

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2235166	(X3) Date Survey Completed 03/14/2022
Name of Provider or Supplier Easy Lab Services Inc	Street Address, City, State 4909 W Division St - Ste 511, Chicago, IL	
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	<p>Laboratory location: 7474 W Military Drive San Antonio, Texas 78227 The laboratory was operating as a temporary testing site under the CLIA certificate for: Easy Lab Services 566 N Ellsworth Ave Addison, IL 60101 CLIA number: 14D2235166 During an interview with the testing personnel on 03/14/2022 at 11:05 am in the testing area, he was asked to provide documentation of the laboratory's CLIA certificate. He provided picture on his cell phone of the CLIA certificate for Easy Lab Services as identified above. He stated the facility was a temporary testing site for the Illinois laboratory. He stated all patient forms were sent to the parent laboratory at the end of the day.</p>
D1001	<p>CERTIFICATE OF WAIVER TESTS 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 review of the manufacturer's instructions, surveyor observation of testing being performed and staff interview, it was revealed the laboratory failed to follow the manufacturer's instructions for: A) storage for 1 of 1 test kits, B) collection of the sample, C) rotation of the swab in the diluent, D) addition of the diluent to the test device E) interpreting the test results at the required time, and F) training for 1 of 1 testing personnel. The findings include: A) Storage of test kits 1. A review of the manufacturer's instructions for the Phase Scientific Indicaid Covid-19 Rapid Antigen Test (IC04QS2021, PI-2110400ENG, Rev A, July 2021) under the section titled "Storage and Stability" revealed: "Store the test kit in a cool, dry place between 2-30C (36-86F). Do not freeze." And, under "Limitations" "Test performance is dependent upon proper specimen collection, handling, storage and preparation. Failure to follow proper procedures may produce inaccurate results." 2. Surveyor observation on 03/14</p>

/2022 at 11:05 am identified the only box of test kits available for testing was inside the testing person's automobile on the floorboard on the passenger's side of the car. The kit was removed from the vehicle and then placed in a cooler with ice. Neither the car or the cooler had a thermometer to monitor the temperature to ensure the kits were kept at the required temperature. 3. The laboratory was asked to provide documentation of monitoring the temperature of wherever the kit was stored. No documentation was provided. 4. The laboratory reported performing 9468 tests from January 6, 2022 to March 13, 2022 (see patient alias list). 5. An interview with the testing personnel on 03/14/2022 at 11:08 am revealed the temperature was not monitored where the kit was stored. He stated the kit was either in his car or in the cooler during the day when testing was occurring. This confirmed the findings. B) Collection of the swab 1. A review of the manufacturer's instructions for the Phase Scientific Indicaid Covid-19 Rapid Antigen Test (IC04QS2021, PI-2110400ENG, Rev A, July 2021) under the section titled "Specimen Collection, Handling and Transport" revealed: "Insert the entire collection tip of the swab provided (usually 1/2 to 3/4 of an inch, or 1 to 1.5 cm) inside the nostril. Firmly sample the nasal wall by rotating the swab in a circular path against the nasal wall at least 4 times. Take approximately 15 seconds to collect the specimen. Be sure to collect any nasal drainage that may be present on the swab. Repeat in the other nostril using the same swab." And, "Inadequate specimen collection or improper handling, storage and transport may lead to incorrect results." And, under "Limitations" "Test performance is dependent upon proper specimen collection, handling, storage and preparation. Failure to follow proper procedures may produce inaccurate results." 2. Surveyor observation on 03/14/2022 at 11:15 am of the testing person instructing a patient to self-collect by rotating the swab in both nostrils for approximately 5 seconds total. 3. An interview with the testing person on 03/14/2022 at 11:30 am in the testing area revealed he did not know the collection of the swab required at least 4 rotations of the swab for a time of 15 seconds in each nostril. He stated all patients that he instructed were told 5 seconds for both nostrils was enough time. He added that he was the only testing person who performed the testing at this facility. This confirmed the findings. 4. The laboratory reported performing 9468 tests from January 6, 2022 to March 13, 2022 (see patient alias list). C) Rotation of swab in diluent 1. A review of the manufacturer's instructions for the Phase Scientific Indicaid Covid-19 Rapid Antigen Test (IC04QS2021, PI-2110400ENG, Rev A, July 2021) under the section titled "Specimen Collection, Handling and Transport" revealed: "Stir the swab into the Buffer Solution, ensuring that the swab head is fully submerged by tilting the vial. Twist the swab back and forth 20 times in the Buffer Solution. Roll the swab head against the inner wall of the vial to release the liquid from the swab, then discard the swab." And, "Inadequate specimen collection or improper handling, storage and transport may lead to incorrect results." And, under "Limitations" "Test performance is dependent upon proper specimen collection, handling, storage and preparation. Failure to follow proper procedures may produce inaccurate results." 2. Surveyor observation on 03/14/2022 at 11:12 am in the testing area revealed the testing person rotated the swab in the buffer solution a total of 7 times. 3. An interview with the testing person on 03/14/2022 at 11:30 am revealed he rotated the swab between 7 - 10 times in the buffer and was unaware the manufacturer's instructions stated the swab needed to be rotated 20 times against the inner wall of the vial. This confirmed the findings. 4. The laboratory reported performing 9468 tests from January 6, 2022 to March 13, 2022 (see patient alias list). The testing person stated he was the only person who performed testing at this location. D) Addition of diluent to test device 1. A review of the manufacturer's instructions for the Phase Scientific Indicaid Covid-19 Rapid Antigen Test (IC04QS2021, PI-2110400ENG, Rev A, July 2021) under the section titled "Test Procedure for Patient Swabs" revealed: "Remove the purple top

