Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2252315	12/29/2023
Name of Provider or Supplier	**Street Address, City, State**	
Instavaxx Llc	2674 N Halsted St, Chicago, IL	

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
D0000	An initial survey was completed on December 29th, 2023. It was determined that Immediate Jeopardy (IJ) existed for the following condition level deficiencies: 42 C.F. R. 493.801 Condition: Enrollment and Testing of Samples 42 C.F.R 493.1230 Condition: General Laboratory Systems 42 C.F.R 493.1250 Condition: Analytic Systems 42 C.F.R 493.1403 Condition: Laboratory Director 42 C.F.R 493.1409 Condition: Technical Consultant
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on review of laboratory records, lack of documentation, and interview with testing personnel (TP 1), the laboratory failed to enroll in an approved Centers for Medicare and Medicaid Services (CMS) proficiency testing (PT) program for 28 of 28 moderate complexity analytes before reporting red blood cell count, white blood cell count, hemoglobin, hematocrit, platelet cell count, cell differential patient test results for hematology, Chlamydia trachomatis, Neisseria gonorrhoeae, Influenza A, Influenza A / H1, Influenza A / H3, Influenza B, Respiratory Syncytial Virus A, Respiratory Syncytial Virus B, Group A Strep, SARS-CoV2, Parainfluenza 1, Parainfluenza 2, Parainfluenza 3, Parainfluenza 4, hMPV-8, Adenovirus 3, B. parapertussis / B. bronciseptica, Rhinovirus 1A, B. pertussis, B.holmesii, and Herpes

	Simplex Virus 1 & Herpes Simplex Virus 2 patient test results for bacteriology / virology in 2022 and 2023. More than 967 samples were tested without meeting this mandatory requirement for compliance. Findings Include: 1. Review of the "Quality Assurance Plan for Instavaxx PLLC" revealed: "System and Performance Audits - Proficiency Testing / Performance Evaluation: Studies on proficiency testing (PT), also known as performance evaluation (PE), are carried out in accordance with our regulations and the different testing schedules used by INSTAVAXX Laboratories. Semi-annually, acceptable outcomes are presented for every analyte and technique utilized in regulatory testing." 2. 2. Review of laboratory records revealed the laboratory began moderate complexity Strep Group A bacteriology and SARS-CoV-2, Influenza A, Influenza B, and Respiratory Syncytial Virus, Herpes Simplex Virus 1 & Herpes Simplex Virus 2 virology testing utilizing the DiaSorin Liaison MDX system in the month of April 2022. 3. Review of laboratory records revealed the laboratory began moderate complexity virology testing of Influenza A, Influenza A / H1, Influenza A / H3, Influenza B, Parainfluenza 1, Parainfluenza 2, Parainfluenza 3, Parainfluenza 4, hMPV-8, Adenovirus 3, B. parapertussis / B. bronciseptica, Rhinovirus 1A, Respiratory Syncytial Virus A, Respiratory Syncytial Virus B, B. pertussis, and B.holmesii testing utilizing the Verigene RP Flex - Luminex system in the month of November 2022. 4. Review of laboratory records revealed the laboratory began moderate complexity hematology testing of red blood cell count, white blood cell count, hemoglobin, hematocrit, platelet cell count, cell differential testing utilizing the Sysmex XN 430 system in the month of January 2023. 5. Review of laboratory records revealed the laboratory began moderate complexity virology SARS-CoV-2, Influenza A, Influenza B, Respiratory Syncytial Virus B, Chlamydia trachomatis, and Neisseria gonorrhoeae testing utilizing the GeneXpert Dx System in the month of February 2023. 6. Review of laboratory records revealed no documented evidence of PT enrollment in an approved CMS program for the following 28 of 28 analytes: Red blood cell count, white blood cell count, hemoglobin, hematocrit, platelet cell count, cell differential, Chlamydia trachomatis, Neisseria gonorrhoeae, Influenza A, Influenza A / H1, Influenza A / H3, Influenza B, Respiratory Syncytial Virus A, Respiratory Syncytial Virus B, Group A Strep, SARS-CoV2, Parainfluenza 1, Parainfluenza 2, Parainfluenza 3, Parainfluenza 4, hMPV-8, Adenovirus 3, B. parapertussis / B. bronciseptica, Rhinovirus 1A, B. pertussis, B.holmesii, and Herpes Simplex Virus 1 & Herpes Simplex Virus 2 in 2022 and 2023. 7. On 12/28/2023 at 3: 00 p.m., an interview with TP 1 confirmed the above findings.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) 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. This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of documentation, and interview with testing personnel (TP 1), the laboratory failed to retain quality control records for at least two years for three of three moderate complexity testing systems (Verigene RP Flex (Luminex), DiaSorin Liaison MDX, and GeneXpert Dx) for reporting bacteriology and virology in 2022 and 2023. Affecting more than 663 test results. Findings include: 1. Review of laboratory records revealed the laboratory utilized the following test systems to perform moderately complex testing and report patients test results during the years of 2022 and 2023 for the following analytes: Verigene RP

	Flex (Luminex) system Influenzas A, A/H1, and A/H3 Influenza B Parainfluenzas 1, 2, 3,and 4 hMPV-8 Adenovirus 3, B. parapertussis / B. bronciseptica Rhinovirus 1A Respiratory Syncytial Virus A and B B. pertussis B. holmesii Simplexa (DiaSorin Liaison MDX) system Strep Group A SARS-CoV-2 Influenzas A and B Respiratory Syncytial Virus Herpes Simplex Virus 1 & 2 GeneXpert Dx System (Cepheid) SARS-CoV-2, Influenzas A and B Respiratory Syncytial Virus B Chlamydia trachomatis Neisseria gonorrhoeae 2. Further review of these records showed the documents failed to include any quality control data from the tests listed in Finding 1. 3. On 12/29/23, at 3:23 p.m., an interview with TP 1 revealed, "No QC available for Luminex, DiaSorin, or GeneXpert - can't locate the binder." 4. During the time period reviewed 663 patients were tested and reported. 5. On 12/29/23, at 3:23 p.m., an interview with TP 1 confirmed the above findings.
