Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	32D2197985	03/09/2021
Name of Provider or Supplier	**Street Address, City, State**	
Southwest Labs, Llc-Alamogordo	2474 Indian Wells Road, Ste A, Alamogordo, NM	

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	During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS CoV-2 test results to the Secretary of Health and Human Services in such form and manner, and at such timing and frequency, as the Secretary may prescribe. During an CMS-3401-IFC survey completed on March 9, 2021 for 42 CFR part 493 Laboratory Requirements, the facility was found out of compliance with the following condition: 42 CFR Part 493.41 Condition: Reporting of SARS-CoV-2 test results.
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on observation, review of manufacturer's Instructions for Use, and interviews with laboratory staff, the laboratory failed to follow the manufacturer's instructions for the Becton Dickinson Veritor Plus Analyzer System for the Rapid Detection of SARS-CoV-2 (COVID19), Group A Strep (a type of bacteria) and Flu A+B (Types of Influenza viruses). Findings are: A. During observation of the testing process for one patient (Pt#1) and review of manufacturer's instructions for the SARS-CoV-2 rapid test, Group A Strep, and Flu A+B, using the BD Veritor Plus Analyzer System, revealed that the Lead Phlebotomist did not follow the manufacturer's testing instructions for the incubation timing. 1. Samples from Pt#1 were collected on 3/4/21 2:49 - 2:54 pm for SAR-CoV-2, for Influenza A+B, and for Group A Strep. All three devices/cartridges were pre-labeled with the patient's first and last initials only. a. The Lead Phlebotomist collected the sample for the COVID-19 test first. She put the swab

into the extraction reagent tube and plunged the swab up and down for 15 seconds. She removed the swab while squeezing tube to extract liquid, discarded the swab, and recapped the extraction reagent tube with the dispensing tip. She dispensed the three drops of the processed sample onto the COVID-19 test device/cartridge, which was placed in front of the COVID-19 Test Kit (Box), which was her method of knowing which test device she was running. The manufacturer's instructions indicated "Allow test to develop for 15 minutes" after the three drops were dispensed onto the cartridge. The manufacturer's instructions also indicated under the section labeled "Limitations of the Procedure" "Do not read test devices before 15 minutes as this could result in a false negative or invalid result. Do not read devices after 20 minutes as false positive, false negative or invalid results may occur." b. The Lead Phlebotomist collected the nasopharyngeal swab (a type of swab used to collect samples from inside the nose) for Influenza A+B. She processed the Influenza A+B in the same manner as the COVID19 swabs and placed the three drops in the appropriate device, labeled only with the patient's initials and placed in front of the Influenza Test Kit (Box). The manufacturer's instructions indicated, "Allow test to develop for 10 minutes" after the three drops were dispensed onto the cartridge. c. The Lead Phlebotomist collected the third sample, a throat swab for the Group A Step Test. The Group A swab was processed in the same manner as the two previous samples and she immediately placed the three drops into device/cartridge in front of the Group A Test kit (box) on the counter. The manufacturer's instructions indicated the following steps: "Incubate for 1-2 minutes," "plunge the sward up and down, remove and squeeze swab," "Press and attach dispensing tip," "Add three drops to test device sample well" "Let the test run for 5 minutes before inserting into the reader" after the three drops are dispensed onto device. 2. After the three drops of sample were dispensed onto the devices /cartridges for all three tests for Pt#1, the Lead Phlebotomist noted the time of collection, using the digital clock on the counter, added 15 minutes, and estimated the time of completion as "3:09 pm" and wrote it on each of the three cartridges. No timer was used or programmed during the testing phase. The Lead Phlebotomist read all three cartridges at 3:17 pm, 8 minutes past the estimated incubation time of 3:09 pm. a. The SARS-CoV-2 test cartridge was read at 3:17 pm. The cartridge should have been read 15 minutes after collection, processing and dropping the sample onto the cartridge at approximately 3:04 pm. b. The Group A Strep cartridge was read at 3:17 pm. The cartridge should have been read 10 minutes after collection, processing and dropping the sample onto the cartridge at approximately 3:01 pm. c. The Flu A+B cartridge was read at 3:17 pm. The cartridge should have been read at 5 minutes after collection, processing and dropping the sample onto the cartridge at approximately 2: 58 pm. 3. The IFU (Instructions For Use) indicated that a timer is required but not provided in each kit/box. During observation of laboratory supplies and layout, a timer, with 3 available settings, was seen on the top of a blood collection tube storage container attached to the wall between the phlebotomy chairs. 