Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2192800	02/25/2022
Name of Provider or Supplier	**Street Address, City, State**	
Curative Labs Inc	1700 Royston Lane Suite B, Round Rock, TX	

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 onsite survey conducted February 22, 2022 through February 25, 2022 found the laboratory out of compliance based on the following CONDITION LEVEL DEFICIENCIES: D3000 - 42 C.F.R. 493.1101 Condition: Facility Administration; D5300 - 42 C.F.R. 493.1240 Condition: Preanalytic systems; D5400 - 42 C.F.R. 493.1250 Condition: Analytic systems; D6076 - 42 C.F.R. 493.1441 Condition: Laboratories performing high complexity testing; laboratory director;
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) 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. This STANDARD is not met as evidenced by: I. Based on review of the Emergency Use Authorization (EUA), manufacturer's instructions, interview, observation, review of temperature charts, pre-survey paperwork, and interview and email, the laboratory failed to monitor the room temperature where Abbott ID NOW COVID-19 test kits were stored for five of five days. Findings follow. 1. Review of the EUA for the Abbott ID NOW COVID-19 test kit under Storage and Stability stated, "Store kit at 2-30 degrees Celsius." 2. Review of the manufacturer's instructions on the Abbott ID NOW COVID-19 test kit label on the box had a temperature range of 2-30 degrees Celsius. 3. Interview with waived testing personnel #? on February 25, 2022 at 0930 hours at the field site in Georgetown stated they had been taking test kits home [after closure], but since switching to the Abbott ID NOW, they have been storing the test kits at an off-site storage unit for about 2-3 weeks. Interview with the Director of Compliance and Safety on February 25, 2022 at 1000 hours at the off-site climate-controlled storage unit confirmed, they did not record temperatures at the storage unit. 4. Observation of the storage unit utilized for the storage of reagents for the Georgetown field station

showed the following Abbott ID NOW COVID-19 test kits in the storage unit: a. Lot 1061640, Expiration 10-26-2022 22 boxes (24 tests/box) b. Lot M181220, Expiration 10-19-2022 1 box c. an additional 6 cases (6 boxes in each case) 5. Review of temperature charts showed no temperature charts for one of one storage units visited utilized to store reagents by a field site in Georgetown. 6. Phone interview with the Director of Compliance and Safety on February 25, 2022 at 1430 hours requested temperature logs from the storage unit. Email from the Director of Compliance and Safety on March 1, 2022 at 3:04 PM stated the storage unit was leased on 02/20/2022 and temperature logs were not provided to her by the storage unit. 7. Review of the CMS form 116 showed approximately 4 million waived tests were performed annually (across their multi-sites). II. Based on review of the Emergency Use Authorization (EUA), interview, review of temperature charts, email, and pre-survey paperwork, the laboratory failed to monitor the room temperature where Abbott ID NOW COVID-19 test kits were stored overnight from 02/01/2021 - 02/19/2022 for one of one field site for 19 out of 19 days. Findings follow. 1. Review of the EUA for the Abbott ID NOW COVID-19 test kit under Storage and Stability stated, "Store kit at 2-30 degrees Celsius." 2. Interview with the Director of Compliance and Safety on February 25, 2022 at 0900 hours at the Georgetown field site acknowledged testing personnel had been taking test kits home with them but was not monitoring temperatures at home. Interview with waived testing personnel #? on February 25, 2022 at 0930 hours at the field site in Georgetown stated they had been taking test kits home [after closure], but since switching to the Abbott ID NOW, they have been storing the test kits at an off-site storage unit for about 2-3 weeks. 3. Review of temperature charts showed no temperature charts for the testing personnel's' home serving one field site inspected in Georgetown. 4. Email from the Director of Compliance and Safety on March 1, 2022 at 3:04 PM stated test volumes at this site with the Abbott ID NOW was 2,226 from 02/01/2022 - 03/01/2022. 