D3039	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(5) Quality system assessment records. Retain all laboratory quality system assessment records for at least 2 years. This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of documentation, and interview with testing personnel (TP 1), the laboratory failed to maintain laboratory quality system assessment records for monitoring room, refrigerator and freezer temperatures and room humidity values for one of six dates reviewed for bacteriology, virology and hematology patient testing in 2022 and 2023. Findings include: 1. Review of the "Quality Assurance Plan for Instavaxx PLLC" revealed: "Temperature Record Keeping - Temperatures are monitored and recorded for all active temperature-regulating devices including ovens, incubators and refrigerators. An electronic monitoring system is used to track temperatures in a number of refrigerators and freezers." 2. Review of the laboratory patient records revealed the laboratory failed to document room, refrigerator, and freezer temperatures and humidity values for the following patient testing date: 04/14/2022 3. On 12/29/2023, at 1:52 p.m., TP 1 confirmed the above findings.
D5301	TEST REQUEST CFR(s): 493.1241(a) The laboratory must have a written or electronic request for patient testing from an authorized person. This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of documentation and interview with testing personnel (TP 1), the laboratory failed to document patient tests requests from an authorized person for six of six patient testing dates selected in 2022 and 2023. Findings Include: 1. Review of the "Quality Assurance Plan for Instavaxx PLLC" revealed this statement: "Sample, Logging, & Tracking: Sample receipt into the laboratory is governed by Standard Operating Procedures. These processes ensure that samples are received, appropriately logged into the laboratory, and that all related paperwork - such as chain of custody forms - is accurate and matches the samples that were received." 2. Review of laboratory patient test records revealed the laboratory failed to provide any documentation of an authorized person requesting the patients'

	tests to be performed on the following dates: a. Date: 04/14/2022 Sample ID: 002510422 Test(s) performed: Group A Strep, SARS-CoV-2, Influenza A / B, and Respiratory Syncytial Virus A / B Authorized Test Request: Not documented b. Date: 11/08/2022 Sample ID: 003731122 and 003831122 Test(s) performed: SARS-CoV-2 Authorized Test Request: Not documented c. Date: 11/11/2022 Cartridge: 02480344 Test(s) performed: Influenza A / B, and Respiratory Syncytial Virus A / B, Parainfluenza 1 - 4, hMPV-8, Adenovirus 3, B. parapertussis, Rhinovirus 1A, B. parapertussis and B.holmesii Authorization: Not documented d. Date: 03/23/2023 Sample No: 20 Test(s) performed: Complete Blood Count and differential Authorizationt: Not documented e. Date: 07/22/2023 Sample ID: XXXXX 3-28-95 Test(s) performed: Candida group, Candida glab-krus Authorization: Not documented f. Date: 10/11/2023 Sample No: 76 Test(s) performed: Complete Blood Count and differential Authorization: Not documented 3. On 12/29/2023, at 1:52 a.m., TP 1 confirmed the above findings.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 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. This CONDITION is not met as evidenced by: Based on review of laboratory records, manufacturer's verification procedures, manufacturer's product inserts, lack of documentation and interview with testing personnel (TP 1), the laboratory: a) failed to demonstrate performance specifications comparable to the manufacturer's characteristics for accuracy, precision, reportable range of test results, and verification of the manufacturer's reference intervals for four of four moderate complexity test systems performing tests in the specialty of Hematology and subspecialties of Virology and Bacteriology prior to testing patients during the years of 2022 and 2023.(refer to D5421); b) failed to have documentation of the Sysmex XN - 430 calibration verification (refer to D5439); c) failed to have documentation of control materials for one of two complete blood count and cell differential test report (refer to D5447); d) failed to have documentation of the positive and negative control procedures for three of three moderate complexity testing systems (refer to D5449).
