Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 42D0253229	(X3) Date Survey Completed 11/08/2021
Name of Provider or Supplier Doctor's Care - Simpsonville	**Street Address, City, State** 35 Ray E Tally Court, Simpsonville, SC	

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
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: During an onsite recertification and complaint survey on 11/08/2021, based on ID Now COVID 19 package insert review, laboratory procedure manual review, lack of documentation and testing personnel interview the laboratory failed to follow manufacturers' instructions for performing the test quality control for 1 out of 10 months reviewed (January 2021 through October 2021). Findings include: 1. Review of the ID Now COVID 19 package insert revealed that positive and negative controls should be conducted once with each new shipment received and once for each untrained operator. 2. Review of the laboratory procedure manual revealed that for qualitative tests that have an internal procedural control incorporated into the test system, an external positive and negative control must be tested when each new test kit is opened. 3. Review of the laboratory quality control records revealed that quality control results for the following kit/lot shipments for COVID 19 testing were unavailable for review on the day of the survey: a. Lot M163532; opened 09/04/2021 b. Lot 1026879; opened 09/04/2021 c. Lot 1027703; opened 09/05/2021 d. Lot M164450; opened 09/19/2021 4. Testing personnel confirmed during an onsite interview on 11/08/2021 at 1:30pm that the laboratory failed to follow manufacturers' instructions for performing the test quality control for 1 out of 10 months reviewed (January 2021 through October 2021).
D5787	TEST RECORDS CFR(s): 493.1283(a)

	The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: During an onsite recertification and complaint survey on 11/08/2021, based on procedure manual review, laboratory test log review, and testing personnel interview the laboratory failed to maintain the records and dates of specimen testing, including the identity of the personnel who performed the test(s) for one of two patients reviewed. Findings include: 1. Review of the laboratory procedure manual revealed that all test results are recorded on test worksheets in the laboratory which include the patients name and patient number, date and time of analysis, test results, initials of the individuals performing the test, and description of less than optimal specimens. 2. Review of the laboratory test log revealed the following: a. patient MA; COVID 19 test performed 09/05/2021-patient number, test result testing personnel identification not documented. 3. Testing personnel confirmed during an onsite interview on 11/08 /2021 that the laboratory failed to maintain the records and dates of specimen testing, including the identity of the personnel who performed the test(s) for one of two patients reviewed