Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0961225	(X3) Date Survey Completed 12/05/2019
Name of Provider or Supplier Dbm Medical Pllc	**Street Address, City, State** 11630 Old Country Rd,, Plainview, NY	

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
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 a surveyor review of temperature records an and interview with the technical consultant, the laboratory failed to follow the manufacturer's and laboratory's written temperature requirement. Findings Include: 1. It was confirmed by the technical consultant on December 5, 2019 at approximately 10:00 AM that the laboratory failed to follow the laboratory's and the manufacturer's written criteria to monitor and document that the refrigerator, freezer, and room temperatures, and humidity level where testing is performed from August 21, 2019 when testing was initiated through August 30, 2019. 2. Approximately 10 patients specimens were tested and reported for respiratory panel testing during this time period.
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 a surveyor review of laboratory records records and confirmed in an interview with the technical consultant at the time of the survey, the laboratory failed to have a written quality control plan (QCP) as part of their individualized quality control plan (IQCP) for testing Respiratory Panel 2 using the Bio Fire Film Array. Findings: On December 5, 2019 at approximately 10:00 AM the technical consultant confirmed surveyor's findings that the laboratory failed to establish a QCP to include the frequency of testing positive and negative QC as part of a complete IQCP.

D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the surveyor's review of respiratory panel Quality Control (QC) records and an interview with the laboratory director/testing person and the technical consultant, the laboratory failed to check each run of the respiratory panel for positive reactivity from August 2019 through October 2019. FINDINGS: 1. The laboratory initiated the respiratory panel on the Bio Fire analyzer on August 21, 2019. 2. On December 5, 2019 at approximately 10:00 AM, the laboratory director/testing person and the technical consultant confirmed the surveyor's findings that the laboratory failed to have documentation of the required positive quality control to include all 14 viral and 4 bacterial analytes for each run from August 21, 2019 when testing was initiated through October 2019. 3. Approximately 20 patients specimens were tested and reported for respiratory panel testing during this time period.
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 reviewing randomly selected test reports and confirmation by the laboratory director/testing person and the technical consultant, the patient reports reviewed failed to include the name and address of the laboratory location where the test is performed. Findings include: On December 5, 2019 at approximately 10:00 AM, the laboratory director/testing person and the technical consultant confirmed surveyor's findings that patients' test reports failed to include the name and address of the laboratory where the test is performed.