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:
Based on review of laboratory records, lack of documentation, and interview with testing personnel (TP 1), the laboratory failed to demonstrate performance specifications comparable to the manufacturer's characteristics for accuracy, precision, reportable range of test results, and verification of the manufacturer's reference intervals for four of four moderate complexity test systems performing tests in the specialty of Hematology and subspecialties of Virology and Bacteriology prior to testing patients during the years of 2022 and 2023. Findings include: 1. Review of laboratory procedures and records revealed the laboratory performed patient testing using the following moderately complex test systems: Verigene RP Flex (Luminex) system Influenzas A, A/H1, and A/H3 Influenza B Parainfluenzas 1, 2, 3,and 4 hMPV-8 Adenovirus 3, B. parapertussis / B. bronciseptica Rhinovirus 1A Respiratory Syncytial Virus A and B B. pertussis B. holmesii Simplexa (DiaSorin Liaison MDX) system Strep Group A SARS-CoV-2 Influenzas A and B Respiratory Syncytial Virus Herpes Simplex Virus 1 & 2 GeneXpert Dx System (Cepheid) SARS-CoV-2, Influenzas A and B Respiratory Syncytial Virus B Chlamydia trachomatis Neisseria gonorrhoeae Sysmex XN 430 Red Blood Cell Count White Blood Cell Count Hemoglobin Hematocrit Platelet Cell Count Cell Differential 2. Review of the "Cepheid Xpert CT/NG and Xpert Xpress CoV-2/Flu/RSV Verification Protocols" and records revealed the laboratory failed to provide any documentation that demonstrated the performance specifications comparable to the manufacturer's characteristics for accuracy, precision, reportable range of test results, and verification of the manufacturer's reference intervals on the GeneXpert Dx System (System Serial Number: 110017789) were verified for six of six analytes tested prior to testing and reporting patients results, affecting more than 298 test results in 2023. 3. Review of the "Sysmex XN - L Method Verification Manual" for "Model: Sysmex XN - 430, Serial # 11774" and records revealed the laboratory failed to provide any documentation that demonstrated the performance specifications comparable to the manufacturer's characteristics for accuracy, precision, reportable range of test results, and verification of the manufacturer's reference intervals on the Sysmex XN 430 were verified for six of six analytes prior to testing and reporting patients results in 2022 and 2023, affecting 304 patient tests performed. 4. Review of the Verigene RP Flex (Luminex) records revealed the laboratory failed to provide any documentation that demonstrated the performance specifications comparable to the manufacturer's characteristics for accuracy, precision, reportable range of test results, and verification of the manufacturer's reference intervals were verified for 16 of 16 analytes on four of four Verigene RP Flex (Luminex) system analyzers prior to testing and reporting patients results in 2022 and 2023, affecting more than 140 test results. a. Verigene RP Flex (Luminex) - "S/N: 19260004" b. Verigene RP Flex (Luminex) - "S/N: 15208084" c. Verigene RP Flex (Luminex) - "Serial # 15055042" d. Verigene RP Flex (Luminex) - "Serial # 20036007" 5. Review of the Simplexa (DiaSorin Liaison MDX) records revealed the laboratory failed to provide any documentation that demonstrated the performance specifications comparable to the manufacturer's characteristics for accuracy, precision, reportable range of test results, and verification of the manufacturer's reference intervals were verified for seven of seven analytes on four of four Simplexa (DiaSorin Liaison MDX) system analyzers in 2022 and 2023, affecting more than 35 test results. a. Simplexa (DiaSorin Liaison MDX) - 1 b. Simplexa (DiaSorin Liaison MDX) - 2 c. Simplexa (DiaSorin Liaison MDX) - 3 d. Simplexa (DiaSorin Liaison MDX) - 4 6. Review of the "Quality Assurance Plan for Instavaxx PLLC" stated the following: "Internal Quality Control - An Internal Quality Control program has been designed to ensure systematic in-house production of high-quality analytical data. The objectives of this program are: 1. To provide a measure of the precision of analytical methods. 2. To maintain a continuing assessment of the

	accuracy, precision and completeness of individual analyses performed in the laboratory. 3. To identify methods that can be strengthened and provide a source of data to overcome these deficiencies and weaknesses. 4. To detect training needs within the analytical group." The laboratory failed to provide any documentation that the quality assurance plan had been implemented to monitor the four test systems prior to testing and reporting patient results. 7. On 12/28/2023, at 2:14 p.m., an interview with TP 1 confirmed the above findings.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of documentation and interview with the lab director (LD), the laboratory failed to document the calibration verification procedure at least once every six months for one of one hematology analyzer during the year of 2023. Findings Include: 1. Review of the Calibration records for red blood cell count, white blood cell count, hemoglobin, hematocrit, platelet cell count, cell differential testing records revealed the following: a."Sysmex Certificate of Calibration - Laboratory: INSTAVAXX - Model: XN-430 Serial #: 11774 - Certificate Date: Tuesday, December 27, 2022 - Certificate Exp Date: Tuesday, June 27, 2023" 2. The laboratory failed to provide any documentation that showed the required calibrations were perfomed after December 27, 2022. 3. On 12/28/23, at 4:00 p.m., the LD confirmed the above findings.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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 quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of documentation and interview with testing personnel (TP 1), the laboratory failed to perform and document two levels of control for one of two patients' testing dates for the six analytes that comprise the Complete Blood Count with cell differential (CBC) test reported in 2023. Findings include: 1. Review of the "Instavaxx Sysmex hematology XN-430 series Standard Operating Procedures" revealed: "F. Quality Control: XNL-CHECK bi level whole blood commercial controls are used. One level of control is run on a daily basis or as needed, like after reagent change etc. Documentation: File detailed prints of both instruments and write comments with technologist name and ID in Sysmex QC file." 2. Review of laboratory records and lack of documentation revealed the laboratory failed to document control values for the red blood cell count, white blood cell count, hemoglobin, hematocrit, platelet cell count, cell differential patient report dated 03/23 /2023. 3. On 12/29/23, at 1:52 p.m., TP 1 confirmed the above findings.
