Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D2108253	09/30/2020
Name of Provider or Supplier	**Street Address, City, State**	
Stone Clinical Laboratories, Llc	615 Baronne St, Ste 100, New Orleans, LA	

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	A Complaint Survey was performed at Stone Clinical Laboratories, LLC- CLIA ID 19D2108253 on September 28, 2020 through September 30, 2020. Stone Clinical Laboratories, LLC was found not in compliance with the following CONDITION LEVEL DEFICIENCIES which constitute an IMMEDIATE JEOPARDY to the patients serviced by the laboratory: 42 CFR 493.1240 CONDITION: Preanalytic Systems 42 CFR 493.1441 CONDITION: Laboratories performing high complexity testing, Laboratory Director 42 CFR 493.1447 CONDITION: Laboratories performing high complexity testing, Technical Supervisor
D5205	COMPLAINT INVESTIGATIONS CFR(s): 493.1233 The laboratory must have a system in place to ensure that it documents all complaints and problems reported to the laboratory. The laboratory must conduct investigations of complaints, when appropriate. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, complaint records, and interview with personnel, the laboratory failed to have a system for handling complaints and issues reported to the laboratory. Findings: 1. Review of the laboratory's "Communication and Complaints SOP Gen 5.1 Effective date 9/9/2020" located in the laboratory's MediaLab revealed the following: "All communication /complaints between the laboratory and clients/patients will be documented. The following information will be recorded on Incident Tracker Log in SharePoint: a) Date of communication b) Form of communication (e-mail, fax, phone) c) Communication recipient d) Brief summary of communication (to include copies of email or fax) e) Corrective action taken (if necessary) f) Date received Investigations and corrective actions will be performed as necessary and documented on the SharePoint Corrective Action Report. An assessment will be made of each corrective action report to determine effectiveness of all corrective actions taken by the

Laboratory Director. Incident Tracker log will be reviewed during the monthly QA audit." 2. The laboratory was asked to provide their policy/procedure for handling client complaints and "Instructions for calls about results or clinical questions" policy was provided. Review of the laboratory's policy revealed the purpose and scope as "Instructions for speaking to a provider, problem solving and documentation when a result is needed that is not complete or reported and for answering clinical questions." The following instructions were included: a) "Office calls looking for a report that is not complete b) Call the office back c) Escalate and Document: If the testing is being done at SCL and the person is upset you can offer to have a laboratorian call them. If that is requested to go to the Lab Director, give the information, and ask for a follow up from them when the call is made. Document the call to the VP of Client Services in an email." 3. Further review of the laboratory's "Instructions for calls about results or clinical questions" policy revealed "If the client has a questions that is clinical in nature use the SME (subject matter expert) to answer questions if Client Services is not available." The policy listed non current laboratory personnel; the current Laboratory Director was not listed. 4. On September 28, 2020 at 1:20pm, surveyors provided written request for records and documentation to include: "Laboratory complaint/communications - inquiries from clients regarding accuracy/quality of COVID results. All communications." 5. Review of the laboratory's complaint logs provided to surveyor on September 29, 2020 revealed the laboratory provided included January 16, 2020 and issues documented in September 2020. Information for issues that occurred in February through August 2020 were not included. 6. Further review of the laboratory's complaint log revealed for twenty (20) issues documented September 9, 2020 through September 24, 2020 the laboratory did not have documented resolutions. The "root cause" analysis and/or "resolved date" columns were blank. The "status code" indicated "in process." The following complaints were doecumented without resolutions: a) September 9, 2020: Turn around time (TAT) complaint: "Called in a positive to client from Aug.5. Client is upset about the TAT as well as the accuracy of the test from that collection date b)September 21, 2020: Turn around time (TAT) delay: "Positive was not resulted out within our 24-72 hour TAT" Eight (8) clients reported issues related to TAT delay on September 21, 2020 c) September 22, 2020:: Turn around time (TAT) delay: "Client asked for and ETA on specimen. Specimen was col 9/17 Recvd 9/18 and has not been resulted out yet. This is not within out (sic) 48/72 HR TAT. Turn around time (TAT) delay: "Positive was not within our 48-72 HR TAT" d) September 24, 2020: Turn around time (TAT) delay: "called inquiring about her test results collected on 9/18. She was told they would be resulted out y (sic) end of day 9/23 and she still does not have results." 7. Interview with the Lab Operations Director on September 29, 2020 at 3:45pm confirmed the log provided was the only documentation of communications with providers or complaints and that they were mostly regarding turnaround times. 8. In interview on September 29, 2020 at 4:25 pm, the Laboratory Director stated he did not know the laboratory's complaint handling process. The Laboratory Director further stated he was unaware of any issues with quality of results. 9. During the exit conference on September 30, 2020 at 11:30am, the owner stated the only question they've received about the quality of testing performed at Stone was investigated by Stone. This included having the samples in question tested by CDC and the results were within 10% which is more than acceptable. When questioned by surveyors why this information was not provided with the complaint logs and multiple requests for concerns about quality of testing, the owner stated this wasn't a complaint, it was just a concern from the department of health. No further information was provided detailing the concern in question, internal investigation, laboratory director involvement, patient assessment or process for tracking of this specific concern or other concerns of quality of testing.

