Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 32D2207990	(X3) Date Survey Completed 03/30/2022
Name of Provider or Supplier New Mexico Urgent Care Walk-In Clinic Llc	**Street Address, City, State** 3111 Eubank Blvd Ne, Albuquerque, 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 an CMS-3401-IFC survey completed on March 30, 2022 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: I. Based on direct observation, review of Manufacturer's Instructions for Use, and interviews with the staff, the laboratory failed to monitor and document the room temperature and humidity of 3 of 3 testing and storage areas, as required by the manufacturer's instructions. Findings included: 1. During a tour of the 3 laboratory areas on 03/30/2022 at 9:15 am, the following test kits were observed: a. Sienna Covid -19 Antigen Rapid Test Cassettes/kits - located in the cabinets in the main Laboratory area, nearest the employee lounge and in the cabinet in the COVID-19 collection room. There was a total of 21 boxes/ kits (Lot #22020207 Exp. 01/10 /2023). b. Henry Schein One Step+ Strep A Dipstick kits - located in the cabinet, in the laboratory near the COVID-19 collection room. There was a total of 3 boxes/kits (Lot STA0122006 Exp. 11-30-2022). c. Henry Schein One Step+ Mono kit - located in the cabinet, in the laboratory near the COVID-19 collection room. There was a total of 1 box/kit (Lot MONO062015 Exp. 05/31/2022). d. Henry Schein One Step+ Ultra Flu test kit - located in the cabinet, in the laboratory near the COVID-19 collection room. There was a total of 1 box/kit (Lot 06201291 Exp. 03/31/2022). e. Henry Schein One Step+ hCG Urine Strip test/kit - located in the cabinet, in the laboratory near the COVID-19 collection room. There was a total of 1 box/kit (Lot#ACG1102031 Exp. 09/30/2023). f. Quidel QuickVue SARS Antigen Test kits -

located in the cabinets, in the main Laboratory area, nearest the employee lounge. There was a total of 3 boxes/kits (Lot#707496 Exp 1112012022). g. Clarity BG 1000-Blood Glucose Monitoring System - in the cabinets, in the main Laboratory area, nearest the employee lounge. There was a total of 13 packages containing the test strips (Lot#02104120 Exp. 03/31/2023). h. UriSpec Plus V2.01 (Model # UR32496) - This analyzer and the 11-way UriSpec test strips were sitting on the counter in the main laboratory near the employee lounge. There was a total of 1 container of UriSpec 11-way urine test strips (Lot#651371 Exp. 10/31/2023). 2. Review of the Manufacturer's Instructions for Use revealed the following temperature storage requirements for each of the following testing kits; a. The manufacturer's instructions of the Sienna Covid -19 Antigen Rapid Test Cassette stated; "The test kit should be stored as packaged at room temperature or refrigerated 2C - 30C (36 - 86F)." b. The manufacturer's instructions of the Henry Schein One Step+ Strep A Dipstick kit stated; "The kit can be stored at room temperature or refrigerated 2C - 30C." c. The manufacturer's instructions of the Henry Schein One Step+ Mono kit stated; "Store the Test Sticks and reagents tightly capped at 15C to 30C (59 - 86F)." d. The manufacturer's instructions of the Henry Schein One Step+ Ultra Flu test kit stated; "Store the Henry Schein One Step+ Ultra Flu Test at room temperature (15 - 30C/59 - 86F) in the original packaging, away from direct sunlight. Kit contents are stable until the expiration date printed on the kit box." e. The manufacturer's instructions of the Henry Schein One Step+ hCG Urine Strip test/kit stated; ""Store as packaged in the sealed pouch at 2C - 30C (36 - 86F)." f. The manufacturer's instructions of the Quidel QuickVue SARS Antigen Test kit stated; "Store the kit at room temperature, 59F to 86F (15C to 30C), out of direct sunlight. Kit contents are stable until the expiration date printed on the outer box. Do not freeze." g. The manufacturer's User Manual of the Clarity BG 1000-Blood Glucose Monitoring System stated; "Do not store or use the meter or test strips at high humidity levels, such as in the bathroom or kitchen." The following temperature requirements listed are; "Operating Humidity 10-90% RH", "Storage Temp 39.2 - 86F", and "Operating Temp 50 - 104F." h. The manufacturer's User Manual for the UriSpec Plus V2.01 (Model # UR32496) listed the following instrument requirements; "Range of Ambient Air Temperature 5 - 40C (41 - 104F)" and "Humidity 20 - 80 % RH". 3. During an interview on 03/30/2022 at 9:30 am, the laboratory office manager confirmed there was no process in place for monitoring and recording temperatures and humidity II. Based on direct observation of the UriSpec Plus analyzer, review of operator's manual/manufacturer's instructions and patient test records, and interview, the laboratory failed to follow manufacturer's instructions for performing and documenting Quality Control (QC) for the UriSpec Plus V2.01, Urinalysis instrument/reader for 12 of 12 months (May 2021 to April 2022). Findings included: 1. A tour of the laboratory areas on 03/30/2022 at 9:15 am revealed the laboratory was using a UriSpec Plus analyzer (Serial # UR32496) and the UriSpec 11-way urine test strips (Lot 651371, exp. 10/31/2023) to perform urinalysis testing. 2. The Office Manager was asked to provide the manufacturer's instructions and/or the operator's manual for the UriSpec Plus analyzer. She was not able to provide the manufacturer's instructions or the User manual for the UriSpec. The User Manual was provided by the manufacturer, via email, as requested by the surveyor, on April 04, 2022. The User Manual for the UriSpec Plus stated: "Test at least one known negative and one known positive specimen or control, whenever a new bottle of strips is first opened, for each new shipment, for each new lot or a least monthly .... Positive and Negative control solutions provide a convenient basis for a quality control program." The laboratory failed to perform and record quality control as required by the manufacturer. 3. Review of the patient test records for the UriSpec revealed a total of 106 patients, tested from 01/14/2022 to 3/28/2022. The laboratory did not keep daily patient logs of tested patients prior to 01/14/2022. 4. During an

