Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2246122	09/11/2023
Name of Provider or Supplier	**Street Address, City, State**	
Mobvilvax	1000 N North Branch 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
D2025	BACTERIOLOGY CFR(s): 493.823(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event. This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of documentation, and interview with the laboratory director (LD), the laboratory failed to return proficiency testing (PT) results to the PT program within the time requested for one of two molecular biology SARS-CoV-2 PT events in 2022. Findings Include: 1. Review of the "COLLEGE of AMERICAN PATHOLOGIST Original Evaluation COV2-A 2022 SARS-CoV-2, Molecular" form revealed the following: "INSTITUTION: LabX, Chicago IL, 60642 ATTENTION: XXX CAP NUMBER: 9310794-01 KIT# 1 KIT ID: 36044081 KIT MAILED: 5/23/2022 ORIGINAL EVALUATION: 7/21/2022 NEXT MAILING DATE: 11/21/2022 COPIED TO: CAP LEGEND: Exception Reason Codes appearing in this evaluation: [40] = Results for this kit were not received." 2. Review of laboratory PT records and lack of documentation revealed the laboratory failed to return PT results within the time requested for one of two SARS- CoV-2 PT events in 2022. 3. On 9/11/2023 at 2:20 p.m., the LD confirmed the above findings.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) 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. 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 temperatures and room humidity values for one of five dates reviewed for high complexity molecular biology SARS-CoV-2 (Lumira DX) patient testing in 2022 and 2023. Findings include: 1. Review of the laboratory patient records and lack of documentation revealed the laboratory failed to document room temperatures and humidity values for one of five SARS-CoV-2 (Lumira DX) patient test dates reviewed in 2022 and 2023. - 05/03/2023 2. On 09/11 /2023 at 1:20 p.m., TP 1 confirmed the above findings.
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 the laboratory director (LD), the laboratory failed to perform and document twice a year evaluations of the test results between three of three test systems in use for SARS- CoV-2 molecular testing; two analyzers utilizing the LumiraDx RNA Star assay and one Hologic Panther system performing the Aptima SARS- CoV-2 Assay in 2022 and 2023. Findings Include: 1. On 09/11/2023 at 12:01 p.m., surveyor's direct observation, and review of laboratory records, revealed three of three molecular biology SARS- CoV-2 test systems in use: a. "LumiraDx RNA Star (Quant Studio 6 Flex): Serial # 278860690" b. "LumiraDx RNA Star (Quant Studio 7 Flex): Serial # 278875079" c. "Aptima SARS- CoV-2 Assay (Hologic Panther System): Serial # 10527" 2. Review of laboratory records and lack of documentation revealed the laboratory failed to perform and document twice a year evaluation of the test results between the SARS- CoV-2 testing systems listed in Finding 1. 3. On 09/11 /2023 at 1:44 p.m., an interview with the LD confirmed the above findings.
D5789	TEST RECORDS CFR(s): 493.1283(b) Records of patient testing including, if applicable, instrument printouts, must be retained. This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of documentation, and interview with the laboratory director (LD), the laboratory failed to retain patient test records for two of two dates reviewed for SARS- CoV-2 patient testing and instrument printouts utilizing the Hologic Panther assay in 2022. Affecting 124 patient tests. Findings

	Include: 1. Review of the "Lab X" policy manual revealed the following: a. Page 27 - # 12. Test results shall print when the accession is final and shall be filed; retained for at least two years. 2. Review of laboratory patient records and lack of documentation revealed the laboratory failed to retain patient testing records and instrument printouts for two of two Hologic Panther patient testing dates (04/12/2022 and 06/28/2022). Affecting 124 patient tests. 3. On 09/11/2023 at 3:49 p.m., the LD confirmed the above findings.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of laboratory records, lack of documentation, Laboratory Personnel Report (CMS-209), and interview with testing personnel (TP 1), the laboratory director (LD) failed to fulfill responsibility for ensuring eight of eleven testing personnel were qualified for high complexity molecular biology testing of SARS-CoV-2 in 2022 and 2023. (Refer to D6101).
D6101	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(11) The laboratory director must employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart. This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of documentation, and interview with the laboratory director (LD), the laboratory director failed to employ a sufficient number of testing personnel with appropriate education and training to perform and report high complexity molecular biology SARS-CoV-2 testing in 2022 and 2023. Findings Include: 1. Based on review of laboratory records, lack of documentation, Laboratory Personnel Report (CMS-209), and interview with testing personnel (TP 1), the laboratory failed to ensure eight of eleven testing personnel were qualified for high complexity molecular biology testing of SARS- CoV-2 in 2022 and 2023. (Refer to D6171).
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on review of laboratory records, lack of documentation, Laboratory Personnel

	Report (CMS-209), and interview with testing personnel (TP 1), the laboratory failed to ensure employees met the qualification requirements for high complexity laboratory testing for eight of eleven testing personnel (TP) listed on the CMS - 209 (09/11/2023). (Refer to D6171).
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry 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; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high

	complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations. This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of documentation, Laboratory Personnel Report (CMS-209), and interview with testing personnel (TP 1), the laboratory failed to ensure eight of eleven testing personnel were qualified for high complexity molecular biology testing of SARS- CoV-2 in 2022 and 2023. Findings Include: 1. Review of the "LabX" procedures manual revealed the following: a. "D. Personnel: 6. Evidence in personnel records that all testing personnel have been evaluated against CLIA requirements. 2. Review of the "scholaro Credential Evaluation Report - Bachelor of Science degree in Agriculture" found TP 1 failed to meet qualification requirements for high complexity SARS-CoV-2 testing in 2022 and 2023. 3. Review of the CMS-209 (09/11/2023) and lack of documentation revealed the laboratory failed to retain education transcripts to qualify seven of eleven TP (TP 2, TP 3, TP 4, TP 5, TP 8, TP 9, and TP 11) for high complexity SARS-CoV-2 testing in 2022 and 2023. 4. On 09/11/2023 at 10:00 a.m., TP 1 confirmed the above finding.