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 direct observation, record review and interview with personnel, the laboratory's system failed to meet the requirements of the preanalytical system. Findings: 1. The laboratory failed to ensure a time of collection was solicited on requisitions for 5 of 6 COVID specimens that have a defined manufacturer stability. Refer to D5305 2. The laboratory failed to ensure COVID specimens shipped to the laboratory maintained manufacturers' temperature requirements throughout transport. Refer to D5311 I. 3. The laboratory failed to reject Run Mei collection devices for COVID testing after identification of a contamination issue. Refer to D5311 II. 4. The laboratory failed to reject twenty two (22) COVID specimens that were beyond the manufacturer's stability requirements. Refer to D5311 III. 5. The laboratory failed to ensure the written instructions detailing specimen stability for clients were consistent. Refer to D5317. 6. The laboratory failed to ensure monitors identified issues within the preanalytic system. Refer to D5393.
D5305	TEST REQUEST CFR(s): 493.1241(c) The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. This STANDARD is not met as evidenced by: Based on direct observation, review of the laboratory's policies, and interview with personnel, the laboratory failed to ensure a time of collection was solicited on requisitions for 5 of 6 COVID specimens that have a defined manufacturer stability. Findings: 1. Review of the laboratory's "Specimen Acceptance and Rejections (SOP#: GEN-3.1)" policy revealed "specimen collection date & time" is required for requisition acceptance. The identified policy stated "Specimens received with incomplete requisitions will be held and results will not be reported until missing information if retrieved." 2. During an observation on 9/29/2020 at 7:40 am, the

	following patient Run Mei swabs were observed during accessioning and were placed on "hold" because of missing information: Patient 2013221001 requisition did not include a "Date Collected:" and "Time Collected"; the swab was observed to have the documented collection date of 09/25/2020. Affidavit provided by client stated the collection date was 9/28/2020. Patient 2013221301 requisition did not include a "Date Collected:" and "Time Collected"; the swab was observed to have the documented collection date of 09/25/2020. Affidavit provided by client stated the collection date was 9/28/2020. Patient 2013220601 requisition did not include a "Time Collected." (date collected was 9/25/2020) Patient 2013220301 requisition did not include a "Date Collected:" and "Time Collected"; the swab was observed to have the documented collection date of 09/25/2020. Affidavit provided by client stated the collection date was 9/28/2020. Patient 2013223401 requisition included "Date Collected: 9/28/2020"; the swab observed had a documented collection date of 9/25/2020. Client affidavits are requested by the specimen management team for specimens on hold that are missing information on the requisitions. In interview on 9/30/2020 at 9:45 am, the specimen management personnel was asked why did the client affidavits not include collection times and only collection dates, she stated the collection time for Hologic samples (Run Mei swabs) is not required. 3. Review of the laboratory's "Specimen Collection & Shipping (SOP #: GEN-2.0)" policy under "Patient Identification and Specimen Labeling" section revealed "Respiratory Pathogens testing requires the addition of the collection date and time on the specimen tube." 4. Review of the laboratory's "Client Manual & Collection Guide" revealed the following specimen stability information: a) "Collection Device" section: "Specimen Stability-72 hours" b) "Beaver Sample Collection Kit" instruction guide section: "Patient sample must be received at laboratory within 7 days of collection" c) "Run Mei" instruction guide section: "Patient must be received at laboratory within 96 hours of collection" d) "eSwab"instruction guide section: "Patient sample must be received at laboratory within 48 hours of collection" The collection devices manufacturer included stability and the laboratory did not ensure collection times were solicited on requisitions to ensure stability was met. The client services manual was also inconsistent about stability (72 hours versus manufacturer's instructions). The laboratory did not follow their own written policy for ensuring times of collection for COVID specimens.
