Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D2189295	11/08/2022
Name of Provider or Supplier	**Street Address, City, State**	
Viral Solutions, Llc	2900 Chamblee Tucker Road, Building #3, Atlanta, GA	

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	On March 31, 2023 an off site follow-up review (following an on site re-visit on 03/23 /2023) was completed. The report revealed that the plan of correction was found to be acceptable. The facility is now in compliance with CLIA regulations.
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, 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 preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of the procedures, the laboratory failed to have a procedure for specimen collection, specimen labeling, specimen storage and preservation, conditions for specimen transportation and specimen acceptability and rejection. (see D5311). Based on interview with laboratory staff, the laboratory failed to make available to clients written instructions for submitting specimens for laboratory testing (see D5317).
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions

	for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on record review, the laboratory failed to have a policy or procedure for specimen collection, specimen labeling, specimen storage and preservation, conditions for specimen transportation and specimen acceptability and rejection for 2 of 3 laboratory developed tests (LDTs). Findings: I. The surveyor requested the procedure for the laboratory developed Monkeypox Real Time PCR Assay and was provide a procedure titled " RNA EXTRACTION PROCEDURE using Kingfisher Flex" and a procedure titled "Preparation of Mastermix for qPCR detection of MPV and RNAseP (Endogenous Control)". Review of these procedures on December 8, 2022, found no requirements for specimen collection, specimen labeling, specimen storage and preservation, conditions for specimen transportation and specimen acceptability and rejection. The procedure titled "Preparation of Mastermix for qPCR detection of MPV and RNAseP (Endogenous Control)" included the following: "5. SPECIMEN INFORMATION / PROCESSING 5.1 Acceptable specimens 5.1.1 Specimen types need to be validated in the laboratory before testing begins. 5.1.2 DNA extracted from lesion material. DNA can be extracted from acceptable specimen types including, but not limited to, lesion fluid on a dry swab, lesion fluid swab in viral transport media, lesion fluid on a slide, crust, or lesion roof. 5.1.3 DNA extract solely from whole blood alone is not a suitable specimen for Monkeypox virus diagnostic testing as the viremic phase may have already passed at the time of rash onset. As such, a negative result from only a whole blood specimen cannot rule out a Monkeypox virus infection. 5.2 REJECTION CRITERIA 5.2.1 Visible contamination. 5.2.2 Incomplete labeling so as contents 5.2.3 cannot be identified. Incomplete documentation. [sic] 5.2.4 Specimen received outside of established storage and shipping acceptance criteria." Established storage and shipping acceptance criteria were not defined in the procedure titled "Preparation of Mastermix for qPCR detection of MPV and RNAseP (Endogenous Control)". II. The surveyor requested the procedure for the Influenza-Covid19-RSV Multiplex Assay. The laboratory provided the procedures titled " RNA EXTRACTION PROCEDURE using Kingfisher Flex", "Preparation of Mastermix for qPCR detection of Influenza A/B, SC2, RSV and Endogenous Control" and "Preparation of Mastermix for qPCR detection of RSV and Endogenous Control". Review of these procedures found no requirements for specimen collection, specimen labeling, specimen storage and preservation, conditions for specimen transportation and specimen acceptability and rejection. The procedures titled "Preparation of Mastermix for qPCR detection of Influenza A/B, SC2, RSV and Endogenous Control" and "Preparation of Mastermix for qPCR detection of RSV and Endogenous Control" did not include the requirements for specimen collection, specimen labeling, specimen storage and preservation, conditions for specimen transportation and specimen acceptability and rejection. The two procedures included the following: "13. ACCEPTABLE SPECIMENS A. Acceptable specimens include nucleic acid extracts from clinical specimens. B. Basis for rejected samples o Incomplete specimen labeling or documentation o Inappropriate specimen type o Insufficient specimen volume o Specimen leakage" Neither of these three procedures defined the clinical specimens acceptable for nucleic acid extraction.
D5317	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d)

	If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section. This STANDARD is not met as evidenced by: Based on interview with laboratory staff, the laboratory failed to make available to clients written instructions for specimen collection, specimen labeling, specimen storage and preservation and conditions for specimen transportation. Findings: 1. On November 8, 2022 at approximately 12:15 pm, the surveyor requested a client services manual or written instructions provided to clients for the collection, labeling, storage, preservation and transportation conditions for specimens. The Chief Information Officer (CIO) stated the laboratory does not have a client service manual or written instructions for clients. 2. The laboratory provides services to the film industry, school systems and penal systems in addition to the general public at drive up collection sites.
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 record review and staff interview, the laboratory failed to ensure laboratory personnel followed their procedures (see D5401), failed to ensure the procedures contained all requirements applicable to the test procedure (see D5403), and failed to establish all test performance specifications for laboratory developed tests (see D5423).
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: Based on review of the laboratory procedure titled "Laboratory Protocol for Detection of SARS-CoV 2 (COVID-19) using Real-Time Polymerase Chain Reaction (RT-PCR)" and review of temperature logs, the laboratory failed to follow their procedure. Findings: 1. Review of the "Laboratory Protocol for Detection of SARS-CoV 2 (COVID-19) using Real-Time Polymerase Chain Reaction (RT-PCR)" on December 8, 2022, found the following statement: "28. Transport the well to the incubator-verifying the temperature reading on the incubator is at least 96.5 degrees Celsius." 2. Review of the "Daily Incubator Log" on December 8, 2022, revealed the temperature