5. Review of the CMS form 116 showed approximately 4 million waived tests were performed annually (across multi-sites). 36342 I. Based on review of laboratory documents, observation, and interviews with the Site Supervisors at the time of survey, the laboratory failed to follow the manufacturer's instructions or instructions for use (IFU) for performing COVID-19 antigen and Accula rapid Polymerase Chain Reaction (PCR) testing. Findings include: Site # 1: Eugene Site Hult Center CLIA# 45D2192800, located at 1 Eugene Center, Eugene, OR 97401 1. Review of the Abbott Binax Now COVID antigen test IFU states: "Store kit at 2-30C. Ensure all test components are at room temperature (15 - 30 degrees C) before use." During the survey conducted on 1/12/2022, the Site Supervisor was unable to provide written or digital documentation of temperature monitoring of testing area for each day of testing for the Abbott Binax Now COVID Antigen test. 2. Review of the Accula rapid PCR IFU states: "Store reagents at room temperature (15C to 30C, 59F to 86F). Do not refrigerate or freeze." During the survey conducted 1/12/2022, the Site Supervisor was unable to provide written or digital documentation of daily temperature monitoring of the storage location for the Accula rapid PCR test. 3. Review of the Accula rapid PCR IFU, page six (6) states "Testing site personnel must provide a physical or digital copy of the Self-Collection Quick Reference Guide to the patient prior to collection." During the site survey on 1/12/2022, the surveyor observed several self-collected samples by patients. At no time were there written or digital instructions provided to the patients. Further investigation of the Curative website failed to reveal any written or digital instructions for patients requesting an Accula Rapid PCR test at the Eugene site. 4. Review of the Accula rapid PCR IFU states: "Authorized laboratories that receive the Accula SARS-CoV-2 Test must notify the relevant public health authorities of their intent to run the test prior to initiating testing." Notification by Curative Labs with intent to offer testing in the state of Oregon was not submitted to

OHA/CLIA prior to initiating patient testing at this site. Site #2: Woodburn Site Hoodview Church of God, Outdoor temporary storage and testing container CLIA#45D2192800, located at 1530 Mt. Hood Ave., Woodburn, OR 97071 1. Review of the Accula rapid PCR IFU states: "Store reagents at room temperature (15C to 30C, 59F to 86F). Do not refrigerate or freeze." During the survey conducted on 1/31/2022, the Site Supervisor was unable to provide written or digital documentation of storage temperatures for the Accula rapid PCR test system and collection kits. 2. Review of the Accula rapid PCR IFU, page six (6) states "Testing site personnel must provide a written or digital copy of the self-collection guide to the patient prior to collection." During the onsite survey, this surveyor observed several self-collected samples by patients. At no time during the onsite survey, were written or digital instructions for the patients provided. Further investigation of the Curative website failed to reveal any written or digital instructions for patients requesting an Accula Rapid PCR test at the Woodburn site. Site#3: Portland Site Outdoor temporary storage and testing container. CLIA#45D2192800, located at 834 NE Martin Luther King Blvd, Portland, OR 97232 1. Review of the Accula rapid PCR IFU states: "Store reagents at room temperature (15C to 30C, 59F to 86F). Do not refrigerate or freeze." During the survey conducted on 2/7/2022, by interview, the Site Supervisor stated "we do not record the daily temperatures for the storage /testing container where the Accula rapid PCR test reagent /collection kits are kept and where testing is performed." 2. Review of the laboratory's standard operating Health and Safety procedure, 6.3 states "Gloves should be worn and changed after each patient to prevent the spread of contamination." Based on observations of staff performing Accula rapid PCR specimen processing and testing, testing personnel did not change gloves with each new patient specimen. 