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: I. Based on direct observation, review of laboratory policies, client service instructions, and interview with personnel, the laboratory failed to ensure COVID specimens shipped to the laboratory maintained manufacturers' temperature requirements throughout transport. Findings: 1. Review of the manufacturer's instructions for the following sample collection/transport devices revealed the following storage requirements: a) Beaver: "RT for 1 week" b) Run Mei (Runmei Amies): "After the sample is collected, it should be transported to the corresponding laboratory for testing within 96 hours at room temperature. It can preserve DNA,

RNA and antigens of bacteria, viruses, and Chlamydia for five days when stored at regular storage temperature (between 20-37 degrees C); 7 days if stored at 4 degrees C and up to 6 months when stored at -20 degrees C or -70 degrees C. The sample should avoid repeated freezing and thawing." 2. Review of the laboratory's "Specimen Collection and Shipping" policy (effective September 9, 2020) revealed the following storage temperature requirements: a) Run Mei Amies: 20-37 degrees C b) Beaver: 15-30 degrees C" 3. Review of the laboratory's "Client Manual and Collection Guide" revealed the following specimen storage requirements: a) Beaver: "must be shipped at room temperature, range 15 degrees C to 30 degrees C' b) Run Mei: "store specimens in a secure location at room temperature, 20 degrees C to 37 degrees C, until pickup" The Run Mei swabs were not listed as part of Hologic or DTPM test method's EUA for COVID testing; and the Beaver swabs were not listed as part of DTPM test method's EUA for COVID testing. The laboratory's policy above was effective September 9, 2020, the Run Mei and the Beaver swabs were distributed to clients for collection on July 22, 2020 (Beaver) and August 13, 2020 (Run Mei). The laboratory did not have studies for the collection devices prior to patient testing (Refer to D5423). 4. In interview on September 28, 2020 at 8:30 am, the Lab Operations Director stated the laboratory receives specimens via FedEx, UPS, and local courier. 5. Direct observation by surveyors on September 29, 2020 at 7:30 am revealed accessioning staff received UPS shipments containing specimens at room temperature. Surveyors observed accessioning staff opening the shipment boxes/packages and taking the internal temperature of the boxes prior to removing samples. The UPS shipment boxes/packages did not include temperature monitoring throughout transport to ensure the storage of the specimen did not exceed the acceptable range per the manufacturer. The laboratory did not have studies to ensure shipment boxes/packages maintained transport conditions in which COVID specimens (Run Mei and Beaver swabs) were shipped. Note: specimens were being shipped from the following states: Louisiana, California, Florida, Mississippi, Missouri, Washington, Georgia, Tennessee, Maryland, Ohio, Colorado, Texas, Alabama, Michigan, Virginia, Kentucky, Nevada, and Arkansas. 6. Direct observation by surveyors on September 28, 2020 at 8:57 am revealed the following sampling of specimens (Run Mei swabs) the laboratory received in shipment boxes/packages for COVID testing: Collection date: 09/24/2020 Patient #1101227701 Patient #1101268301 Patient #1101228101 Patient #1101225501 Patient #1101228601 Patient #1101224601 Patient #1101336101 The laboratory received three hundred and ninety six (396) samples in Run Mei (Amies) collection devices on September 28, 2020. The laboratory did not have studies to ensure shipment boxes/packages maintained transport conditions (20-37C) in which COVID specimens (Run Mei swabs) were shipped. 7. Direct observation by surveyors on September 29, 2020 at 7:46 am revealed the following sampling of specimens (Run Mei and Beaver swabs) the laboratory received in UPS "Laboratory Box" and bags for COVID testing: Patient #496815 Patient #496845 Patient #496875 Patient #496905 Patient #535008 Patient #534900 Patient #534687 Review of the laboratory's manifest log for September 29, 2020 revealed the laboratory received approximately 583 patient samples in Run Mei and 64 patient samples in Beaver collection devices. The laboratory did not have studies to ensure shipment boxes/packages maintained transport conditions (20-37C for Run Mei and 15-30C for Beaver) in which COVID specimens were shipped. 8. Review of data provided by the laboratory and interview with laboratory personnel revealed the following pieces of specimen handling studies: a) Review of the laboratory's "Local Courier Cooler Validation 2020" revealed temperature of specimens were tracked locally in May 2020 and June 2020 utilizing the Rubbermaid cooler and eSwabs. The study did not have a policy, acceptable criteria and was not reviewed/approved by the Laboratory Director. b) Review of an additional laboratory shipping study, performed