half of the cap to expose the dropper tip. Hold the vial vertically above the sample well (S). Slowly squeeze and apply 3 drops of the Buffer Solution into the sample well (S) of the Test Device." And, under "Limitations" "Test performance is dependent upon proper specimen collection, handling, storage and preparation. Failure to follow proper procedures may produce inaccurate results." 2. Surveyor observation on 03/14/2022 at 11:15 am in the testing area revealed the testing person did not recap the diluent with the purple cap after rotating the swab in the buffer solution. He poured the entire contents of the diluent vial into the sample well of the test device. 3. An interview with the testing person on 03/14/2022 at 11:30 am revealed he did not know the purple cap was to be placed back on the diluent vial and that only three drops were to be added to the sample well. This confirmed the findings. 4. The laboratory reported performing 9468 tests from January 6, 2022 to March 13, 2022 (see patient alias list). The testing person stated he was the only person who performed testing at this location. E) Interpreting the test results at the required time 1. A review of the manufacturer's instructions for the Phase Scientific Indicaid Covid-19 Rapid Antigen Test (IC04QS2021, PI-2110400ENG, Rev A, July 2021) under the section titled "Test Procedure for Patient Swabs" revealed: "Read the test line (T) and control line (C) promptly at 20 minutes, and not earlier to ensure proper test performance." And, under "Limitations" "Test performance is dependent upon proper specimen collection, handling, storage and preparation. Failure to follow proper procedures may produce inaccurate results." 2. Surveyor observation on 03/14/2022 at 11:24 am in the testing area revealed the testing person interpreted the results 8 minutes and 47 seconds after the addition of the sample to the sample well. 3. An interview with the testing person on 03/14/2022 at 11:30 am revealed he interpreted the results after 10 minutes. He was asked if he used a timer to determine how long the sample was in the test device and he said 'no'. He would estimate when 10 minutes had passed. This confirmed the findings. 4. The laboratory reported performing 9468 tests from January 6, 2022 to March 13, 2022 (see patient alias list). The testing person stated he was the only person who performed testing at this location. F) Training of testing personnel 1. A review of the manufacturer's instructions for the Phase Scientific Indicaid Covid-19 Rapid Antigen Test (IC04QS2021, PI-2110400ENG, Rev A, July 2021) under the section titled "Intended Use" revealed: "The INDICAID COVID-19 Rapid Antigen Test in intended for use by trained clinical laboratory personnel..." 2. The laboratory was asked to provide documentation of the testing person being trained on how to perform the test procedure. No documentation was provided. 3. An interview with the testing person on 03/14/2022 at 12:15 hours at the testing table revealed that he read the package insert and started performing the test. All the steps which he was doing incorrectly were pointed out to him and he simply stated he was unaware of the stated manufacturer requirements. This confirmed the findings. 4. The laboratory reported performing 9468 tests from January 6, 2022 to March 13, 2022 (see patient alias list). The testing person stated he was the only person who performed testing at this location.