3. Review of the Accula rapid PCR IFU, page six (6) states "Testing site personnel must provide a written or digital copy of the Self-Collection Quick Reference Guide to the patient prior to collection." During site survey, the surveyor observed several self-collected samples by patients. At no time were written or digital instructions provided to the patients. Further investigation of the Curative website failed to reveal written or digital instructions for patients requesting an Accula Rapid PCR test at the Portland site. 4. Review of the Accula rapid PCR IFU states: "Authorized laboratories that receive the Accula SARS-CoV-2 Test must notify the relevant public health authorities of their intent to run the test prior to initiating testing." Notification by Curative Labs of the intent to offer testing in the state of Oregon was not submitted to OHA/CLIA prior to beginning patient testing at the Portland site. Site #4: Clackamas Community College Harmony Campus Outdoor temporary storage and testing container CLIA#45D2192800 located at 7738 SE Harmony Road, Portland, OR 97222 1. Review of the Curative viral transport media collection kits, (for out of state COVID patient test collections) states that they have a temperature range of (15C to 30C, 59F to 86F) noted on the label of the viral transport media tube. During the site visit on 3/23/2022, it was observed that the out of state Curative viral media collection kits, during the hours of the testing, were stored outdoors. At the time of the survey, at approximately 2:00 pm, the outdoor temperature was 57 degrees Fahrenheit. 2. Testing personnel (TP) #1 confirmed by interview on 3/23/22, at approximately 2 pm, the Curative collection kits and collected patient specimens during hours of testing, were stored outdoors. 3. During phone interview with the Laboratory Director (LD) at 3:23 pm 3/23/2022, confirmed that the LD was aware that the Curative viral media collection kits and collected patient specimens were being stored outdoors in cold temperatures during the day when the site is open. Further investigation for the onsite testing area was not possible as entry was denied into the temporary testing / storage container. II. Based on review of the Accula SARS-COV-2 test instructions for use, laboratory temperature records, and interview with facility personnel, the laboratory failed to monitor the temperature

	for storage of the Accula SARS-COV-2 reagents for 67 of 67 days between September 20, 2021 and February 16, 2022 at the Lake Hills Plaza temporary site location. The findings included: 1. Based on review of the Accula SARS-COV-2 test instructions for use (60061-7 (2021-01) Accula SARS-CoV-2 IFU), under STORAGE AND HANDLING, the instructions stated "Store reagents at room temperature (15C to 30C, 59F to 86F). Do not refrigerate or freeze." 2. Based on review of environmental records between 9/20/2021 and 2/16/2022, the laboratory records did not indicate the measurement of the temperature inside the Lake Hills Plaza location for 67 of 67 recorded days of operation. 3. In an interview in the conference room at 17:10 hours on 2/24/2021, the Director of Compliance stated the laboratory had monitored outdoor temperatures between September 20, 2021 and February 16, 2022 but had not monitored the temperature inside the Lake Hills Plaza location. The Director of Compliance confirmed the laboratory had been using the Accula SARS-COV-2 test reagents between September 20, 2021 and February 16, 2022 and had used the following lots of reagents for testing patients during this timeframe: P21253-015 P21270-074 P21251-014 P21278-005 P21287-001 P21284-038 P21333-053 P21319-027 P21341-013 P21319-027 P21341-013 P21319-027 P21341-017 P22010-021
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). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on surveyor observations, review of laboratory policies and procedures, laboratory environment wipe-test contamination records, biosafety cabinet records, and interview with facility personnel, the laboratory failed to ensure that contamination of patient specimens were minimized (refer to D3003) and failed to have a unidirectional workflow for the laboratory developed test (LDT) for SARS-CoV-2 (refer to D3005).