May 6, 2020 through May 7, 2020, revealed the laboratory tracked the temperature of specimens utilizing different transport devices and "Specimen types" (eSwab and Aptima tubes); however, the specimens were shipped overnight within Louisiana (Baton Rouge to New Orleans over 12 hours) and did not include shipping from further distances. The study did not have a policy, acceptable criteria and was not reviewed/approved by the laboratory Director. c) Review of the laboratory's temperature tracking study data "UPS Laboratory PAK Biological Substance , Cat B UN3373" with "MaxQ temperature monitoring/GPS tracking device on revealed the studies were performed starting September 26, 2020." The study did not indicate the sample collection tube tested and has not been completed or reviewed/approved by Laboratory Director. d) In interview on September 30, 2020 at 9:05 am, the Laboratory Manager stated the laboratory has started a shipping study using the MaxQ temperature devices. The Laboratory Manager stated the study is still ongoing. 9. Review of the laboratory's specimen count from "03/01/2020 through 09/28/2020" revealed the laboratory received 139,474 specimens for COVID testing. II. Based on direct observation, record review, and interview with personnel, the laboratory failed to reject Run Mei collection devices for COVID testing after identification of a contamination issue. Findings: 1. Direct observation on September 28, 2020 at 8:54 am, revealed the laboratory accessioners receiving specimens in Run Mei collection tubes for testing. Further direct observation by surveyors revealed one (1) COVID specimen in Run Mei collection tube located in green bin with note that stated "1 moldy specimen." (Patient #1101181801). Surveyors visually noted significant mold throughout the patient sample. 2. In interview on September 28, 2020 at 10:23 am in the laboratory's warehouse (Suite 202), the Lab Operations Director stated the Amies (Run Mei) tubes were no longer being sent to clients because of mold issue. The Lab Operations Director stated the laboratory learned of the mold issue Friday (September 25, 2020). The Lab Operations Director further stated currently only Beaver collection tubes are being sent to clients. 3. In further interview on September 28, 2020 at 10:25 am, the Lab Operations Director stated the accessioning and lab staff are doing visual checks on Run Mei tubes that are received. If the tube looks contaminated the sample is put on "hold" for rejection. The Lab Operations Director stated the specimen is processed if visual inspection passes. The Lab Operations Director stated clients were verbally notified Friday (September 25, 2020) of the issue with Run Mei tubes. The Lab Operations Director further stated clients would be notified via letter that day (September 28, 2020). 4. Review of the laboratory's complaint log revealed on September 25, 2020 at 10:00 am a client reported "she found a swab that has 'bacteria' growing in it." The laboratory's resolution comment stated "MANUFACTURER ERROR DID INTERNAL AUDIT OF ALL SWABS, NOTIFIED MANUFACTURER AND NOTIFIED CLIENTS NOT TO USE AND PULLED ALL RUN MEI SWABS AND SEND BACK TO STONE." 5. On September 30, 2020 at 12:20 pm, the Lab Operations Director provided surveyors a letter on the laboratory's letter head dated September 28, 2020. The Lab Operations Director stated the letter was issued to clients regarding the Run Mei tubes. The letter stated "It has come to our attention that there is a quality issue with the Run Mae collection device currently in use for Covid-19 testing. This issue has affected the transport media but not the swab itself. The laboratory will be providing an alternate swab and transport media option to all customers immediately. We have reported this problem to the manufacturer of the Run Mae collection device. We ask that you cease using any remaining devices and return any unused devices as soon as possible." 6. Direct observation by surveyors on September 29, 2020 at 7:30 am revealed specimens in Run Mei collection devices were being received and accessioned for testing. 7. Review of COVID laboratory worksheets and patient final reports revealed the laboratory processed and reported patient samples received in Run Mei devices after

the contamination issue was identified. The following fifteen (15) patients reviewed were reported: a) Report Date 09/25/2020: Patient 11010843 Patient 11010835 Patient 11010845 Patient 11010819 Patient 11011354 b) Report Date 09/26/2020: Patient 11012382 Patient 11012548 Patient 11012547 Patient 11012523 Patient 11012501 c) Report Date 09/27/2020: Patient 11013159 Patient 11013254 Patient 11013232 Patient 11013206 Patient 11013183 d) Report Date 09/29/2020: Patient 20132058 Patient 20132057 Patient 20132053 Patient 11013301 Patient 20132059 8. In interview on September 29, 2020 at 3:40 pm, the Laboratory Director stated he recently became aware of the contamination issue with the Run Mei tubes. The Laboratory Director further stated he was unaware of the laboratory performing visual inspections and still accepting the Run Mei tubes for testing. 