D6076

LABORATORY DIRECTOR
CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:
Based on review of the manufacturer's instructions for the Phase Scientific Indicaid

COVID-19 Rapid Antigen Test, surveyor observation, and staff interview, it was revealed the laboratory director failed to ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing (Refer to D6082).

D6082

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(1)

The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing.

This STANDARD is not met as evidenced by:

Based on review of the manufacturer's instructions for the Phase Scientific Indicaid COVID-19 Rapid Antigen Test, surveyor observation, and staff interview, it was revealed the laboratory director failed to ensure test systems used in the laboratory provide quality laboratory services for all aspects of test performance for the Phase Scientific Indicaid COVID-19 rapid antigen testing and failed to follow the manufacturer's instructions for: A) storage for 1 of 1 test kits, B) collection of the sample, C) rotation of the swab in the diluent, D) addition of the diluent to the test device E) interpreting the test results at the required time, and F) training for 1 of 1 testing personnel. The findings include: A) Storage of test kits 1. A review of the manufacturer's instructions for the Phase Scientific Indicaid Covid-19 Rapid Antigen Test (IC04QS2021, PI-2110400ENG, Rev A, July 2021) under the section titled "Storage and Stability" revealed: "Store the test kit in a cool, dry place between 2-30C (36-86F). Do not freeze." And, under "Limitations" "Test performance is dependent upon proper specimen collection, handling, storage and preparation. Failure to follow proper procedures may produce inaccurate results." 2. Surveyor observation on 03/14/2022 at 11:05 am identified the only box of test kits available for testing was inside the testing person's automobile on the floorboard on the passenger's side of the car. The kit was removed from the vehicle and then placed in a cooler with ice. Neither the car or the cooler had a thermometer to monitor the temperature to ensure the kits were kept at the required temperature. 3. The laboratory was asked to provide documentation of monitoring the temperature of wherever the kit was stored. No documentation was provided. 4. The laboratory reported performing 9468 tests from January 6, 2022 to March 13, 2022 (see patient alias list). 5. An interview with the testing personnel on 03/14/2022 at 11:08 am revealed the temperature was not monitored where the kit was stored. He stated the kit was either in his car or in the cooler during the day when testing was occurring. This confirmed the findings. B) Collection of the swab 1. A review of the manufacturer's instructions for the Phase Scientific Indicaid Covid-19 Rapid Antigen Test (IC04QS2021, PI-2110400ENG, Rev A, July 2021) under the section titled "Specimen Collection, Handling and Transport" revealed: "Insert the entire collection tip of the swab provided (usually 1/2 to 3/4 of an inch, or 1 to 1.5 cm) inside the nostril. Firmly sample the nasal wall by rotating the swab in a circular path against the nasal wall at least 4 times. Take approximately 15 seconds to collect the specimen. Be sure to collect any nasal drainage that may be present on the swab. Repeat in the other nostril using the same swab." And, "Inadequate specimen collection or improper handling, storage and transport may lead to incorrect results." And, under "Limitations" "Test performance is dependent upon proper specimen collection, handling, storage and preparation.