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: Based on review of laboratory records, lack of documentation, and interview with testing personnel (TP 1), the laboratory failed to perform positive and negative control materials for 29 of 29 analytes in the subspecialty of bacteriology and virology utilizing the Verigene RP Flex - Luminex, Simplexa DiaSorin Liaison MDX and the GeneXpert Dx System in 2022 through the dates of survey (12/28/2023 and 12/29 /2023). Findings include: 1. Review of laboratory records identified the laboratory performs testing for 29 analytes utilizing the three following test systems in the years 2022 and 2023: Verigene RP Flex (Luminex) system Influenza A, Influenza A/H1, and Influenza A/H3 Influenza B Parainfluenza 1, Parainfluenza 2, Parainfluenza 3, and Parainfluenza 4 hMPV-8 Adenovirus 3, B. parapertussis / B. bronciseptica Rhinovirus 1A Respiratory Syncytial Virus A and Respiratory Syncytial Virus B B. pertussis B. holmesii Simplexa (DiaSorin Liaison MDX) system Strep Group A SARS-CoV-2 Influenza A and Influenza B Respiratory Syncytial Virus Herpes Simplex Virus 1 & Herpes Simplex Virus 2 GeneXpert Dx System (Cepheid) SARS-CoV-2 Influenza A and Influenza B Respiratory Syncytial Virus B Chlamydia trachomatis Neisseria gonorrhoeae 2. Review of laboratory records revealed no positive and negative control procedures performed on the Verigene RP Flex - Luminex system for reporting 16 of 16 analytes on one of one patient test report for the following date: 11/11/2022: (Sample: BXXX MXXX) 3. Review of laboratory records revealed no positive and negative control procedures performed on the Simplexa DiaSorin Liaison MDX system for reporting seven of seven analytes on three of three patient test reports for the following dates: a. 04/14/2022: SARS-CoV-2, Influenza A and Influenza B, Strep Group A, Respiratory Syncytial Virus (Sample ID: 002510422) b. 11/08/2022: SARS-CoV-2 (Sample ID: 003731122) c. 11/08/2022: SARS-CoV-2 (Sample ID: 003831122) 4. Further review of the laboratory records

	showed that positive and negative control procedures were not performed from 2022 through the two of two dates of survey (12/28/2023 and 12/29/2023) for tests performed on the Verigene RP Flex - Luminex and Simplexa DiaSorin Liaison MDX test systems. 5. On 12/29/2023, at 3:14 p.m., an interview with TP 1 revealed the laboratory performs Chlamydia trachomatis and Neisseria gonorrhoeae testing on the GeneXpert Dx System, "Each sample must be manually entered. Can do one patient at a time." 6. Review of laboratory records revealed no positive and negative control procedures performed on the GeneXpert Dx System for reporting two of two (Chlamydia trachomatis and Neisseria gonorrhoeae) analytes utilizing the GeneXpert Dx System in 2022 through the dates of survey (12/28/2023 and 12/29/2023). 7. On 12 /29/23 at 3:23 p.m., an interview with TP 1 revealed, "No QC available for Luminex, DiaSorin, or GeneXpert - can't locate the binder."
