

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 07D2112724	<b>(X3) Date Survey Completed</b> 10/22/2020
<b>Name of Provider or Supplier</b> Docs Medical Inc- Southington	<b>Street Address, City, State</b> 832 Queen St, Southington, CT	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A complaint investigation of the DOCS Medical Inc- Southington was conducted pursuant to 42CFR Part 493 of the Clinical Laboratory Improvement Amendments (CLIA) of 1988.
<b>D1001</b>	<p><b>CERTIFICATE OF WAIVER TESTS</b> CFR(s): 493.15(e)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review, surveyor observation and staff interview, the laboratory failed to follow the manufacturer's instructions for adding the correct sample volume into the Sofia SARS Antigen FIA test cassette. Findings include: 1. Record review on 10/22/2020 of the Quidel Sofia SARS Antigen FIA manufacturer instructions revealed the following statements: a. "Warnings and Precautions:...To obtain accurate results, the Package Insert instructions must be followed... Do not pour sample from the Reagent Tube into the Test Cassette sample well. Use the provided Small, Clear 120 ul Fixed Volume Pipette when adding the sample to the Test Cassette." b. "Test Procedure: ....Fill the provided Small, Clear 120 ul Fixed Volume Pipette with the patient sample from the Reagent Tube...Note: The Fixed Volume Pipettes are designed to collect and dispense the correct amount of liquid sample...Note: Do not pour sample from the Reagent Tube. Use the provided Small, Clear 120 ul Fixed Volume Pipette." c. "Limitations: ...Failure to follow the Test Procedure may adversely affect test performance and/or invalidate the test result." 2. Record review of the laboratory's 'How to do a COVID test (SARS) using Sofia' procedure on 10/22/2020 revealed: a. The above procedure was not signed or dated. b. Instructions to 'squeeze the top bulb on the pipette and draw up the solution' was noted. 3. Surveyor observation on 10/22/2020 at 11:38 AM of the laboratory's collection and testing</p>

process for the Sofia SARS Antigen FIA test revealed: a. After sample collection, the nasal swab was placed into the reagent tube, swirled around and left for one minute. b. The swab was then pressed against the side of the reagent tube to remove the excess liquid and discarded. c. Testing personnel #1 (TP#1) poured the entire contents of the reagent tube directly into the test cassette sample well without using the fixed volume pipette provided by the manufacturer. 4. Staff interview with TP#1 on 10/22/2020 at 11:39 AM confirmed when performing the Sofia SARS Antigen FIA test he/she pours the entire contents of the reagent tube into the sample well on the testing cassette. TP#1 was not aware of the requirement to use the fixed volume pipette supplied with the test kit to inoculate the test cassette. 5. Staff interviews with 2 of 2 other testing personnel on 10/22/2020 at 11:45 AM confirmed they did not use the supplied fixed volume pipette to inoculate the test cassette sample well and poured the reagent tube contents. 6. The laboratory has performed 4,884 Sofia SARS Antigen FIA tests since 7/28/2020.

**D8100**

**INSPECTION REQUIREMENTS**  
CFR(s): 493.1771

Each laboratory issued a CLIA certificate must meet the requirements in 493.1773 and the specific requirements for its certificate type, as specified in 493.1775 through 493.1780. All CLIA-exempt laboratories must comply with the inspection requirements in 493.1773 and 493.1780, when applicable.

This CONDITION is not met as evidenced by:  
Based on review of the manufacturer's instructions for use, surveyor observation and staff interview, the laboratory failed to meet the requirements in 493.1773 and specific requirements for its certificate type 493.1775 through 493.1780 for SARS COV Antigen testing. Findings include: 1. The laboratory was performing SARS COV Antigen testing on a sample size other than that required by the manufacturer. Refer to D8201.

**D8201**

**INSPECTION OF COW OR PPMP LABS**  
CFR(s): 493.1775(b)

(b) If necessary, CMS or a CMS agent may conduct an inspection of a laboratory issued a certificate of waiver or a certificate for provider-performed microscopy procedures at anytime during the laboratory's hours of operation to do the following: (b)(1) Determine if the laboratory is operated and testing is performed in a manner that does not constitute an imminent and serious risk to public health. (b)(2) Evaluate a complaint from the public. (b)(3) Determine whether the laboratory is performing tests beyond the scope of the certificate held by the laboratory. (b)(4) Collect information regarding the appropriateness of tests specified as waived tests or provider-performed microscopy procedures.

This STANDARD is not met as evidenced by:  
Based on review of the manufacturer's instructions for use, surveyor observation and staff interview, the laboratory failed to perform SARS COV Antigen testing on a sample size required by the manufacturer. Findings include: 1. Record review on 10/22/2020 of the Sofia SARS Antigen FIA manufacturer instructions revealed the following statements: a. "Warnings and Precautions:...To obtain accurate results, the Package Insert instructions must be followed... Do not pour sample from the Reagent

Tube into the Test Cassette sample well. Use the provided Small, Clear 120 ul Fixed Volume Pipette when adding the sample to the Test Cassette." b. "Test Procedure: .... Fill the provided Small, Clear 120 ul Fixed Volume Pipette with the patient sample from the Reagent Tube...Note: The Fixed Volume Pipettes are designed to collect and dispense the correct amount of liquid sample...Note: Do not pour sample from the Reagent Tube. Use the provided Small, Clear 120 ul Fixed Volume Pipette." c. "Limitations: ...Failure to follow the Test Procedure may adversely affect test performance and/or invalidate the test result." 2. Record review of the laboratory's 'How to do a COVID test (SARS) using Sofia' procedure on 10/22/2020 revealed: a. The above procedure was not signed or dated. b. Instructions to 'squeeze the top bulb on the pipette and draw up the solution' was noted. 3. Surveyor observation on 10/22/2020 at 11:38 AM of the laboratory's collection and testing process for the Sofia SARS Antigen FIA test revealed: a. After sample collection, the nasal swab was placed into the reagent tube, swirled around and left for one minute. b. The swab was then pressed against the side of the reagent tube to remove the excess liquid and discarded. c. Testing personnel #1 (TP#1) poured the entire contents of the reagent tube directly into the test cassette sample well without using the fixed volume pipette provided by the manufacturer. 4. Staff interview with TP#1 on 10/22/2020 at 11:39 AM confirmed when performing the Sofia SARS Antigen FIA test he/she pours the entire contents of the reagent tube into the sample well on the testing cassette. TP#1 was not aware of the requirement to use the fixed volume pipette supplied with the test kit to inoculate the test cassette. 5. Staff interviews with 2 of 2 other testing personnel on 10/22/2020 at 11:45 AM confirmed they did not use the supplied fixed volume pipette to inoculate the test cassette sample well and poured the reagent tube contents. 6. The laboratory has performed 4,884 Sofia SARS Antigen FIA tests since 7/28/2020.