9. In interview on September 30, 2020 at 9:01 am, the Lab Manager stated as of September 30, 2020 she believes the laboratory is rejecting the Run Mei specimens. 10. Direct observation by surveyor on September 30, 2020 at 9:47 am, revealed the laboratory's "Specimen Management" whiteboard had a "Moldy Samples" section indicating client name and number of specimens received as follows: Sandy Lake: 1 Los Arcos: 2 Accel at College Station: 3 Hillcrest of N Dallas: 3 Monarch: 2 Northgate: 2 Woodlands: 1 Park Manor Mickinney: 1 College Park Rehab: 2 Spanish Hills: 5 III. Based on review of laboratory policies, manufacturer package inserts, instrument raw data and patient final reports and interview with personnel, the laboratory failed to reject twenty two (22) COVID specimens that were beyond the manufacturer's stability requirements. Findings: 1. Review of the specimen collection tubes' manufacturer package inserts revealed the following specimen stability requirements: a) Aptima: "Specimens in the Panther Specimen Lysis Tube or Multitest Tube may be stored under one of the following conditions: 15 degrees C to 30 degrees C up to 6 days or 2 degrees C to 8 degrees C up to 3 months" b) e-Swab:"Immediate delivery or processing is delayed, then specimens should be refrigerated at 4-8 degrees C or stored at room temperature (20-25 degrees C) and processed within 48 hours." 2. Review of the laboratory's "Specimen Acceptance and Rejections (SOP #: GE-3.1)" policy revealed the following specimen requirements: a) "Aptima Multitest: 6 days" b) "Copan eSwab: 48 hours" 3. Review of random selection of patient test reports and Hologic instrument raw data for June 2020 revealed the following specimens collected in Aptima tubes exceeded the six (6) day stability requirement: Patient 20021303: Collected 06/03/2020, Tested 06/10/2020 Patient 20021310: Collected 06 /03/2020, Tested 06/10/2020 Patient 20021314: Collected 06/03/2020; Tested 06/10 /2020 Patient 20021318: Collected 06/03/2020; Tested 06/10/2020 Patient 20020977: Collected 06/04/2020 at 13:30; Tested 06/10/2020 at 15:22 Patient 20020974: Collected 06/04/2020 at 13:50; Tested 06/10/2020 at 15:17 Patient 20020997: Collected 06/04/2020 at 12:00; Tested 06/10/2020 at 15:22 Patient 20020976: Collected 06/04/2020 at 13:00; Tested 06/10/2020 at 15: 22 Patient 20020969: Collected 06/04/2020 at 13:10; Tested 06/10/2020 at 15:37 4. In interview on September 30, 2020 at 9:35 am, the Technical Supervisor for molecular testing and Accessioning Front End Supervisor stated that Aptima swabs that are received close to the 6 day stability required by the manufacturer would be pulled by accessioning to be put in refrigerators where a longer stability would then be applicable. The Accessioning Front End Supervisor stated this would be the responsibility of each accessioner to identify Aptima specimens close to the stability and that there was no written policy detailing this practice. The Technical Supervisor confirmed there was no written log or documentation of different storage requirements used for specific specimens. 5. Review of random selection of patient test reports and Quant Studio instrument raw data for July 2020 revealed the following specimens collected in eSwab tubes exceeded the 48 hour stability requirement: Patient 20067649: Collected 07/09/2020; Tested 07/14/2020 Patient 20067594: Collected 07/09/2020; Tested 07/14

	/2020 Patient 20066889: Collected 07/09/2020; Tested 07/15/2020 Patient 20067007: Collected 07/09/2020; Tested 07/15/2020 Patient 20067034: Collected 07/10/2020; Tested 07/15/2020 Patient 20072113: Collected 07/13/2020; Tested 07/21/2020 Patient 20071485: Collected 07/12/2020; Tested 07/20/2020 Patient 20071486: Collected 07/12/2020; Tested 07/20/2020 Patient 20071380: Collected 07/12/2020; Tested 07/20/2020 Patient 20077504: Collected 07/14/2020; Tested 07/21/2020 Patient 20071949: Collected 07/13/2020; Tested 07/21/2020 Patient 20076925: Collected 07/13/2020; Tested 07/21/2020 Patient 20077468: Collected 07/14/2020; Tested 07/21/2020 6. In interview on September 28, 2020 at 12:05 pm, extraction testing personnel stated that extraction takes place the day specimens are received. Testing personnel further stated occasionally samples are stored in the refrigerator if they are extracted late in the afternoon and not amplified the same day. The molecular technical supervisor stated on September 29, 2020 at 2:30 pm that extracted samples are not stored in freezers for days and that they are rarely held in the freezer after extraction waiting for amplification. 7. In interview on September 30, 2020 at 9:15 am, molecular technical supervisor stated all extraction takes place the day samples are received, any extracted samples are then frozen until amplification can be performed. The above samples would have been extracted upon receipt and then frozen until the tested date. The technical supervisor did confirm that there was no record that would detail when samples were extracted in July.