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on review of laboratory records, direct observation, lack of documentation, and interview with testing personnel (TP 1), the laboratory failed to perform and document twice a year evaluations of the test results between three of three testing systems testing and reporting the same analytes in the subspecialty of bacteriology and virology in 2022 and 2023. Findings Include: 1. Review of laboratory records revealed three of three moderate complexity virology Influenza A and Influenza B patient testing systems in use: a. Verigene RP Flex (Luminex) b. Simplexa (DiaSorin Liaison MDX) c. GeneXpert Dx System (Cepheid) 2. Review of laboratory records revealed the laboratory failed to provide any documentation of the performance of twice a year evaluations of the Influenza A and Influenza B test results between the three testing systems listed in Finding 1. 3. Review of laboratory records revealed two of two moderate complexity virology SARS- CoV-2 patient testing systems in use: a. Simplexa (DiaSorin Liaison MDX) b. GeneXpert Dx System (Cepheid) 4. Review of laboratory records revealed the laboratory failed to provide any documentation of the performance of twice a year evaluations of the SARS- CoV-2 test results between the two testing systems listed in Finding 3. 5. On 12/28/23, at 10:30 a.m., surveyor's direct observation, revealed four of four Simplexa (DiaSorin Liaison MDX) moderate complexity virology and bacteriology analyzers for SARS-CoV-2, Influenza A and Influenza B, Strep Group A, Respiratory Syncytial Virus, and Herpes Simplex 1 and Herpes Simplex 2 patient testing in use: a. Simplexa (DiaSorin Liaison MDX) - 1 b. Simplexa (DiaSorin Liaison MDX) - 2 c. Simplexa (DiaSorin Liaison MDX) - 3 d. Simplexa (DiaSorin Liaison MDX) - 4 6. Review of laboratory records revealed the laboratory failed to provide any documentation of the performance of twice a year evaluations of the SARS-CoV-2, Influenza A and Influenza B, Strep Group A, Respiratory Syncytial Virus, and Herpes Simplex 1 and Herpes Simplex 2 test results between the four testing instruments listed in Finding 5. 7. On 12/28/23, at 10:30 a.m., surveyor's direct observation, revealed four of four Verigene RP Flex (Luminex) moderate complexity virology system instruments for Influenza A, Influenza A / H1, Influenza A / H3, Influenza B, Parainfluenza 1, Parainfluenza 2, Parainfluenza 3,

	Parainfluenza 4, hMPV-8, Adenovirus 3, B. parapertussis / B. bronciseptica, Rhinovirus 1A, Respiratory Syncytial Virus A, Respiratory Syncytial Virus B, B. pertussis, and B. holmesii patient testing in use: a. Verigene RP Flex (Luminex) - "S /N: 19260004" b. Verigene RP Flex (Luminex) - "S/N: 15208084" c. Verigene RP Flex (Luminex) - "Serial # 15055042" d. Verigene RP Flex (Luminex) - "Serial # 20036007" 8. Review of laboratory records revealed the laboratory failed to provide any documentation of the performance of twice a year evaluations of the Influenza A, Influenza A / H1, Influenza A / H3, Influenza B, Parainfluenza 1, Parainfluenza 2, Parainfluenza 3, Parainfluenza 4, hMPV-8, Adenovirus 3, B. parapertussis / B. bronciseptica, Rhinovirus 1A, Respiratory Syncytial Virus A, Respiratory Syncytial Virus B, B. pertussis, and B. holmesii test results between the four testing instruments listed in Finding 7. 9. On 12/28/23, at 2:18 p.m., TP 1 confirmed the above findings.
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 review of laboratory records and interview with testing personnel (TP 1), the laboratory failed to indicate a unique patient identifier, specimen source, and the name and location of the testing laboratory for four of four patient test reports on the three test systems (Verigene RP Flex (Luminex), GeneXpert Dx System (Cepheid) and Simplexa (DiaSorin Liaison MDX) in-use during 2022 and 2023. Findings Include: 1. Review of laboratory patient reports revealed the following elements failed to be indicated: Test Report A - System: Verigene RP Flex (Luminex) Date: 11-11-22 Patient name: BXXX Not Indicated: Second Patient Identifier, Laboratory Name and Address, specimen source Test Report B - System: GeneXpert Dx System (Cepheid) Date: 07-22-23 Sample ID: SXXX 3-28-95 Not Indicated: Second Patient Identifier, Laboratory Address, specimen source Test Report C - System: Simplexa (DiaSorin Liaison MDX) Date: 11-08-22 Patient name: BXXX Sample ID: 00373112 Not Indicated: Laboratory Address Test Report D - System: Simplexa (DiaSorin Liaison MDX) Date: 11-08-22 Patient name: DXXX Sample ID: 003831122 Not Indicated: Laboratory Address 2. On 12/29/23 at 1:52 p.m., an interview with TP 1 confirmed the above findings.
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:

	Based on review of laboratory records and interview with testing personnel (TP 1), the laboratory failed to make available the reference intervals for reporting 16 of 16 analytes reported utilizing the Verigene RP Flex (Luminex) test system for one of one patient in 2022. Findings Include: 1. Review of laboratory patient records revealed the laboratory failed to make available the reference intervals for 16 of 16 moderate complexity virology analytes (Influenza A, Influenza A / H1, Influenza A / H3, Influenza B, Parainfluenza 1, Parainfluenza 2, Parainfluenza 3, Parainfluenza 4, hMPV-8, Adenovirus 3, B. parapertussis / B. bronciseptica, Rhinovirus 1A, Respiratory Syncytial Virus A, Respiratory Syncytial Virus B, B. pertussis, and B. holmesii) utilizing the Verigene RP Flex (Luminex) system in 2022. a. System: Verigene RP Flex (Luminex) Date: 11-11-22 Patient name: BXXX Test Results: Influenza A - Not Detected Influenza A / H1 - Not Detected Influenza A / H3 - Not Detected Influenza B - Not Detected Parainfluenza 1 - Not Detected Parainfluenza 2 - Not Detected Parainfluenza 3 - Not Detected Parainfluenza 4 - Not Detected hMPV-8 - Not Detected Adenovirus 3 - Not Detected B.parapertussis / B. bronciseptica - Not Detected Rhinovirus 1A - Not Detected Respiratory Syncytial Virus A - Not Detected Respiratory Syncytial Virus B - Not Detected B. pertussis - Not Detected B. holmesii - Not Detected Reference Intervals: Not indicated 2. On 12/29/23 at 1:52 p.m., an interview with TP 1 confirmed the above finding.