interview on 03/30/2022 at 09:40 am, Testing Personnel (TP)#1 confirmed that they did not perform QC for the UriSpec Plus instrument. III. Based on direct observation, review of manufacturer's instructions, and interviews with laboratory staff, the laboratory failed to have a mechanism in place to ensure accurate timing for interpretation of results for 6 of 8 test kits, as required by the manufacturer's instructions. Findings included: 1. Direct observation of the collection and testing process on 03/30/2022 at 11:05am for the Sienna Covid-19 Antigen Rapid Test Cassette, revealed the testing person failed to use a timer device when performing patient testing. During the testing process, TP#1 stated that she estimates the approximate time (15 minutes) for the test completion by glancing over at the nearby computer, making a mental note of the start time, then estimating the completion time for the test to be read and interpreted. 2. Review of the manufacturer's instructions revealed 6 test kits had the following timing requirements; a. Sienna Covid-19 Antigen Rapid Test Cassette: The manufacturer's instructions stated, "Read and interpret the results at 10 minutes, do not interpret the results after 20 minutes ....Note: Erroneous results can occur if the test results are read before or after 10-20 minutes." b. Henry Schein One Step+ (Strep A Dipstick test): The manufacturer's instructions stated, "Leave the dipstick in the tube and read the result at 5 minutes. The result is invalid after 10 minutes." c. Henry Schein One Step+ (hCG Urine Strip test): The manufacturer's instructions stated, "Read the result at 3-4 minutes. Do not interpret results after the appropriate read time." d. Henry Schein One Step+ (Ultra Flu test Kit): The manufacturer's instructions stated, "Read test at 10 minutes." e. Henry Schein One Step+ (Ultra Mono Test Kit): The manufacturer's instructions stated, "Read results at 5 minutes." f. Quidel QuickVue SARS Antigen Test: The manufacturer's instructions stated, "At ten (10) minutes, the appearance of ANY shade of a pink-to-red Test Line AND the appearance of a blue procedural Control Line indicates a positive result for the presence of SARS antigen. Results will remain stable for five (5) minutes after the recommended read time. Do not read the results more than fifteen minutes after placing into the Reagent Tube." "Test strips should be read between 10-15 minutes after placing into the Reagent Tube. False positive, false negative or invalid results may occur if the strip is read beyond the recommended time period." 3. During an interview on 3/30/2022 at 11:25 am, TP#1 confirmed the above findings. IV. Based on review of manufacturer's instructions and interview with the Office Manager, the laboratory failed to provide documentation of training for 3 of 3 testing personnel. Findings included: 1. Review of manufacturer's instructions revealed the following: a. The manufacturer's instructions for the Sienna Covid-19 Antigen Rapid Test Cassette stated; "All operators using your product must be appropriately trained in performing and interpreting the results of your product." b. The manufacturer's instructions for the Quidel QuickVue SARS Antigen Test stated; "All operators using your product must be appropriately trained in performing and interpreting the results of your product." 2. During an interview on 03/30/2022 at 4:20 pm, the Office Manager was asked to provide documentation of testing personnel's training. No documentation was provided. This confirmed the above findings. V. Based on direct observation, and interview with the Office Manager, the laboratory failed to retain manufacturer's instructions for the UriSpec Plus V2.01 analyzer (Serial # UR32496) and for the UriSpec 11-way urinalysis test Strips (Lot #651371 exp 10/31 /2023) as required to assess compliance. Findings included: 1. Direct observation on 03/30/2022 at 09:40 am revealed that testing for Urinalysis was performed on a UriSpec Plus V2.01 analyzer (Serial # UR32496) and the UriSpec 11-way urinalysis test strips (Lot # 651371, expiration date 10/31/2023). 2. During interview on 03/30 /2022 at 2:30 pm with the Office Manager, she confirmed that the manufacturer's instructions for use and/or the User Manual for the UriSpec were not available on site during the inspection and could not be provided to assess compliance.

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 manufacturer instructions, patient testing results, inquiry with New Mexico Public Health Department (NMDOH), and interview with laboratory manager, the laboratory failed to report positive SARS-Co-V-2 test results as required for 5 of 9 days from February 21, 2022 through March 1, 2022. Findings included: 1. Review of the Sienna COVID-19 Antigen Rapid Test Cassette instructions for use (IFU), under the section labeled "Precautions", stated; "Laboratories within the United States and its territories are required to report all results to the appropriate public health laboratories." 2. Review of the Quidel QuickVue SARS Antigen Test instructions for use (IFU), under the section labeled "Conditions of Authorization for the Laboratory and Patient Care Settings", stated; "Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate." 3. SARS-CoV-2 test result reporting documentation was reviewed from February 21, 2022 through March 1, 2022. Ten positive test results were not reported as required for the 5 days. 4. Inquiry with the NMDOH revealed that the laboratory failed to report positive COVID-19 test results for 5 days from February 21, 2022 to March 1, 2022. 5. During an interview on 03/30/2022 at 10:24 am, the office manager stated that only positive COVID-19 results were being faxed to the NMDOH. The office manager was asked to provide documentation of reporting positive COVID-19 results. No documentation was provided.