D3003	FACILITIES CFR(s): 493.1101(a)(2) The laboratory must be constructed, arranged, and maintained to ensure contamination of patient specimens, equipment, instruments, reagents, materials, and supplies is minimized. This STANDARD is not met as evidenced by: Based on observation, laboratory policy, and laboratory environmental records, and interview, the laboratory failed to ensure that contamination of patient specimens was minimized as evidence by: 1. In a tour of the laboratory on 2/23/2022 at 19:44

	surveyor observed a specimen processor vortexing, uncapping, and recapping SARS-CoV-2 specimens in a biosafety cabinet (BSC), serial number 300411850, that did not have a functional blower. The surveyor noted that the biosafety cabinet daily maintenance checklist taped to the front of the hood had the following comment in the note section: "BSC only used for recapping. Blower has not worked since Dec (?) '21" Surveyor queried on 2/23/2022 at 19:45, as to why they hadn't taken the biosafety cabinet out of use. The specimen processor stated that they had been instructed only to use it for specimen uncapping and recapping. 2. Review of the laboratory policy titled "Detection of SARS-CoV-2 Using the Abbot Alinity m SARS-CoV-2 Assay kit, section 11.0 "Policy", subsection 11.2 "Minimization of Contamination by Aerosols" had the following statement: "11.2.1 use a biosafety hood when transferring specimens manually from one container to another or when opening a specimen container with a potentially contaminated cap." 3. Review of the laboratory policy titled "Detection of SARS-CoV-2 Using the Abbot Alinity m SARS-CoV-2 Assay kit, section 12.8 "Preparation of Samples", subsection 12.8.3.1.1 had the following statement: "Caution: Specimens in transport media may form aerosols upon removal of the tube cap, posing a risk of contamination." 4. The following 33 specimens were processed 2/23/2022 under BSC 300411850 and tested on the Abbott Alinity m Analyzer: Patient Barcode - Result A110241715314 - Negative A164257142334 - Negative A346781453223 - Positive A360039419693 - Negative A368340390760 - Negative A383825015673 - Negative A420580613055 - Negative A515659515370 - Negative A527358481443 - Negative A554194522813 - Positive A561355759730 - Negative A570119896762 - Negative A596835211116 - Negative A630970079205 - Negative A647507450956 - Negative A679016586994 - Negative A685974848085 - Negative A719537228556 - Negative A730723396144 - Negative A735473088671 - Negative A781253485463 - Negative A808589917601 - Negative A824028614627 - Negative A824828283086 - Negative A833245562980 - Negative A862646952936 - Negative A937563211855 - Negative A939856915695 - Negative A947254269924 - Negative A968016260924 - Negative A979458803485 - Negative A984133586835 - Negative A989624534150 - Negative 5. In an interview on 2/24/2022 at 15:57 hours, in the conference room, the laboratory director confirmed that the laboratory was utilizing the BSC with a broken blower for the uncapping and recapping of SARS-CoV-2 specimens. The laboratory director stated that there was no chance that there would be cross contamination from a positive specimen to a negative specimen when being recapped in the BSC with a failed blower. 6. Review of the January 2022 site wide environmental swab tests for viral RNA contamination results are as follows: - 1/4/2022 - 37 of 83, 44.5%, of the tested sites resulted positive for viral RNA contamination. - 1/6/2022 - 22 of 82, 26.8%, of the tested sites resulted positive for viral RNA contamination. - 1/10/2022 - 3 of 83, 3.4%, of the tested sites resulted positive for viral RNA contamination. - 1/11/2022 - 8 of 111, 7.2%, of the tested sites resulted positive for viral RNA contamination. - 1/19/2022 - 31 of 110, 28.1%, of the tested sites resulted positive for viral RNA contamination. - 1/21/2022 - 25 of 110, 22.7%, of the tested sites resulted positive for viral RNA contamination. - 1/25/2022 - 33 of 110, 30.0%, of the tested sites resulted positive for viral RNA contamination. - 1/27/2022 - 23 of 111, 20.7%, of the tested sites resulted positive for viral RNA contamination. 7. In an interview on 2/24/2022 at 1535 in the conference room, the technical supervisor stated that the laboratory decontaminates areas that have resulted positive for viral RNA contaminations.