D5809	TEST REPORT CFR(s): 493.1291(e) The laboratory must, upon request, make available to clients a list of test methods employed by the laboratory and, as applicable, the performance specifications established or verified as specified in 493.1253. In addition, information that may affect the interpretation of test results, for example test interferences, must be provided upon request. Pertinent updates on testing information must be provided to clients whenever changes occur that affect the test results or interpretation of test results. This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of documentation, and interview with testing personnel (TP 1), the laboratory failed to make available to clients a list of test methods utilized for for 35 of 35 moderate complexity hematology, bacteriology, and virology analytes; red blood cell count, white blood cell count, hemoglobin, hematocrit, platelet cell count, cell differential, Chlamydia trachomatis, Neisseria gonorrhoeae, Influenza A, Influenza A / H1, Influenza A / H3, Influenza B, Respiratory Syncytial Virus A, Respiratory Syncytial Virus B, Group A Strep, SARS-CoV-2, Parainfluenza 1, Parainfluenza 2, Parainfluenza 3, Parainfluenza 4, hMPV-8, Adenovirus 3, B. parapertussis / B. bronciseptica, Rhinovirus 1A, B. pertussis, B. holmesii, and Herpes Simplex Virus 1 & Herpes Simplex Virus 2 in 2022 and 2023. Findings Include: 1. Review of laboratory records and lack of documentation revealed the laboratory failed to make available to clients a list of test methods for 35 of 35 moderate complexity hematology, bacteriology, and virology analytes; red blood cell count, white blood cell count, hemoglobin, hematocrit, platelet cell count, cell differential, Chlamydia trachomatis, Neisseria gonorrhoeae, Influenza A, Influenza A / H1, Influenza A / H3, Influenza B, Respiratory Syncytial Virus A Respiratory Syncytial Virus A, Respiratory Syncytial Virus B, Group A Strep, SARS-CoV-2, Parainfluenza 1, Parainfluenza 2, Parainfluenza 3, Parainfluenza 4, hMPV-8,

	Adenovirus 3, B. parapertussis / B. bronciseptica, Rhinovirus 1A, B. pertussis, B. holmesii, and Herpes Simplex Virus 1 & Herpes Simplex Virus 2 in 2022 and 2023. 2. On 12/29/2023, at 4:21 p.m., TP 1 confirmed the above finding.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of laboratory records, lack of documentation, and interview with testing personnel (TP 1), the laboratory director (LD): a) failed to employ competent testing personnel for moderate complexity hematology, bacteriology, and virology analytes patient testing on four of four test systems (Sysmex XN 430, GeneXpert Dx System (Cepheid), Verigene RP Flex (Luminex), and DiaSorin Liaison MDX (refer to D6004); b) failed to ensure the verification of test procedures and the establishment of the laboratory's test performance characteristics for accuracy and precision for four of four moderate complexity testing systems (Sysmex XN 430, GeneXpert Dx System (Cepheid), Verigene RP Flex (Luminex), and DiaSorin Liaison MDX) before reporting moderate complexity hematology, bacteriology, and virology analytes (refer to D6013).
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) 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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of documentation, and interview with testing personnel (TP 1), the laboratory director (LD) failed to ensure two of two testing personnel were qualified and competent to perform moderately complex testing before testing and reporting patient test results in 2022 and 2023. Findings Include: 1. The LD failed to ensure the training needs were identified for two of two testing personnel (TP 1 and TP 2) performing bacteriology, virology, and hematology patient testing in 2022 and 2023. (Refer to D6045). 2. The LD failed to ensure one of two testing personnel (TP 1) was qualified to perform moderately complex testing for 35 of 35 analytes in the subspecialties of bacteriology, virology, and hematology before testing and reporting patients' results during 2022 and 2023. (Refer to D6065).