4. During interview on 3 /3/2021 at 3:25 pm, the Lead Phlebotomist stated that she was told that it was okay for the sample to sit up to one hour in the cartridge before inserting and obtaining a reading from the BD Veritor analyzer. The surveyor then asked, "Are you saying, after you place the three drops in the device, it can sit up to 1 hr?" Lead Phlebotomist responded "most of the time they are resulted within 20 min, maybe sometimes up to 30 min, but they never go over 1 hour." B. During interview on 3/3/2021 at 3:40 pm, the Lead Phlebotomist stated that the laboratory will use the left-over supplies from one kit, with another kit, if the lot number is the same. Review of the Instructions for Use (IFU) for the BD Veritor System for the Rapid Detection of SARS-CoV-2, under the section labeled "Warnings and Precautions," indicated "Do not use components from any other BD Veritor test with the BD Veritor System for Rapid Detection of SARS-CoV-2. While components from other BD Veritor tests may appear similar,

	they are not the same." C. Observation and interviews with laboratory staff revealed that the laboratory did not adhere to the Conditions of Authorization for laboratories, operating under a CLIA Certificate of Waiver, and using an Emergency Use Authorization (EUA) test system, and set forth by the FDA as stated in the manufacturer's instructions. 1. Review of the Veritor IFU indicated all laboratories using The BD Veritor System for Rapid Detection of SARS-CoV-2, which was issued an Emergency Use Authorization (EUA), must adhere to relevant Conditions of Authorization listed under section labeled "Conditions of Authorization for the Laboratory (Applicable in the USA)" of the IFU documentation. The IFU states "Authorized laboratories using your product must include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used which may include mass media." 2. Observation of the collection and testing process for 3 patients (Pt#1 - Pt#3) on 3/03 /2021 from 2:49 pm - 3:55 pm confirmed that no Patient Fact Sheets were given to patients at any time during the collection, testing, and reporting process. 3. During the interview with Doctor on 3/3/21 at 3:50 pm, the doctor was asked by the surveyor if she was giving the patients any documentation about the test along with their COVID-19 results. The doctor said that she was not handing out any documentation to the patients. However, she would conduct phone consultations with all of her positive patients. 4. During interview on 3/5/2021 at 2:31 pm, the Technical Consultant stated the staff were supposed to give the Patient Fact Sheets to each patient because the Laboratory Director felt they were important. She also stated that the laboratory staff were provided a stack of pre-printed Patient Fact Sheets when the laboratory opened in November 2020.
D1002	REPORTING OF SARS-CoV-2 TEST RESULTS During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on the review of patient testing results and interviews with laboratory staff, the laboratory failed to report positive and negative COVID-19 testing results to the local /State New Mexico Department of Health (NMDOH) from January 8, 2021 to March 3, 2021. Findings are: A. Review of the patient testing reports of all the SARS-CoV-2 testing performed from January 8, 2021 to March 3, 2021 revealed that the laboratory failed to report positive and negative results for the following patients. 1. The total number of SARS-CoV-2 tests performed in January 2021 was 470. The record shows that 34 patients (Jan Pt#1-Jan Pt#34) results performed in January were reported after the surveyors left the laboratory on March 3, 2021 at 1600. The patients that were not reported are as follows: Jan Pt#1, accession #296436, pt ID# IWFP-121468, tested Negative on 01/04/21 and reported 03/03/21 at 20:21. Jan Pt#2, accession #296113, pt ID# IWFP-082258, tested Negative on 01/04/21 and reported 03/03/21 at 19:40. Jan Pt#3, accession #296188, pt ID# IWFP-042677, tested Positive on 01/04/21 and reported 03/03/21 at 19:41. Jan Pt#4, accession #296190, pt ID# IWFP-042297, tested Negative on 01/04/21 and reported 03/03/21 at 19:42. Jan Pt#5, accession #296202, pt ID# IWFP-100482, tested Negative on 01/04/21 and reported 03/03/21 at 19:43. Jan Pt#6, accession #296206, pt ID# IWFP-041602, tested Negative on 01/04/21 and reported 03/03/21 at 19:43. Jan Pt#7, accession #296218, pt ID# IWFP-010100, tested