D5317	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section. This STANDARD is not met as evidenced by: Based on review of the manufacturer's stability requirements, the laboratory's client service manual, and interview with personnel, the laboratory failed to ensure the written instructions detailing specimen stability for clients were consistent.. Findings: 1. Review of the specimen collection tubes' manufacturer package inserts revealed the following specimen stability requirements: a) Beaver: "RT for 1 week" b) Run Mei (Runmei Amies): "After the sample is collected, it should be transported to the corresponding laboratory for testing within 96 hours at room temperature. It can preserve DNA, RNA and antigens of bacteria, viruses, and Chlamydia for five days when stored at regular storage temperature (between 20-37 degrees C); 7 days if stored at 4 degrees C and up to 6 months when stored at -20 degrees C or -70 degrees C. The sample should avoid repeated freezing and thawing. c) e-Swab:"Immediate delivery or processing is delayed, then specimens should be refrigerated at 4-8 degrees C or stored at room temperature (20-25 degrees C) and processed within 48 hours." d) Aptima: "Specimens in the Panther Specimen Lysis Tube or Multitest Tube may be stored under one of the following conditions: 15 degrees C to 30 degrees C up to 6 days or 2 degrees C to 8 degrees C up to 3 months" 2. Direct observation by surveyors on September 28, 2020 at 8:57 am revealed the laboratory received Run Mei (Amies) sample collection tubes for COVID testing. 3. Direct observation by surveyors on September 29, 2020 at 7:46 am revealed the laboratory received Beaver sample collection tubes for COVID testing. 4. In interview on September 28, 2020 at 8:57 am, the accessioning personnel stated the Run Mei stability was four (4) days. The accessioning personnel further stated at 9:02 am, the eSwab stability was 48 hours. 5. Review of the laboratory's "Client Manual & Collection Guide" revealed the

	following information: a) "Collection Device" section: "Specimen Stability-72 hours" b) "Beaver Sample Collection Kit" instruction guide section: "Patient sample must be received at laboratory within 7 days of collection" c) "Run Mei" instruction guide section: "Patient must be received at laboratory within 96 hours of collection" d) "eSwab"instruction guide section: "Patient sample must be received at laboratory within 48 hours of collection" 6. In interview on September 30, 2020 at 9:10 am, the Client Service Supervisor confirmed the 72 hour stability instructions are not consistent with the stability guidelines indicated on the instruction guide sheets.
D5393	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(b)(c) The preanalytic systems assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of preanalytic systems quality assessment reviews with appropriate staff. The laboratory must document all preanalytic systems quality assessment activities. This STANDARD is not met as evidenced by: Based on direct observation, record review, and interview with personnel, the laboratory failed to ensure monitors identified issues within the preanalytic system. Findings: 1. The laboratory failed to ensure a time of collection was solicited on requisitions for 5 of 6 COVID specimens that have a defined manufacturer stability. Refer to D5305 2. The laboratory failed to ensure COVID specimens shipped to the laboratory maintained manufacturers' temperature requirements throughout transport. Refer to D5311 I. 3. The laboratory failed to reject Run Mei collection devices for COVID testing after identification of a contamination issue. Refer to D5311 II. 4. The laboratory failed to reject twenty two (22) COVID specimens that were beyond the manufacturer's stability requirements. Refer to D5311 III. 5. The laboratory failed to ensure the written instructions detailing specimen stability for clients were consistent. Refer to D5317.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies/procedures and interview with personnel, the laboratory failed to have complete policies for COVID test reporting. Findings: 1. Review of the laboratory's"Determination of SARS-CoV-2 (COVID-19) using Real-Time Polymerase Chain Reaction (RT-PCR) " procedures revealed the laboratory did not include: a) Detailed written instructions for data analysis process, to include but not limited to, what parameters are evaluated, documentation of review, and corrective action if reviewers disagree b) Procedure for Endogenous Control failures 2. Review of the laboratory's "Aptima SARS-CoV-2" procedures revealed the laboratory did not include: a) Detailed written instructions for flags on the Hologic analyzer such as "CLT", "p", "VVFS" 3. In interview on September 29, 2020 at 10:

	00am, the Technical Supervisor stated for the DTPM COVID procedure performed on the Quant Studio 5, the patient results are evaluated by two (2) reviewers. The Technical Supervisor confirmed the laboratory did not document who performed the 1st and 2nd reviews.