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii)

	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 director must-- (e)(3) Ensure that-- (e)(3)(ii) 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 review of laboratory records, lack of documentation, and interview with testing personnel (TP 1), the laboratory director (LD) failed to ensure the verification procedures of the laboratory's test performance characteristics for accuracy and precision for four of four moderate complexity testing systems were performed before testing and reporting patients' results during the years of 2022 and 2023, affecting more than 967 reported patients' tests. Findings include: 1. The LD failed to ensure performance specification were verified prior to testing and reporting patients' results for four of four moderately complexity test systems in 2022 and 2023 (Refer to D5421). The systems in-use are GeneXpert Dx System (Cepheid); Verigene RP Flex (Luminex) system; Simplexa (DiaSorin Liaison MDX) system; and the Sysmex XN 430 system.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on review of laboratory records, lack of documentation, and interviews with the laboratory director and testing personnel (TP 1), the technical consultant (TC): a) failed to ensure the verification of test procedures and the establishment of the laboratory's test performance characteristics for accuracy and precision for four of four moderate complexity hematology, bacteriology, and virology testing systems (refer to D6040); b) failed to ensure the laboratory was enrolled in proficiency testing for the specialties of microbiology (subspecialities bacteriology and virology) and hematology (refer to D6041); c) failed to ensure two of two TP received training for moderate complexity hematology, bacteriology, and virology patient testing (refer to D6045); d) failed to ensure competency evaluations at least semiannually for moderate complexity hematology, bacteriology, and virology patient testing for two of two TP (refer to D6053); e) failed to ensure competency evaluations at least annually for moderate complexity hematology, bacteriology, and virology patient testing for two of two TP (refer to D6053).
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.

	This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of documentation, and interview with testing personnel (TP 1), the technical consultant (TC) failed to ensure the verification of the test procedures and the establishment of the laboratory's test performance characteristics for accuracy and precision for four of four moderate complexity testing systems were performed before testing and reporting patients' results for 35 of 35 analytes (red blood cell count, white blood cell count, hemoglobin, hematocrit, platelet cell count, cell differential patient test results for hematology, Chlamydia trachomatis, Neisseria gonorrhoeae, Influenza A, Influenza A / H1, Influenza A / H3, Influenza B, Respiratory Syncytial Virus A, Respiratory Syncytial Virus B, Group A Strep, SARS-CoV2, Parainfluenza 1, Parainfluenza 2, Parainfluenza 3, Parainfluenza 4, hMPV-8, Adenovirus 3, B. parapertussis / B. bronciseptica, Rhinovirus 1A, B. pertussis, B. holmesii, and Herpes Simplex Virus 1 & Herpes Simplex Virus 2) in the subspecialties of virology and bacteriology, and specialty of Hematology during the years of 2022 and 2023, affecting more than 967 patient tests performed. Findings Include: 1. The TC failed to verify the performance specifications of the following moderately complex test systems in-use during 2022 and 2023 (Refer to D5421): GeneXpert Dx System (Cepheid); Verigene RP Flex (Luminex) system; Simplexa (DiaSorin Liaison MDX) system; Sysmex XN 430 system 2. The TC failed to ensure the retention of quality control records for three of three (Verigene RP Flex (Luminex), Simplexa (DiaSorin Liaison MDX), and GeneXpert Dx) moderate complexity testing systems for at least two years. (Refer to D3031).
D6041	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(3) (b) The technical consultant is responsible for-- (b)(3) Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered; This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of documentation, and interview with testing personnel (TP 1), the technical consultant (TC) failed to enroll the laboratory testing in an approved Centers for Medicare and Medicaid Services (CMS) proficiency testing (PT) program for 28 of 28 analytes before testing and reporting patient test results in the specialty of Hematology and subspecialties of Bacteriology and Virology for the years of 2022 and 2023. Findings Include: 1. The TC failed to enroll in an approved Centers for Medicare and Medicaid Services (CMS) proficiency testing (PT) program for 28 of 28 moderate complexity hematology, bacteriology, and virology analytes. (Refer to D2000).
D6045	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(7) (b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed;

	This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of documentation, and interview with the testing personnel (TP 1), the technical consultant (TC) failed to identify the training needs of two of two testing personnel (TP 1 and TP 2) for four of four (Sysmex XN 430, GeneXpert Dx System (Cepheid), Verigene RP Flex (Luminex), and DiaSorin Liaison MDX) moderate complexity hematology, bacteriology, and virology patient testing systems in 2022 and 2023. Findings Include: 1. Review of the "Quality Assurance Plan for Instavaxx PLLC" procedure revealed these instructions: "Along with method-specific training, new hires receive recorded training on the Quality Assurance Plan, laboratory safety, standard operating procedures, and data integrity. The Personnel Training folders contain a record of any specialized training that staff members have either provided or received." 