	of the incubator was less than 96.5 for 30 of 30 days in September 2022. The temperature of the incubator was not within the limits indicated in the laboratory's procedure.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on review of establishment test performance specifications records and interview with laboratory staff, the laboratory failed to perform specimen stability studies for two out of three laboratory developed tests (LDT). Findings: 1. Review of records for the establishment of test performance specifications for Monkeypox Real Time PCR Assay and the Influenza-Covid19-RSV Multiplex Assay on the afternoons of November 8, 2022, and November 9, 2022, found no record of studies to determine the optimum conditions for specimen storage, preservation, or specimen transportation to ensure the integrity of the sample. 2. During interview the afternoon of November 9, 2022, the laboratory director confirmed the laboratory failed to perform specimen stability studies when establishing test performance specifications for the two above named LDTs.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on Quality Assessment (QA) document review and staff interview, the laboratory failed to document quality assessment activities on a monthly basis as stated in their QA policy manual from November 2021 to October 2022. Findings: 1. A review of the laboratory QA documents revealed the technical supervisor (TS) did not review and sign monthly quality activity checklists from November 2021 through October 2022. 2. A review of daily maintenance logs including: Room Temperature, Humidity, Eye Wash and Refrigerator logs were not reviewed and signed by the laboratory director (LD) or TS from November 2021 through October 2022. 3. Interviews with the LD and TS on 11/08/2022, at approximately 03:35 pm in the break room confirmed the above laboratory logs and QA checklists were not reviewed and signed by the TS or LD from November 2021 through October 2022.

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 record review of laboratory competency assessment procedures and evaluation documentation and interview with the laboratory director, the laboratory failed to provide overall management as evidenced by: The laboratory director failed to provide documentation of 1 year of laboratory training or 2 years of experience directing a high complexity testing laboratory. (refer to D6078)
D6078	LABORATORY DIRECTOR QUALIFICATIONS CFR(s): 493.1443 The laboratory director must be qualified to manage and direct the laboratory personnel and performance of high complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2) Be a doctor of medicine, a doctor of osteopathy or doctor of podiatric medicine licensed to practice medicine, osteopathy or podiatry in the State in which the laboratory is located; and (b)(2)(i) Have at least one year of laboratory training during medical residency (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(2)(ii) Have at least 2 years of experience directing or supervising high complexity testing; or (b)(3) Hold an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution and-- (b)(3)(i) Be certified and continue to be certified by a board approved by HHS; or (b)(3)(ii) Before February 24, 2003, must have served or be serving as director of a laboratory performing high complexity testing and must have at least-- (b)(3)(ii)(A) Two years of laboratory training or experience, or both; and (b)(3)(ii)(B) Two years of laboratory experience directing or supervising high complexity testing. (b)(4) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under regulations at 42 CFR 493.1415, published March 14, 1990 at 55 FR 9538, on or before February 28, 1992; or (b)(5) On or before February 28, 1992, be qualified under State law to direct a laboratory in the State in which the laboratory is located; or (b)(6) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, the American Osteopathic Board of Pathology, or possess qualifications that are equivalent to those required for certification. This STANDARD is not met as evidenced by: Based on record review and interview with the laboratory director, the laboratory

	director failed to provide evidence of 1 year of laboratory training or 2 years of experience directing a high complexity testing laboratory. Findings: 1. A record review revealed the laboratory provided documentation with their CMS-116 application submission to change the laboratory director in October 2022. 2. A review of the documents submitted found the laboratory director COLA CME certificate and curriculum vitae (CV) were not acceptable evidence of training or experience for directing high complexity testing. 4. A review of the reference letter, dated August 10, 2022, from the previous laboratory director, failed to provide acceptable documentation of training or experience for the current laboratory director to direct a high complexity testing laboratory. 5. An interview with the laboratory director on 11 /08/2022 at 2:00 pm in the break room confirmed the laboratory director did not provide acceptable documentaton of training or experience directing a high complexity laboratory.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for 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; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on record review and interview with the technical supervisor, the laboratory failed to ensure the performance of training and semi-annual competency assessment completed for testing personnel (TP) for SARS COV 2 (COVID 19) using Reat time Polymerase Chain Reaction (RT-PCR), Monkeypox RT-PCR and Influenza-COVID19-RSV Multiplex Assay in 2022. Finding: 1. A review of laboratory training and competency records received by email on 11/17/2022 from the laboratory director failed to identify the training/competency assessment for SARS COV 2- (COVID) RT-PCR (began November 2021), Monkeypox RT-PCR (began August 2022), and Influenza-COVID19-RSV Multiplex Assay (began October 2022) for testing personnel. 2. A review of training and competency assessment records found the laboratory provided one set of records for for 10 of 10 testing personnel, the laboratory failed to provide completed training and semi-annual competency assessment records for SARS COV 2 (COVID 19) RT-PCR, Monkeypox RT-PCR and Influenza-COVID19-RSV Multiplex Assay. The laboratory records submitted did not annotate on the forms the specific name of the test SARS COV 2 (COVID 19) RT-PCR, Monkeypox RT-PCR and Influenza-COVID19-RSV Multiplex Assay. The policy titled, "Competency Assessment" stated, "These assessments will occur at the onset of testing, following training (approximately 3 months from hire date), after 6 months of employment, and then annually on the anniversary of their hire date". 36585