Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D2076793	10/27/2020
Name of Provider or Supplier	**Street Address, City, State**	
Arcpoint Labs Of Eastern Carolina	2780 Dickinson Ave, Greenville, NC	

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 unannounced complaint investigation survey was conducted 10/27/20. Based on the survey findings, Immediate Jeopardy was identified and the laboratory was notified 10/28/20 at approximately 2:45 p.m. The laboratory failed to follow manufacturer's instructions for performing the Quidel Sofia SARS Antigen FIA assay for COVID-19 to ensure accurate and reliable patient test results.
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 record review, the absence of records, observation, review of the FDA (Food and Drug Administration) website, review of manufacturer's instructions, and interview with staff 10/27/20, the laboratory failed to follow manufacturer's instructions for performance of the Quidel Sofia SARS Antigen FIA test. See 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:
A. Based on record review, the absence of records, observation, review of the FDA (Food and Drug Administration) website, review of manufacturer's instructions, and interview with staff 10/27/20, the laboratory failed to follow manufacturer's instructions for performing the Quidel Sofia SARS Antigen FIA test. Findings: 1. The laboratory failed to have a copy of the manufacturer's IFU (Instructions for Use) for the Quidel Sofia SARS Antigen FIA test available to personnel who perform the test. Review of the FDA website revealed manufacturer's instructions for the Quidel Sofia SARS Antigen FIA test "For use under the Emergency Use Authorization (EUA) only". During interview at approximately 11:00 a.m., the medical assistant confirmed that the laboratory did not have the manufacturer's instructions for performing the test. She stated their sister office should have them because they are making a procedure manual for both locations. At approximately 1:20 p.m., the medical assistant stated they had the instructions at one time, but she was unsure what happened to them. 2. The laboratory failed to follow manufacturer's IFU to ensure testing personnel were trained prior to testing patients for SARS-CoV-2 using the Quidel Sofia SARS Antigen FIA test kit. Manufacturer's instructions printed from the FDA website state "INTENDED USE ... The Sofia SARS Antigen FIA is intended for use by trained clinical laboratory personnel and individuals trained in point of care settings, and proficient in performing tests using the Sofia and Sofia 2 instruments. ... CONDITIONS OF AUTHORIZATION FOR THE LABORATORY ... All operators using your product must be appropriately trained in performing and interpreting the results of your product, use appropriate personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling. ..." During interview at approximately 10:35 a.m., the medical assistant stated that the laboratory received their supplies in late June 2020 and started using the Quidel Sofia SARS Antigen FIA for patient testing approximately 7/3/20. Review of laboratory records revealed personnel training was documented on 9/2/20 and 9/3/20, approximately two months after patient testing started. During interview at approximately 2:00 p.m., the medical assistant stated that the training documents were from the online training required by the manufacturer. She stated she also trained the other testing personnel, but the on-site training she did was not documented. 3. The laboratory failed to monitor the temperature of the area where Quidel Sofia SARS Antigen FIA test kits were stored and testing was conducted to ensure manufacturer's IFU were followed. Manufacturer's instructions printed from the FDA website require that kits be stored "at room temperature, 59 degrees F (Fahrenheit) to 86 degrees F (15 degrees C {Celsius} to 30 degrees C), out of direct sunlight. ..." Manufacturer's instructions also state "All clinical samples must be at room temperature before beginning the assay. ..." At approximately 1:00 p.m., surveyors observed kits stored in a cabinet in the laboratory area. There was no thermometer in the laboratory area. During interview at approximately 1:42 p.m., the medical assistant stated that the laboratory does not have a thermometer and they use the thermostat in the hallway to monitor the temperature. She stated they use temperature guns to check the temperature of patients. She also confirmed that the laboratory had not documented the room temperature on a daily basis to ensure proper storage of test kits and testing of patient specimens. 4. The laboratory failed to follow manufacturer's IFU to ensure public health authorities were notified when testing was initiated. Manufacturer's instructions printed from the FDA website state "Authorized laboratories using your product will notify the relevant public health authorities of their intent to run your product prior to initiating testing."

	The laboratory failed to notify the Division of Health Service Regulation that SARS-CoV-2 antigen testing was added to their test menu in July 2020. 5. The laboratory failed to follow manufacturer's IFU to ensure Fact Sheets were included with patient results. Manufacturer's instructions printed from the FDA website state "Authorized laboratories using your product will include with test result reports, all authorized Fact Sheets. ..." Review of the FDA website revealed a "FACT SHEET FOR PATIENTS" and a "FACT SHEET FOR HEALTHCARE PROVIDERS". Review of a random patient test report from 10/26/20 revealed the results did not include either of the fact sheets. During interview at approximately 2:30 p.m., the medical assistant confirmed that the fact sheets were not sent to the patient with the laboratory's results. She stated they did not know it was required. 6. The laboratory failed to follow manufacturer's IFU to establish a process for reporting patient test results to state and/or local public health authorities. Manufacturer's instructions printed from the FDA website state "Authorized laboratories using your product will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate. ..." The laboratory did not have written instructions in place for reporting patient SARS-CoV-2 antigen test results to state and/or local public health authorities. During interview at approximately 10:10 a.m., the medical assistant confirmed that the laboratory did not have a written policy or procedure for reporting patient SARS-CoV-2 antigen test results to the state and local health departments. She stated that they fax results to local health departments and all employees know how to fax. She also stated they send the number of positive and negative test results to their sister facility each day and their sister facility uses a portal to report results from both locations to the state. She stated their sister facility should have instructions for reporting results. B. Based on observation and interview with staff 10/27/20, the laboratory failed to ensure specimen collection tubes that exceeded the manufacturer's expiration dates were discarded and not used for patient specimen collection. At approximately 2:15 p.m., the surveyors observed multiple types of BD (Becton Dickinson) Vacutainer collection tubes in bins in one of the facility's patient rooms. Random review of the bins revealed collection tubes of different types and different lot numbers stored in the same bin. Some of the collection tubes had exceeded their expiration dates and were available for use. Examples: a. SST lot #8206533, expiration date 7/31/19 and lot #9003860, expiration date 12/31/19 b. Sodium citrate lot #B190237, expiration date 7/31/19 and lot #8345993, expiration date 8/31/19; c. PPT Plasma K2E lot #8303924, expiration date 11/30/19; d. Yellow Top Sterile, lot #8215641, expiration date 8/31/19; e. Trace Element, lot #368381, expiration date 11 /30/19; f. CAT Serum Separator Clot Activator lot #B18083TQ, expiration date 12/16 /19 and lot #B19053AB, expiration date 9/12/20; g. SST lot #9003860, expiration date 12/31/19; h. Lithium Heparin, lot # 9004566, expiration date 1/31/20; i. Sodium Fluoride Potassium Oxalate lot #8249553, expiration date 2/29/20, lot #8303713, expiration date 3/31/20, and lot #A190249P, expiration date 6/9/20; j. 6.0 ml (milliliter) Serum lot #8317596, expiration date 3/31/20; k. K2 EDTA lot #8345589, expiration date 4/30/20, lot #8303710, expiration date 4/30/20, and lot B19023K9, expiration date 6/15/20; l. 4.0 ml Serum lot #9003750, expiration date 4/30/20; m. Sodium Heparin, lot #B19043EG, expiration date 10/14/20. During interview at approximately 2:20 p.m., the medical assistant stated that she was aware some of the collection tubes were expired and she stated they just received some of them. She stated they use them to collect specimens to send to outside laboratories.