory Name). It has not been cleared or approved by the U.S. Food and Drug Administration" on FR. 2. The TP #10 listed on CMS 209 confirmed on 3/13/19 at 11: 30 am that Urine Drug confirmation tests were not reported accurately. b. Based on surveyor review of the FR and interview with the General Supervisor (GS), the laboratory failed to report Glenmark ePLEX Respiratory Panel test results accurately from January 2019 to the date of survey. The findings include: 1. Glenmark ePLEX cannot differentiate between Rhinovirus and Enterovirus positive results. 2. Positive results must be confirmed by confirmatory testing but the FR did not include a statement that confirmation was necessary with positive results of Rhinovirus /Enterovirus. 3. The GS confirmed on 3/15/19 at 2:30 pm that Respiratory Panel tests were not reported accurately. c. Based on surveyor review of the FR and interview with the GS, the laboratory failed to ensure that the FR had accurate information from tests performed on the Diasorin and Diasorin 2 from 10/26/17 to the date of survey. The finding includes: 1. All tests performed on the Diasorin analyzers were qualitative tests but the laboratory reported quantitative results. 2. The GS confirmed on 3/15/19 at 2:10 pm that tests performed on the Diasorin analyzers were not reported accurately.
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 surveyor review of the Final Report (FR), Manufacturer Package Insert (MPI) and interview with the General Supervisor (GS), the laboratory failed to identify the source of the Reference Intervals (RI) used for Insulin - like Growth Factor 1 (IGF-1) from July 2018 to the date of survey. The findings include: 1. The GS stated the laboratory used the RI listed in the MPI. 2. Review of the FR revealed that the laboratory had RI for IGF-1 as 109 - 284 ng/ml with an interpretation table. 3. The laboratory did not have a source for the range used on the FR. 4. The GS confirmed on 3/15/19 at 1:00 pm that the source of the RI was unknown. b. Based on surveyor review of the FR, Procedure Manual (PM) and interview with the Testing Personnel (TP), the laboratory failed to use the value of the Reference Intervals (RI) for Creatinine and Specific Gravity tests from the source specified in the PM for Urine Drug Screening from March 2018 to the date of the survey. The findings include: 1. The PM stated the laboratory used the RI on the FR from the Journal of Analytical Toxicology. 2. The RI in the PM differed from the FR as follows: a. Creatinine: FR: 20 - 300 mg/dL - PM: 15 - 276 mg/dL b. Specific Gravity: 1.010 - 1.025 - PM: 1.002 - 1.028. 3. The TP #10 listed on CMS form 209 confirmed on 3/13 /19 at 11:10 am that the RI on the FR was not that of the RI in the PM.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291.

	This STANDARD is not met as evidenced by: Based on surveyor review of Final Reports (FR) and interview with the General Supervisor (GS), the laboratory failed to identify problems and correct them on FR from May 2018 to the date of survey. The findings include: 1. A review of ten FR revealed four of ten had the date received time before the date collected time. 2. A review of five Microbiology FR revealed five out of five had a report date less than 24 hours after the collection date. 3. The GS confirmed on 3/15/19 at 2:20 pm that the laboratory did not identify problems on the FR and correct them.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: Based on surveyor review of the Performance Specification (PS) records and interview with the Testing Personnel (TP) the Laboratory Director (LD) failed to ensure that PS were adequate to perform Urine Toxicology confirmation tests on the Shimadzu LCMS-8045 from March 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. There was no validation of the Hydrolysis control. 3. There was no documented evidence carry over data was reviewed. 4. Specificity and Selectivity were not performed. 5. The TP #10 listed on CMS 209 confirmed on 3/13/19 at 10:30 am the the laboratory did not ensure PS were adequate.