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 surveyor observations and tour of the specimen route for its laboratory developed test (LDT), review of the laboratory's submitted floor plan, quality control records, patient test records, and confirmed in interview of laboratory personnel, the laboratory failed to have a unidirectional workflow for its 1 of 1 LDT for SARS-CoV-2. The findings included: 1. Based on a surveyor observation and tour of the specimen route for the laboratory's LDT performed on February 23, 2022 at 13:34 hours found that after leaving the King Fisher room, the laboratory no longer maintained a unidirectional workflow. The specimen is placed in the refrigerator in the MasterMix area, then it flows down the hallway to qPCR3, and then back up the hallway to qPCR2. 2. Review of the laboratory's submitted workflow map for its LDT found it reflected the above specimen route. 3. Review of quality control records from August 12, 2021 to February 9, 2022 found 180 quality control re-runs of PCR. The following is a random selection of examples that were tested for re-run: Plate ID Date of Request Reason for re-PCR 384-TX008435 08-12-2021 Human Amp in floating blank 384-TX008465 08-13-2021 No amplification on plate HTX007137 384-TX008633 08-20-2021 Amplification in floating blank 384-TX009282 09-09-2021 FB failed, shows amplification 384-TX009555 09-24-2021 Negative control failed 384-TX009850 10-10-2021 Failed Positive Controls 384-TX009888 10-14-2021 Both Negative Controls failed on batch HTX012127 384-TX009994 10-28-2021 Positive control failures 384-TX010214 12-16-2021 Control failure 384-TX010347 12-22-2021 Both Positive controls failed on batch 1 384-TX010383 12-23-2021 Amplification in empty well 384-TX010519 12-25-2021 Positive control failure on Batch 4 384-TX010753 12-31-2021 Abnormal amplifications 384-TX011112 01-05-2022 Negative Control failure 384-TX011785 01-15-2022 Floating Blank failure 384-TX012863 02-08-2022 Positive Control failure 384-TX012875 02-09-2022 Floating Blank failure on HTX022174 4. Review of patient test records (release date February 23, 2022) found the following patients were tested when the laboratory did not maintain a unidirectional workflow: Requisition Number: 56444728 Result: Negative Requisition Number: 56464451 Result: Negative Requisition Number: 56437428 Result: Negative 5. Review of the laboratory's submitted Form CMS-116 approved by the laboratory director on February 23, 2022 listed a SARS-CoV-2 testing volume of 5 million tests annually. 6. The findings were confirmed in interview with the Laboratory Manager on February 21, 2022 at 14:30 hours. He said the laboratory, "Used to have unidirectional workflow." This confirmed the findings. Key: PCR - Polymerase Chain Reaction CMS - Centers for Medicare and Medicaid Services
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records, and patient records, the laboratory failed to follow established procedure for patient identification

	for 1 of 10 records reviewed. The findings included: 1. Based on review of the laboratory policy "FO-009 Patient Identification Procedure", under PROCEDURE, the policy stated: "6.2 Verify the patient's date of birth with either an ID or document. 6.2.1. If a patient does not have an ID or document with their date of birth printed on it, verify the patient's date of birth verbally." 2. Based on a random review of ten patient reports, one of ten patient reports had missing information. Medical Record Number (CUR155610037) Requisition: 54612525 Kit ID: A156594044940 Collected: 1/24/22 08:39:10 AM CST Received: 1/24/22 07:20:19 PM CST The patient's name and date of birth was missing. 3. Based on review of Query_result_2022-02-24T15_21_47.993675-08_00, two medical record numbers were associated with this event: 2654950 27270642 4. Based on review of the form "QA-SOP-011-F01-2022-3391 Customer Feedback/Complaint Form 2/23/2022", the laboratory's investigation stated: "On 25-Jan-2022 at 7:13 a.m., the father of the minor patient contacted Customer Care via phone and spoke with {name redacted} (Tier One Agent, Active) requesting a name change on a resulted test (Reference 155610037). The father of the minor patient stated he placed his name on his daughter's appointment when he registered for a test. {Tier One Agent} informed the parent that since this test has already been resulted, a name change cannot be done, and the minor patient will need to retest. On 25-Jan-2022 at 07:42 a.m., the mother of the minor patient contacted Customer Care via phone and spoke with {name redacted, second agent} (Tier One Agent, Active) request a name change on a resulted test. The minor patient's date of birth and sex do match but the name on the appointment is the father's name. {Name redacted, second agent} informed the parent of the minor that since this test has already been resulted, a name change cannot be done. The mother of the minor patient requested the call to be escalated. On 25-Jan-2022 at 08:08 a.m., the call was escalated to {name redacted, third agent), (Tier Two Agent, Terminated). {Name redacted, third agent} informed the patient that since this test has already ben resulted a name change cannot be done to the appointment. Per Retool, on 25-Jan-2022 at 9:27 a.m., {Name redacted, third agent} removed all Protected Health Information (PHI) from the appointment and replaced it will be missing information default data as Curative cannot confirm who truly tested with this appointment."