Failure to follow proper procedures may produce inaccurate results." 2. Surveyor observation on 03/14/2022 at 11:15 am of the testing person instructing a patient to self-collect by rotating the swab in both nostrils for approximately 5 seconds total. 3. An interview with the testing person on 03/14/2022 at 11:30 am in the testing area revealed he did not know the collection of the swab required at least 4 rotations of the swab for a time of 15 seconds in each nostril. He stated all patients that he instructed were told 5 seconds for both nostrils was enough time. He added that he was the only testing person who performed the testing at this facility. This confirmed the findings. 4. The laboratory reported performing 9468 tests from January 6, 2022 to March 13, 2022 (see patient alias list). C) Rotation of swab in diluent 1. A review of the manufacturer's instructions for the Phase Scientific Indicaid Covid-19 Rapid Antigen Test (IC04QS2021, PI-2110400ENG, Rev A, July 2021) under the section titled "Specimen Collection, Handling and Transport" revealed: "Stir the swab into the Buffer Solution, ensuring that the swab head is fully submerged by tilting the vial. Twist the swab back and forth 20 times in the Buffer Solution. Roll the swab head against the inner wall of the vial to release the liquid from the swab, then discard the swab." And, "Inadequate specimen collection or improper handling, storage and transport may lead to incorrect results." And, under "Limitations" "Test performance is dependent upon proper specimen collection, handling, storage and preparation. Failure to follow proper procedures may produce inaccurate results." 2. Surveyor observation on 03/14/2022 at 11:12 am in the testing area revealed the testing person rotated the swab in the buffer solution a total of 7 times. 3. An interview with the testing person on 03/14/2022 at 11:30 am revealed he rotated the swab between 7 - 10 times in the buffer and was unaware the manufacturer's instructions stated the swab needed to be rotated 20 times against the inner wall of the vial. This confirmed the findings. 4. The laboratory reported performing 9468 tests from January 6, 2022 to March 13, 2022 (see patient alias list). The testing person stated he was the only person who performed testing at this location. D) Addition of diluent to test device 1. A review of the manufacturer's instructions for the Phase Scientific Indicaid Covid-19 Rapid Antigen Test (IC04QS2021, PI-2110400ENG, Rev A, July 2021) under the section titled "Test Procedure for Patient Swabs" revealed: "Remove the purple top half of the cap to expose the dropper tip. Hold the vial vertically above the sample well (S). Slowly squeeze and apply 3 drops of the Buffer Solution into the sample well (S) of the Test Device." And, under "Limitations" "Test performance is dependent upon proper specimen collection, handling, storage and preparation. Failure to follow proper procedures may produce inaccurate results." 2. Surveyor observation on 03/14/2022 at 11:15 am in the testing area revealed the testing person did not recap the diluent with the purple cap after rotating the swab in the buffer solution. He poured the entire contents of the diluent vial into the sample well of the test device. 3. An interview with the testing person on 03/14/2022 at 11:30 am revealed he did not know the purple cap was to be placed back on the diluent vial and that only three drops were to be added to the sample well. This confirmed the findings. 4. The laboratory reported performing 9468 tests from January 6, 2022 to March 13, 2022 (see patient alias list). The testing person stated he was the only person who performed testing at this location. E) Interpreting the test results at the required time 1. A review of the manufacturer's instructions for the Phase Scientific Indicaid Covid-19 Rapid Antigen Test (IC04QS2021, PI-2110400ENG, Rev A, July 2021) under the section titled "Test Procedure for Patient Swabs" revealed: "Read the test line (T) and control line (C) promptly at 20 minutes, and not earlier to ensure proper test performance." And, under "Limitations" "Test performance is dependent upon proper specimen collection, handling, storage and preparation. Failure to follow proper procedures may produce inaccurate results." 2. Surveyor observation on 03/14/2022 at 11:24 am in the testing area revealed the testing person interpreted the results 8

minutes and 47 seconds after the addition of the sample to the sample well. 3. An interview with the testing person on 03/14/2022 at 11:30 am revealed he interpreted the results after 10 minutes. He was asked if he used a timer to determine how long the sample was in the test device and he said 'no'. He would estimate when 10 minutes had passed. This confirmed the findings. 4. The laboratory reported performing 9468 tests from January 6, 2022 to March 13, 2022 (see patient alias list). The testing person stated he was the only person who performed testing at this location. F)

Training of testing personnel 1. A review of the manufacturer's instructions for the Phase Scientific Indicaid Covid-19 Rapid Antigen Test (IC04QS2021, PI-2110400ENG, Rev A, July 2021) under the section titled "Intended Use" revealed: "The INDICAID COVID-19 Rapid Antigen Test is intended for use by trained clinical laboratory personnel..." 2. The laboratory was asked to provide documentation of the testing person being trained on how to perform the test procedure. No documentation was provided. 3. An interview with the testing person on 03/14/2022 at 12:15 hours at the testing table revealed that he read the package insert and started performing the test. All the steps which he was doing incorrectly were pointed out to him and he simply stated he was unaware of the stated manufacturer requirements. This confirmed the findings. 4. The laboratory reported performing 9468 tests from January 6, 2022 to March 13, 2022 (see patient alias list). The testing person stated he was the only person who performed testing at this location.