2. The TC failed to provide the training records for two of two testing personnel (TP 1 and TP 2) for the patient testing of 16 of 16 (Influenza A, Influenza A / H1, Influenza A / H3, Influenza B, Respiratory Syncytial Virus A, Respiratory Syncytial Virus B, Group A Strep, SARS-CoV2, Parainfluenza 1, Parainfluenza 2, Parainfluenza 3, Parainfluenza 4, hMPV-8, Adenovirus 3, B. parapertussis / B. bronciseptica, Rhinovirus 1A, B. pertussis, B. holmesii) moderate complexity bacteriology and virology analytes utilizing the Verigene RP Flex - Luminex system; seven of seven (Strep Group A, SARS-CoV-2, Influenza A, Influenza B, Respiratory Syncytial Virus, Herpes Simplex Virus 1 & Herpes Simplex Virus 2) moderate complexity bacteriology and virology analytes utilizing the Simplexa DiaSorin Liaison MDX system; and two of two (Chlamydia trachomatis and Neisseria gonorrhoeae) bacteriology analytes utilizing the GeneXpert Dx System. 3. The TC failed to provide the training records for one of two testing personnel (TP 1) for the patient testing of six of six (red blood cell count, white blood cell count, hemoglobin, hematocrit, platelet cell count, cell differential) moderate complexity hematology analytes utilizing the Sysmex XN 430 system. 4. On 12/28 /2023 at 3:00 p.m., an interview with TP 1 confirmed the above findings.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of documentation, and interview with testing personnel (TP 1), the technical consultant (TC) failed to evaluate two of two testing personnel (TP 1 and TP 2) for competency at least semiannually during the first year of moderate complexity hematology, bacteriology, and virology patient testing on four of four patient testing systems in-use during 2022 and 2023, affecting 967 patient tests performed. Findings include: 1. Review of the "Quality Assurance Plan for Instavaxx PLLC" revealed the TC failed to implement the following Quality Assurance procedures. "Internal Quality Control - An Internal Quality Control program has been designed to ensure systematic in-house production of high-quality analytical data. The objectives of this program are: To provide a measure of the precision of analytical methods. To maintain a continuing assessment of the accuracy, precision and completeness of individual analyses performed in the laboratory. To identify methods that can be strengthened and provide a source of data to overcome these deficiencies and weaknesses. To detect training needs within the analytical group." 2. The TC failed to document and maintain at least semiannually the

	competency records of TP 1 and TP 2 for the four of four test systems: Sysmex XN 430, GeneXpert Dx System (Cepheid), Verigene RP Flex (Luminex), and DiaSorin Liaison MDX), affecting 967 patient tests performed. 3. On 12/28/2023 at 3:00 p.m., an interview with TP 1 confirmed the above finding.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of documentation, and interview with testing personnel (TP 1), the technical consultant (TC) failed to evaluate two of two testing personnel (TP 1 and TP 2) for competency at least annually for the moderately complex testing performed in the specialty of hematology and subspecialty of bacteriology and virology prior to reporting patient testing on four of four testing systems during 2022 and 2023, affecting 967 patient tests performed. Findings include: 1. Review of the "Quality Assurance Plan for Instavaxx PLLC" procedures revealed the TC failed to follow and implement Quality Assurance training procedures. "Internal Quality Control - An Internal Quality Control program has been designed to ensure systematic in-house production of high-quality analytical data. The objectives of this program are: To provide a measure of the precision of analytical methods. To maintain a continuing assessment of the accuracy, precision and completeness of individual analyses performed in the laboratory. To identify methods that can be strengthened and provide a source of data to overcome these deficiencies and weaknesses. To detect training needs within the analytical group." 2. The TC failed to document and maintain at least annually the competency records of TP 1 and TP 2 for testing 16 of 16 (Influenza A, Influenza A / H1, Influenza A / H3, Influenza B, Respiratory Syncytial Virus A, Respiratory Syncytial Virus B, Group A Strep, SARS-CoV2, Parainfluenza 1, Parainfluenza 2, Parainfluenza 3, Parainfluenza 4, hMPV-8, Adenovirus 3, B. parapertussis / B. bronciseptica, Rhinovirus 1A, B. pertussis, B.holmesii) moderate complexity bacteriology and virology analytes utilizing the Verigene RP Flex - Luminex system; seven of seven (Strep Group A, SARS-CoV-2, Influenza A, Influenza B, Respiratory Syncytial Virus, Herpes Simplex Virus 1 & Herpes Simplex Virus 2) moderate complexity bacteriology and virology analytes utilizing the Simplexa DiaSorin Liaison MDX system; two of two (Chlamydia trachomatis and Neisseria gonorrhoeae) bacteriology analytes utilizing the GeneXpert Dx System; and six of six (red blood cell count, white blood cell count, hemoglobin, hematocrit, platelet cell count, cell differential) moderate complexity hematology analytes utilizing the Sysmex XN 430 system, affecting 967 patient tests performed. 3. On 12/28/2023 at 3:00 p.m., an interview with TP 1 confirmed the above finding.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed.

	This CONDITION is not met as evidenced by: Based on review of laboratory records, Laboratory Personnel Report (CMS-209), lack of documentation, and interview with testing personnel (TP 1), the laboratory failed to ensure one of two testing personnel meet the qualifications for moderate complexity bacteriology, virology, and hematology testing in 2022 and 2023. (Refer to D6065).
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on review of laboratory records, Laboratory Personnel Report (CMS-209), lack of documentation, and interview with testing personnel (TP 1), the laboratory failed to ensure one of two testing personnel (TP) qualified for moderate complexity bacteriology, virology, and hematology testing in 2022 and 2023. Findings Include: 1. Review of the laboratory qualifying records for the TP listed on the CMS-209 and lack of documentation revealed the laboratory failed to have qualifying documentation for one of two testing personnel (TP 1) for moderate complexity bacteriology, virology, and hematology testing. 2. On 12/29/2023 at 1:45 p.m., an interview with TP 1 confirmed the above findings.