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, competency evaluations, pre-survey paperwork, and interview, the laboratory failed to evaluate the competency of its Technical Supervisor and General Supervisors for five of five personnel. Findings follow. 1. Review of the laboratory's procedure titled AH-001 Training and Competency Assessment - Laboratory Personnel, effective 06/30/2021, at 6.11.5 stated, "The General Supervisor and Technical Supervisor Competency Assessment will be conducted by the Laboratory Director or designee." 2. Review of competency evaluations showed no evaluation for one of one Technical Supervisor and four of four General Supervisors. 3. Review of the CMS form 209 and the Laboratory Personnel form showed the following positions with their respective hire date: a. Technical Supervisor #1, 11/05/2020 b. General Supervisor #1, 02/10/2021 c. General Supervisor #2, 12/23/2020 d. General Supervisor #3, 11/02/2020 e. General

	Supervisor #4, 09/03/2021. 4. Interview with Technical Supervisor #1 on February 23, 2022 at 0945 hours in the conference room confirmed there were no competency evaluations specific to the Technical Supervisor and General Supervisors duties.
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 surveyor observations, review of laboratory policies and procedures, review of manufacturer instructions for specimen acceptability, and interview with facility personnel, the laboratory failed to validate the Abbott Molecular Transport Buffer (09N77) contained in the Abbott Universal Collection Kit used for transporting Nasal swab specimens to be tested for SARS/COVID was acceptable for use beyond the manufacturers specifications and the laboratory failed to have a mechanism in place to ensure samples shipped to the facility were maintained at acceptable temperatures through the transport of specimens from the collection site to the laboratory for testing. Refer to D5311-A and D5311-B.
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: A. Review of the manufacturer's instructions for use, policies and procedures, the validation studies and interview of facility personnel, the laboratory failed to validate the Abbott Molecular Transport Buffer (09N77) contained in the Abbott Universal Collection Kit used for transporting Nasal swab specimens to be tested for SARS /COVID was acceptable for use beyond the manufacturers specifications. The findings included: 1. Review of the Abbott Universal Collection Kit instructions for use found on page 3 under the heading SWAB SPECIMEN STORAGE AND TRANSPORT: "After collection, transport and store transport tube at 2 to 25 C (Celsius) for up to 48 hours. If delivery and processing exceed 48 hours, specimens should be transported in dry ice and once in laboratory frozen at -70 C." 2. Review of the General Laboratory Policy titled Specimen Collection, Labeling, Handling and Transport Procedure (Doc#: GL-001 Rev: 11.1 Effective Date 2/16/2022) found on page 2 under the heading SPECIMEN REQUIREMENTS: "9.4 Field Collection Site Post-Collection Stability/Storage: 2C - 40 C up to 50 hours. Longer than 50 hours - 70C or colder. 9.5 Within Laboratory Stability/Storage: 2C - 25C up to 136 hours.