Negative on 01/04/21 and reported 03/03/21 at 19:44. Jan Pt#8, accession #296235, pt ID# IWFP-051036, tested Negative on 01/04/21 and reported 03/03/21 at 19:45. Jan Pt#9, accession #296292, pt ID# IWFP-122147, tested Negative on 01/04/21 and reported 03/03/21 at 19:46. Jan Pt#10, accession #296294, pt ID# IWFP-05041949, tested Negative on 01/04/21 and reported 03/03/21 at 19:46. Jan Pt#11, accession #296326, pt ID# IWFP-032882, tested Negative on 01/04/21 and reported 03/03/21 at 19:52. Jan Pt#12, accession #296335, pt ID# IWFP-032764, tested Negative on 01/04 /21 and reported 03/03/21 at 19:55. Jan Pt#13, accession #296331, pt ID# IWFP-04091964, tested Negative on 01/04/21 and reported 03/03/21 at 19:53. Jan Pt#14, accession #296343, pt ID# IWFP-082668, tested Negative on 01/04/21 and reported 03 /03/21 at 20:12. Jan Pt#15, accession #296357, pt ID# IWFP-051787, tested Negative on 01/04/21 and reported 03/03/21 at 20:14. Jan Pt#16, accession #296361, pt ID# IWFP-082967, tested Negative on 01/04/21 and reported 03/03/21 at 20:15. Jan Pt#17, accession #296371, pt ID# IWFP-051962, tested Negative on 01/04/21 and reported 03/03/21 at 20:15. Jan Pt#18, accession #296385, pt ID# IWFP-060751, tested Negative on 01/04/21 and reported 03/03/21 at 20:16. Jan Pt#19, accession #296398, pt ID# IWFP-082384, tested Positive on 01/04/21 and reported 03/03/21 at 20:18. Jan Pt#20, accession #296408, pt ID# IWFP-092853, tested Negative on 01/04 /21 and reported 03/03/21 at 20:18. Jan Pt#21, accession #296415, pt ID# IWFP-110934, tested Negative on 01/04/21 and reported 03/03/21 at 20:19. Jan Pt#22, accession #296421, pt ID# IWFP-091092, tested Negative on 01/04/21 and reported 03 /03/21 at 20:20. Jan Pt#23, accession #296425, pt ID# IWFP-060442, tested Negative on 01/04/21 and reported 03/03/21 at 20:20. Jan Pt#24, accession #296437, pt ID# IWFP-04021979, tested Negative on 01/04/21 and reported 03/03/21 at 20:22. Jan Pt#25, accession #296438, pt ID# IWFP-063095, tested Negative on 01/04/21 and reported 03/03/21 at 20:23. Jan Pt#26, accession #296452, pt ID# IWFP-06241980, tested Negative on 01/04/21 and reported 03/03/21 at 20:24. Jan Pt#27, accession #296459, pt ID# IWFP-022681, tested Positive on 01/04/21 and reported 03/03/21 at 20:25. Jan Pt#28, accession #296487, pt ID# IWFP-04211938, tested Negative on 01 /04/21 and reported 03/03/21 at 20:26. Jan Pt#29, accession #296494, pt ID# IWFP-103159, tested Positive on 01/04/21 and reported 03/03/21 at 20:27. Jan Pt#30, accession #297479, pt ID# IWFP-12221985, tested Positive on 01/06/21 and reported 03/04/21 at 12:31. Jan Pt#31, accession #297981, pt ID# IWFP-073197, tested Negative on 01/06/21 and reported 03/04/21 at 12:31. Jan Pt#32, accession #302973, pt ID# IWFP-11202001, tested Negative on 01/14/21 and reported 03/04/21 at 12:35. Jan Pt#33, accession #307147, pt ID# IWFP-052975, tested Negative on 01/25/21 and reported 03/04/21 at 12:35. Jan Pt#34, accession #309326, pt ID# IWFP-10041972, tested Negative on 01/28/21 and reported 03/04/21 at 12:36. 2. The total number of SARS-CoV-2 tests performed in February 2021 was 261. The record shows that 33 patients (Feb Pt#1-Feb Pt#33) results performed in February were reported after the surveyors left the laboratory on March 3, 2021 at 1600. The patients that were not reported are as follows: Feb Pt#1, accession #310931, pt ID# IWFP-082285, tested Negative on 02/01/21 and reported 03/04/21 at 12:37. Feb Pt#2, accession #313259, pt ID# IWFP-011711, tested Negative on 02/05/21 and reported 03/04/21 at 12:45. Feb Pt#3, accession #314743, pt ID# IWFP-121094, tested Negative on 02/10/21 and reported 03/04/21 at 12:46. Feb Pt#4, accession #314771, pt ID# IWFP-060520, tested Negative on 02/10/21 and reported 03/04/21 at 12:47. Feb Pt#5, accession #314773, pt ID# IWFP-021618, tested Negative on 02/10/21 and reported 03/04/21 at 12:47. Feb Pt#6, accession #314776, pt ID# IWFP-112500, tested Negative on 02/10 /21 and reported 03/04/21 at 12:48. Feb Pt#7, accession #314901, pt ID# IWFP-021292, tested Negative on 02/10/21 and reported 03/04/21 at 12:48. Feb Pt#8, accession #314904, pt ID# IWFP-082298, tested Negative on 02/10/21 and reported 03 /04/21 at 12:49. Feb Pt#9, accession #315592, pt ID# IWFP-09211964, tested