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 review of the manufacturer's Emergency Use Authorization (EUA) notifications, the laboratory's COVID specimen collection device verification studies and interview with personnel, the laboratory failed to perform stablility studies for COVID specimen handling. Findings: 1. In interview on September 28, 2020 at 8: 32am , the Lab Operations Director stated when the laboratory initially began COVID testing eSwab and Aptima collection tubes were used. The Lab Operations Director further stated at 9:38 am the laboratory started using Beaver and Run Mei collection tubes due to difficulty in getting collection supplies. 2. Review of the EUA and standard operating procedures for the Tide Laboratories DTPM and Hologic Aptima COVID tests revealed the following: a) DTPM (DTPM SARS -CoV-2 COVID 19 SOP): "The Copan ESwab Liquid Amies collection devices are suitable for extended processing and transport times, and for microbiological diagnosis, however, samples will be rejected if specimen exceeds the 72 hour limit. PrimeStore Molecular Transport Media (MTM) may also be utilized to store and transport collected samples intended for nucleic acid extraction and RT-PCR analysis using methods described in the Standard Operating Procedure. Follow manufacturer's on-label guidance for use with additional FDA approved collection devices." b) DTPM (Validation Study Addendum: "The Copan ESwab Liquid Amies collection devices are suitable for extended processing and transport times, and for microbiological diagnosis, however, samples will be rejected if specimen exceeds the 72 hour limit. Follow manufacturer's on-label guidance for use with additional FDA approved collection devices." c) DTPM (DTPM 2020): "Follow manufacturer's on-label guidance for use with additional FDA approved collection devices." d) Hologic Customer Technical Bulletin revealed a list of acceptable alternative transport media; however, the Run Mei collection devices were not listed. 3. The Lab Operations Director on September 30, 2020 at 11:04 am provided to surveyors email correspondence between herself and a Hologic representative. Review of the email revealed on July 28, 2020 at 11:47 am, the Hologic included a "do not use" list that included Hunan Runmei Gene Technology Single Use Samplers (inactivated) 4. Further interview on September 28, 2020 at 10:28am in the warehouse on the second floor, the Lab Operations Director stated the laboratory is working on stability studies for Run Mei collection devices, Beaver collection devices and different coolers for temperature control during

	transport. 5. Verification studies for Run Mei collection devices provided to surveyors by Lab Operations Director on September 29, 2020 at 10:15am revealing five (5) samples tested on the Quant Studio 5 (DTPM EUA), including one positive and four negative samples. The Lab Operations Director stated the positive sample was spiked with quality control material as it was the only thing they had available. These studies were performed September 24, 2020. 6. In interview on September 29, 2020 at 11: 20am the molecular technical supervisor stated the verification study of 5 samples for Run Mei collection devices was performed by using frozen samples from alternate collection devices of known results. One positive patient was added to the Run Mei device and four negative patients were added to Run Mei collection devices. They were then tested on the Quant Studio 5 (DTMP EUA) in duplicate to verify the Run Mei as an acceptable collection and transport device for COVID testing. The technical supervisor confirmed there was no policy in place and the study was not approved by the laboratory director. 7. Verification studies for Beaver collection devices provided to the surveyors by the molecular technical supervisor on September 30, 2020 at 9: 15am revealed five (5) patient samples were tested on the Beaver collection devices in duplicate through the Quant Studio 5 (DTPM EUA). The collection devices were spiked with previously frozen, tested patients from alternate collection kits. The technical supervisor confirmed there was no policy in place and the study was not approved by the laboratory director. 8. In interview on September 30, 2020 at 11:04 am, the Lab Operations Director confirmed the laboratory was using collection kits not covered by the manufacturer's EUAs. The Lab Operations Director thought she had documentation of the Run Mei and Beaver collection tubes being acceptable devices for the DTPM (Quant Studio 5) and Run Mei for the Hologic Panther and Panther Fusion. The Lab Operations Director confirmed she was not able to provide documentation at the time of the survey.
