Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0280394	09/21/2020
Name of Provider or Supplier	**Street Address, City, State**	
Florida Family Laboratory, Inc Dba	7290 Southwest 42nd Street, Miami, FL	

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 survey (#2020014101) was conducted on 09/14/20 - 09/21 /20 at Florida Family Laboratory Inc. DBA Lab 24. The facility was not in compliance with 42 CFR 493, Requirement for clinical laboratories. The following Conditions were cited: D3000 Facility Administration 493.1100 D5300 Preanalytic Systems 493.1240 D5800 Postanalytic Systems 493.1290 D6076 Laboratory Director 493.1441
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). This CONDITION is not met as evidenced by: Based on record review and interview with the Office Manager the laboratory failed to follow the State of Florida Emergency Rule to report all positive and negative COVID-19 test results immediately to the Department Of Health (DOH) for 27 out of 27 Patient reports reviewed (See D3009).
D3005	FACILITIES CFR(s): 493.1101(a)(3) Molecular amplification procedures that are not contained in closed systems have a uni-directional workflow. This must include separate areas for specimen preparation, amplification and product detection, and, as applicable, reagent preparation. This STANDARD is not met as evidenced by:

	Based on observation and interview with the Technical Supervisor the laboratory failed to have a uni-directional workflow for the molecular COVID-19 testing. Findings Included: During a tour of the laboratory on 09/15/20 at 10:28 AM it was observed the workflow of the molecular COVID-19 testing. The extraction was performed in one room, then carried thru 2 doors, the accessioning room, thru another door to the hood for the DNA mix. Then the specimens were carried back to the accessioning room to centrifuge then back thru a door to the instrument to read. This was not a uni-directional workflow. Interview on 09/17/20 at 5:30 PM the Technical Supervisor confirmed that the molecular COVID-19 testing did not have a uni-directional workflow.
D3009	FACILITIES CFR(s): 493.1101(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements. This STANDARD is not met as evidenced by: Based on record review and interview with the Office Manager the laboratory failed to follow the State of Florida Emergency Rule to report all positive and negative COVID-19 test results immediately to the Department Of Health (DOH) for 27 out of 27 Patient reports reviewed. Findings Included: Review of the State of Florida Emergency Rule 64DER20-18 (64D-3.029) states that all positive and negative COVID-19 test results need to be reported immediately. According to 64D-3.029 Diseases or Conditions to be Reported, "Immediately" is defined as "Reportable condition of urgent public health importance. Report without delay upon the occurrence of any of the following: an indicative or confirmatory test, findings indicative thereof, or diagnosis. Reports that cannot timely be made during the County Health Department business day shall be made to the County Health Department after hours duty official." Review of 27 Patient reports revealed the following: 1- Patient tested on 08/11/20 and reported to the DOH on 08/24/20. 2- Patient tested on 08/13/20 and not reported to the DOH. 3- Patient tested on 08/13/20 and reported to the DOH on 08/24/20. 4- Patient tested on 08/17/20 and reported to the DOH on 08/24/20. 5- Patient tested on 08/17/20 and reported to the DOH on 08/24/20. 6- Patient tested on 08/17/20 and not reported to the DOH. 7- Patient tested on 08/17/20 and reported to the DOH on 08/24/20. 8- Patient tested on 08/17/20 and reported to the DOH on 08/24 /20. 9- Patient tested on 08/17/20 and reported to the DOH on 08/21/20. 10- Patient tested on 08/17/20 and reported to the DOH on 08/21/20. 11- Patient tested on 08/17 /20 and reported to the DOH on 08/26/20. 12- Patient tested on 08/17/20 and reported to the DOH on 08/25/20. 13- Patient tested on 08/19/20 and not reported to the DOH. 14- Patient tested on 08/19/20 and reported to the DOH on 08/24/20. 15- Patient tested on 08/17/20 and not reported to the DOH. 16- Patient tested on 08/17/20 and reported to the DOH on 08/25/20. 17- Patient tested on 08/18/20 and reported to the DOH on 08/25/20. 18- Patient tested on 08/24/20 and not reported to the DOH. 19- Patient tested on 08/20/20 and reported to the DOH on 08/25/20. 20- Patient tested on 08/20/20 and reported to the DOH on 08/25/20. 21- Patient tested on 08/21/20 and reported to the DOH on 08/25/20. 22- Patient tested on 08/21/20 and reported to the DOH on 08/25/20. 23- Patient tested on 08/21/20 and reported to the DOH on 08/25 /20. 24- Patient tested on 08/21/20 and reported to the DOH on 08/25/20. 25- Patient tested on 08/24/20 and reported to the DOH on 08/26/20. 26- Patient tested on 08/24 /20 and not reported to the DOH. 27- Patient tested on 08/24/20 and reported to the DOH on 08/26/20. Interview on 09/21/20 at 8:46 PM the Office Manager confirmed