Negative on 02/11/21 and reported 03/04/21 at 12:49. Feb Pt#10, accession #316773, pt ID# IWFP-022680, tested Negative on 02/15/21 and reported 03/04/21 at 12:50. Feb Pt#11, accession #319130, pt ID# IWFP-062191, tested Negative on 02/22/21 and reported 03/05/21 at 16:42. Feb Pt#12, accession #319070, pt ID# IWFP-071040, tested Negative on 02/22/21 and reported 03/08/21 at 14:37. Feb Pt#13, accession #319074, pt ID# IWFP-100542, tested Negative on 02/22/21 and reported 03/08/21 at 14:37. Feb Pt#14, accession #319099, pt ID# IWFP-8612, tested Negative on 02/22 /21 and reported 03/05/21 at 16:39. Feb Pt#15, accession #319101, pt ID# IWFP-11171970, tested Positive on 02/22/21 and reported 03/05/21 at 16:40. Feb Pt#16, accession #319102, pt ID# IWFP-030272, tested Positive on 02/22/21 and reported 03 /05/21 at 16:41. Feb Pt#17, accession #319103, pt ID# IWFP-12222011, tested Positive on 02/22/21 and reported 03/05/21 at 16:41. Feb Pt#18, accession #319104, pt ID# IWFP-09161961, tested Negative on 02/22/21 and reported 03/05/21 at 16:42. Feb Pt#19, accession #319105, pt ID# IWFP-09202005, tested Positive on 02/22/21 and reported 03/05/21 at 16:40. Feb Pt#20, accession #319114, pt ID# IWFP-06171972, tested Negative on 02/22/21 and reported 03/08/21 at 14:38. Feb Pt#21, accession #319131, pt ID# IWFP-022761, tested Negative on 02/22/21 and reported 03 /05/21 at 16:44. Feb Pt#22, accession #319132, pt ID# IWFP-050389, tested Negative on 02/22/21 and reported 03/05/21 at 16:43. Feb Pt#23, accession #319134, pt ID# IWFP-061362, tested Negative on 02/22/21 and reported 03/05/21 at 16:43. Feb Pt#24, accession #319136, pt ID# IWFP-122801, tested Negative on 02/22/21 and reported 03/05/21 at 16:44. Feb Pt#25, accession #319153, pt ID# IWFP-052169, tested Negative on 02/22/21 and reported 03/05/21 at 16:39. Feb Pt#26, accession #319184,pt ID# IWFP-06241980, tested Negative on 02/22/21 and reported 03/05/21 at 16:38. Feb Pt#27, accession #319189, pt ID # IWFP-120108, tested Negative on 02 /22/21 and reported 03/05/21 at 16:37. Feb Pt#28, accession #319202, pt ID# IWFP-092685, tested Negative on 02/22/21 and reported 03/08/21 at 14:39. Feb Pt#29, accession #319205, pt ID# IWFP-103065, tested Negative on 02/22/21 and reported 03 /08/21 at 14:09. Feb Pt#30, accession #319210, pt ID# IWFP-072889, tested Negative 02/22/21 and reported 03/08/21 at 14:40. Feb Pt#31, accession #319224, pt ID# IWFP-05281982, tested Negative on 02/22/21 and reported 03/05/21 at 16:34. Feb Pt#32, accession #319226, pt ID# IWFP-112802, tested Negative on 02/22/21 and reported 03 /05/21 at 16:35. Feb Pt#33, accession #320596, pt ID# IWFP-080776, tested Negative on 02/23/21 and reported 03/05/21 at 17:33. 3. The total number of SARS-CoV-2 tests performed in March 1, 2021 to March 6, 2021 was 89. The record shows that 1 of 89 patients was not reported after the surveyors left the laboratory on March 3, 2021 at 1600. The patient that was not reported is as follows: Mar Pt#1, accession #323220, pt ID# IWFP-08201978, tested Negative on 03/02/21 and reported 03/08/21 at 14:41. B. During an interview on 03/03/21 at 2:30 pm, the Lead Phlebotomist was asked if the lab kept a log/list of all the COVID-tested patients daily and she stated that they did not keep a log. They only keep the paper copy which they scan and send to the person entering the result into the portal (LabDaq), that is linked to the NMDOH. C. During an phone interview on 03/05/21 at 2:59 pm with the Computer IT Technician, he stated that they report and enter results using an HL7 integration LIS system that instantly sends the results as they are entered to the NMDOH. When asked if they had a system in place to check/assure that their results had made it to their final destination he said "no". D. During an phone interview on 03/05/21 at 3:12 pm with the Clinical Sales Manager/Trainer, stated that she receives a scanned copy of the patient results. She enters the result into the portal (LabDaq), which is integrated with the NMDOH. She confirmed that she runs a pending report from the portal to catch any missing COVID-19 patient results. When asked if she has a way of checking if NMDOH received what she sent, she answered "no". E. Review of the patient test results and the information gathered during the interviews, the lab did not

	have a mechanism or procedure in place to track which patient test results were reported to the NMDOH.