D5809	TEST REPORT CFR(s): 493.1291(e) The laboratory must, upon request, make available to clients a list of test methods employed by the laboratory and, as applicable, the performance specifications established or verified as specified in 493.1253. In addition, information that may affect the interpretation of test results, for example test interferences, must be provided upon request. Pertinent updates on testing information must be provided to clients whenever changes occur that affect the test results or interpretation of test results. This STANDARD is not met as evidenced by: Based on interview with Client Service personnel and review of Emergency Use Authorized (EUA) instructions, the laboratory failed to include "Fact Sheets" to providers or patients for Emergency Use Authorized (EUA) COVID tests. Findings: 1. Direct observation during the laboratory tour on September 28, 2020 at 9:00am revealed the laboratory utilized Hologic Panther and Panther Fusion as well as Quant Studio for COVID testing. 2. Interview with Lab Operations Director on September 28, 2020 at 9:00 am confirmed all the testing platforms and methods used by the laboratory for COVID testing are under Emergency Use Authorization. 2. Review of the Federal Drug Administration (FDA) COVID EUA site revealed that EUAs state that "Authorized laboratories using your product will include with test result reports, all authorized Fact Sheets". 3. In interview on September 30, 2020 at 9:39 am, the

	Client Service Supervisor confirmed the laboratory does not provide the "Fact Sheet" specific to the EUA COVID test methods used by the laboratory to patients or providers.
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 direct observation, record review and interview with personnel, the Laboratory Director failed to provide overall management and direction. Findings: 1. The Laboratory Director failed to ensure the laboratory personnel were performing test methods as required. Refer to D6087. 2. The Laboratory Director failed to ensure that a quality assessment (QA) program was established to assure the quality of laboratory services provided. Refer to D6094. 3. The Laboratory Director failed to ensure "Fact Sheets" were provided for Emergency Use Authorization (EUA) COVID tests. Refer to D6098. 4. The Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D6106. 5. The laboratory director failed to ensure the laboratory established the performance specifications of alternate COVID collection devices not covered under an EUA. Refer to D6806.
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 the manufacturer's Emergency Use Authorization (EUA) notifications, the laboratory's COVID specimen collection device verification studies and interview with personnel, the Laboratory Director failed to ensure the laboratory performed stability studies for COVID specimen handling. Refer to D5423.
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on direct observation, record review, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel were performing test methods as required. Findings: 1. The laboratory failed to ensure a time of collection was solicited on requisitions for 5 of 6 COVID specimens that have a defined manufacturer stability. Refer to D5305 2. The laboratory failed to ensure COVID specimens shipped to the laboratory maintained manufacturers' temperature

	requirements throughout transport. Refer to D5311 I. 3. The laboratory failed to reject Run Mei collection devices for COVID testing after identification of a contamination issue. Refer to D5311 II. 4. The laboratory failed to reject twenty two (22) COVID specimens that were beyond the manufacturer's stability requirements. Refer to D5311 III. 5. The laboratory failed to ensure the written instructions detailing specimen stability for clients were consistent. Refer to D5317.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on direct observation, record review, and interview with personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was established to assure the quality of laboratory services provided. Refer to D5393.
D6098	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(8) The laboratory director must ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: Based on interview with personnel, the Laboratory Director failed to ensure "Fact Sheets" were provided for Emergency Use Authorization (EUA) COVID tests. Refer to D5809.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on policy and procedure manual review and interview with laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Findings: 1. The laboratory failed to have a system for handling complaints and issues reported to the laboratory. Refer to D5205. 2. The laboratory failed to have complete policies for COVID test reporting. Refer to D5401.
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart.

	This CONDITION is not met as evidenced by: Based on direct observation, record review, and interview with personnel, the Technical Supervisor failed to provide technical oversight for high complexity testing. Refer to D6112.
D6112	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451 The technical supervisor is responsible for the technical and scientific oversight of the laboratory. The technical supervisor is not required to be on site at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide supervision as specified in (a) of this section. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Supervisor failed to provide technical and scientific oversight for the laboratory. Findings: 1. The laboratory failed to ensure a time of collection was solicited on requisitions for 5 of 6 COVID specimens that have a defined manufacturer stability. Refer to D5305 2. The laboratory failed to ensure COVID specimens shipped to the laboratory maintained manufacturers' temperature requirements throughout transport. Refer to D5311 I. 3. The laboratory failed to reject Run Mei collection devices for COVID testing after identification of a contamination issue. Refer to D5311 II. 4. The laboratory failed to reject twenty two (22) COVID specimens that were beyond the manufacturer's stability requirements. Refer to D5311 III.