

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D2031586	(X3) Date Survey Completed 09/01/2020
Name of Provider or Supplier Convenient Care, Llc	Street Address, City, State 207 31st Avenue, Se, Moultrie, 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	An onsite survey was on performed on Sept 1, 2020, to investigate complaint number GA00207409. The allegation was unsubstantiated. The following deficiencies were cited :
D1000	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(c)</p> <p>Certificate of waiver tests. A laboratory may qualify for a certificate of waiver under section 353 of the PHS Act if it restricts the tests that it performs to one or more of the following tests or examinations (or additional tests added to this list as provided under paragraph (d) of this section) and no others: (1) Dipstick or Tablet Reagent Urinalysis (non-automated) for the following: (i) Bilirubin; (ii) Glucose; (iii) Hemoglobin; (iv) Ketone; (v) Leukocytes; (vi) Nitrite; (vii) pH; (viii) Protein; (ix) Specific gravity; and (x) Urobilinogen. (2) Fecal occult blood; (3) Ovulation tests-visual color comparison tests for human luteinizing hormone; (4) Urine pregnancy tests - visual color comparison tests; (5) Erythrocyte sedimentation rate-non-automated; (6) Hemoglobin-copper sulfate-non-automated; (7) Blood glucose by glucose monitoring devices cleared by the FDA specifically for home use; (8) Spun microhematocrit; and (9) Hemoglobin by single analyte instruments with self-contained or component features to perform specimen/reagent interaction, providing direct measurement and readout.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Abbot Sofia 2 system manual, test performance list, and staff interview, the laboratory failed to provide documentation for monitoring the room temperature and relative humidity in the laboratory. The laboratory failed to provide documentation of the receiving of test kits, logging of lot numbers, open dates of test kits, date and results of Quality Control (QC) performance, no written procedure for Quality Assurance (QA), and failed to provide Policy and Procedures for each test kit performed on the Sofia 2 reader. Observation of testing samples showed the specimens were not being labeled with two unique identifiers. Findings: 1. During a</p>

tour of the laboratory on 9/1/20 at approximately 10:10 AM, observation was made of multiple specimens being labeled with the first initial of the patient's first and last name. Interview with the Licensed Practical Nurse (LPN), and Nurse Practitioner (NP), on 09/01/2020 at approximately 10:10 am, in the laboratory, confirmed that the specimens were being labeled with the first and last name initials only. 2. Review of the Standard Operation Procedures (SOP) Manual determined that there was no Procedures for the Sofia 2 reader, or any other testing performed, and there was no procedures/package inserts for each test kit that was being read on the Sofia 2, or any other test performed. The laboratory was performing Rapid Strep, RSV, Flu A+B, Mono, and Covid SARS Antigen testing on the Sofia 2 reader, and Urine dipstick chemistry testing, H. Pylori, and Urine Pregnancy Test. Interview with the LPN on 09/01/2020 at approximately 10:15 am, in the exam room, confirmed there were no procedures specifically for the laboratory, and they did not have a copy of the package insert for each test kit read on the Sofia 2 for review, or other test performed in the laboratory as listed above. 3. The laboratory did not have documentation of training or competencies for each testing personnel for the Sofia 2 reader, the Urine Dipstick Chemistry test, H. Pylori test kit, and the Urine Pregnancy Test kit. Interview with the LPN and NP, on 09/01/2020 at approximately 10:20 am in the exam room, confirmed that the lab did not have training or competency documents for each testing personnel on the above listed test. 4. The laboratory did not have documentation of received dates of new test kit lot numbers, date and QC results for the new test kit lots, and monthly QC if the same kit is still in use for 30 days, or for each shipment received. Interview with the LPN on 09/01/2020 at approximately 10:30 am, in the exam room, confirmed there was not a log for receiving new test kits, documenting Lot numbers, QC performance, and repeat QC every 30 days a kit is open. 5. The laboratory did not have documentation of QC performed each day of patient testing for the testing being performed on the Sofia 2 reader. Interview with the Radiology Tech (RT) on 09/01/2020 at approximately 11:00 am, in the exam room, confirmed that QC was being run, but was not being documented. 6. Review of the patient test report, revealed there was documentation that the patients were being told if their results were POSITIVE, they should quarantine for 10 days, and NEGATIVE they should quarantine for 14 days and follow up with a local Health Department.* Interview with the LPN and NP on 09/01/2020 at approximately 11:30 am, in the exam room, confirmed that they were documenting that the patient was told in their results were POSITIVE, they should quarantine for 10 days, and if NEGATIVE they should quarantine for 14 days and follow up with their local Health Department. 7. The laboratory did not have documentation that the temperature and humidity was within the manufacturers requirements for test performance and test kit storage. The manufacture states the test kits should be stored between 15 - 30 degrees Celsius, and 20 - 85% relative humidity. Collected nasal and Nasopharyngeal samples should be tested immediately, but are stable for 48 hours at 2 -8 degrees Celsius or 59 - 86 degrees Fahrenheit. Interview with the LPN on 09/01/2020 at approximately 12:30 pm, in the exam room, confirmed that the temperature and relative humidity in the storage and testing area was not being monitored, but confirmed that the samples were being brought in immediately to be tested in the laboratory. 8. The laboratory did not have documentation or policy of Quality Assurance (QA) in the laboratory. Interview with the LPN on 09/01/2020 at approximately 1:00 pm, in the exam room, confirmed the laboratory did not have a QA policy and no QA was being performed.