	the dates the tests were performed and on 09/16/20 at 3:00 PM confirmed the dates of faxing results to the DOH.
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on record review, observations, and Staff interview the laboratory failed to ensure that COVID-19 specimens were stored and shipped within acceptable temperatures prior to testing since starting testing on 05/19/20 (See D5311), and failed to document the date and time it receives a COVID-19 specimen for 35 of 35 Patient reports reviewed (See D5313).
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on record review, observations, and Staff interview the laboratory failed to ensure that COVID-19 specimens were stored and shipped within acceptable temperatures prior to testing since starting testing on 05/19/20. Findings Included: Review of Policy and Procedure signed by the Laboratory Director on 04/01/20 states that COVID-19 specimens must be stored "at 2-8 degrees Celsius for up to 72 hours after collection. If a delay in testing or shipping is expected, store specimens at -70 degrees Celsius or below." Observations on 09/15/20 at 10:00 AM revealed that local specimens are brought to laboratory by courier. Interview on 09/21/20 at 11:00 AM the Office Manager confirmed that the courier has a temperature regulated cooler that keeps the specimens 2-8 degrees Celsius, however, there is no documentation of the temperature. Other specimens are shipped to the laboratory. There is no temperature indicator in the shipping containers to ensure specimens were kept 2-8 degrees Celsius. Interview on 09/15/20 at 10:28 AM the Processing Staff member confirmed that there were no temperature indicators received with the specimens. She also confirmed that there is no documentation as to when each specimen was put into the -70 degree Celsius freezer to indicate it was greater than the required 72 hours. Review of the policy "Criteria for Specimen Rejection" reviewed by the Laboratory Director on 04/01/20 does not list specimens received outside of the acceptable range as a criteria for rejection, even though improper storage will result in a loss of efficacy.

D5313	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(b) The laboratory must document the date and time it receives a specimen. This STANDARD is not met as evidenced by: Based on record review and interview with the Processing Staff the laboratory failed to document the date and time it receives a COVID-19 specimen for 35 of 35 Patient reports reviewed. Findings Included: Review of 35 Patient reports revealed a collected date/time, a received date/time, and a printed date/time. These were not accurate dates or times. Interview on 09/15/20 at 5:30 PM the Processing Staff confirmed that there is no collection time on the specimens. The received date/time and collected time is actually when the specimen is accessioned, not time collected or date/time received. These missing dates and times are not recorded anywhere else in the laboratory. She also confirmed that the printed date/time is when the results are uploaded into the system and not when the specimen is ran. This date and time is only found on the instrument print outs.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to have a procedure on how to identify and retest inconclusive samples for COVID-19 from lab develop testing with Taqpath COVID-19 Combo Kit. Findings Included: Review of SARS COV 2 EUA states inconclusive COVID-19 samples will repeat test from extraction step. If second run is invalid again, new sample is required. Review of Procedure Manual no documentation of a procedure for inconclusive COVID-19 samples. During an interview on 09/17/2020 at 1:57 pm, General Supervisor A confirmed that there was no procedure on how to identify and retest inconclusive samples for COVID-19 from lab develop testing with Taqpath COVID-19 Combo Kit.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

	CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation, record review, and interview, the laboratory failed to store the King Fisher 96 deep well according to manufacturer's guidelines for COVID-19 testing. Findings Included: Review of King Fisher 96 deep well Package Kit reveals 96 deep well plates can be stored at 15 C to 30 C. An observation of the molecular room showed King Fisher deep well plates placed into a deep freezer for storage or continued testing. Review of the Deep Freezer log displayed temperatures of -15 C to -22 C. Review of SARS COV 2 EUA states King Fisher 96 deep well plate is used as an Elution plate and no documentation of a validation was preformed to stored King fisher plates at negative temperatures. During an interview on 09/17/2020 at 1:57 pm, General Supervisor A confirmed that King Fisher 96 deep well plates were stored in a deep freezer.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on observation, record review and interview, the laboratory failed to complete a validation on design and analysis software using presence and absence analysis for the Taqpath COVID-19 Combo Kit on a Quant Studio 12Flex Real Time PCR system to determine if COVID-19 patient results are valid from May 2020 to Sept .18th 2020 . Findings Included: An observation of PCR COVID-19 testing revealed a technologist running a 384 well plate on Quant Studio 12Flex PCR System then taking the data from the machine on to a USB. The USB is inserted into a computer in another room with the data and analysis software using presence and absence analysis to give COVID-19 results. Review of Taqpath COVID-19 Combo Kit package insert does not list Quant Studio 12 Flex Real Time PCR as an instrument compatible with the design and analysis software for COVID -19. Presence and Absence Software is not listed as COVID-19 Interpretive software. Review of email letter with Thermo Fisher for May 15, 2020 showed an issue with ABY (S protein target) and background calibration but no documentation of a rerun to determine the issue was fixed . Review of COVID-19 Patient sample run revealed no amplification curve data to determine the presence of

	target calls . Review of the Laboratory Developed Testing validation data revealed that the laboratory failed to evaluate interfering substances on the instrument and plates being used. During an interview on 09/15/2020 at 3:00 PM , General Supervisor confirmed that Design And Analysis software was used for presence and absence analysis for Taqpath COVID-19 Combo Kit with Quantstudio 12Flex Real time PCR system without a validation. Interview on 09/17/20 at 1:00 PM the General Supervisor confirmed that they did not perform interfering substances for their validation.
D5800	POSTANALYTIC SYSTEMS CFR(s): 493.1290 Each laboratory that performs nonwaived testing must meet the applicable postanalytic systems requirements in 493.1291 unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7) that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the postanalytic systems and correct identified problems as specified in 493. 1299 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on record review and interview with the Office Manager the laboratory failed to have the test report date documented for COVID-19 testing for 35 of 35 Patient reports reviewed (See D5805).
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on record review and interview with the Office Manager the laboratory failed to have the test report date documented for COVID-19 testing for 35 of 35 Patient reports reviewed. Findings Included: Review of 35 Patient reports revealed that the printed date and time was not the testing time and date. Interview on 09/17/20 at 5:00 PM the Office Manager confirmed that the printed date and time is actually when the results are uploaded and not when specimens ran. She stated that to find out when specimens were ran, instrument reports would have to be reviewed. She confirmed that the test report date was not on the test reports.
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 observations, record review, and Staff interviews the Laboratory Director failed to have oversight of the Laboratory in reporting COVID-19 to the Department of Health (See D6079), failed to have oversight of Preanalytic and Postanalytic phases of testing (See D6082), and failed to ensure instrumentation had an acceptable and approved validation prior to patient testing (See D6086).
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on record review and Staff interviews the Laboratory Director failed to have oversight of laboratory operations regarding Department of Health (DOH) guidelines for reportable diseases since began testing COVID-19 on 05/19/20. Findings Included: See D3009.
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 observations, record review, and Staff interviews the Laboratory Director failed to ensure quality laboratory services for Preanalytic and Postanalytic phases of testing since testing began on 05/19/20. Findings Included: Refer to D5311 Refer to D5313 Refer to D5805
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.

	This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory director failed to validate the laboratory procedure for Taqpath COVID-19 Combo Kit; which was used from May 20, 2020 to Sept 21, 2020. Findings Included: A review of Taqpath COVID-19 Combo Kit validation procedure revealed no documentation of the Laboratory Director signing or reviewing this procedure. A review of COVID-19 patient logs revealed that the first patient was tested on May 20, 2020 and testing continued through Sept 21, 2020. During an interview on 09/17/2020 at 2 pm, General Supervisor A confirmed that the laboratory director did not sign the laboratory developed procedure for Taqpath COVID-19 Combo Kit.