Longer than 48 hours: -70C or colder." 3. Review of Validation Reports found: a. Review of the Validation and Qualification Report titled Sample Transportation Stability Study: Nasal Samples in Abbott Specimen Transport Buffer Tested With SARS-CoV-2 Multiplex Assay (LDT2) (Doc#: VR006 Rev: 1.0 Effective 7/30/2021) found on page on page 2 under the heading Methodology: " 40 Contrived samples (20 negative and 20 positive at1X LOD, or 100 copies /ml) were aliquoted into Abbott Universal Collection tubes and tested with the SARS-CoV-2 Multiplex Assay to produce baseline values. Samples were subsequently subjected to temperature cycling ranging from 22C to 40C for 50 hours before retesting with the SARS-CoV-2 Multiplex Assay." Further review found on page 5 under the heading CONCLUSION: "The data collected verify the stability of SARS-CoV-2-negative and positive samples (viral concentration 100 copies/mL) in Specimen Transport Buffer during shipping. Samples produce qualitatively consistent results on the SARS-CoV-2 Multiplex Assay even after exposure to high and variable temperatures for up to 50 hours." b. Review of the Validation and Qualification Report titled Patient Sample Stability Within Abbott Molecular Transport Buffer (09N77) (Doc# VR-009 Rev:1 Effective 09/02 /2021) found on page 1 under notes: "This stability study is performed at Curative Labs, DC and the results extended to all Curative labs sites." Further review found on page 1 of 7 under the heading SCOPE: "This document applies to the use of the Abbott Molecular transport Buffer (09N77) to preserve patient specimens over the course of 5.5 days. Comparative clinical performance was assessed by measuring agreement between the results obtained from the 1.5-day old samples and the results obtained from the same samples after four additional days. This study was executed at the DC Curative Lab Division located in Washington DC using equipment and software representative of the San Dimas, Washington DC, and Texas Laboratories." On page 4 under the heading CONCLUSIONS: " The Laboratory Director has reviewed these data and report and has determined it is acceptable to store nasal samples suspended in Abbott Molecular Transport Buffer (09N77) over an extended period of time (up to 136 + 2 hours) at room temperature (15 - 25 C)." 4. Interview of the Laboratory Director conducted February 23, 2022 at 1:42 PM in the conference room confirmed that the laboratory did not validate the Abbott Specimen Buffer at temperatures below 22C because the manufacturer included that in their own study. He went on to say that the validation studies were not performed at this site but performed in the laboratory located in DC and that as Laboratory Director, he evaluated the studies and thought they were low risk and would be acceptable at all sites. B. Based on review of the laboratory's procedures, specimen stability validations, surveyor observation, specimen accessioning records and staff interview, it was revealed the laboratory failed to have a mechanism in place to ensure samples shipped to the facility were maintained at acceptable temperatures through the transport of specimens from the collection site to the laboratory for testing. The findings included: 1. Review of the Abbott Universal Collection Kit instructions for use found on page 3 under the heading SWAB SPECIMEN STORAGE AND TRANSPORT: "After collection, transport and store transport tube at 2 to 25 C (Celsius) for up to 48 hours. If delivery and processing exceed 48 hours, specimens should be transported in dry ice and once in laboratory frozen at -70 C." 2. Review of the General Laboratory Policy titled Specimen Collection, Labeling, Handling and Transport Procedure (Doc#: GL-001 Rev: 11.1 Effective Date 2/16/2022) found on page 5 under the heading Packaging instructions for Shipping Specimens to a Curative Laboratory: "Place the patient sample test kits into a UPS laboratory box or equivalent and label it with a UN3373 label of the following sizes and maximum kit quantity: Small - Maximum 20 Specimens Medium - Maximum 40 Specimens Large - Maximum 50 Specimens Seal the box with packing tape, and write in permanent marker, clearly on the outside of the box, the following: The Site Name The number

	of kits in the box Do Not cover the UN 3373 label or the delivery service will not be able to accept the package." 3. Review of Validation Reports found: a. Review of the Validation and Qualification Report titled Sample Transportation Stability Study: Nasal Samples in Abbott Specimen Transport Buffer Tested With SARS-CoV-2 Multiplex Assay (LDT2) (Doc#: VR006 Rev: 1.0 Effective 7/30/2021) found on page on page 2 under the heading Methodology: " 40 Contrived samples (20 negative and 20 positive a1X LOD, or 100 copies /ml) were aliquoted into Abbott Universal Collection tubes and tested with the SARS-CoV-2 Multiplex Assay to produce baseline values. Samples were subsequently subjected to temperature cycling ranging from 22C to 40C for 50 hours before retesting with the SARS-CoV-2 Multiplex Assay." Further review found on page 5 under the heading CONCLUSION: "The data collected verify the stability of SARS-CoV-2-negative and positive samples (viral concentration 100 copies/mL) in Specimen Transport Buffer during shipping. Samples produce qualitatively consistent results on the SARS-CoV-2 Multiplex Assay even after exposure to high and variable temperatures for up to 50 hours." b. Review of the Validation and Qualification Report titled Patient Sample Stability Within Abbott Molecular Transport Buffer (09N77) (Doc# VR-009 Rev:1 Effective 09/02/2021) found on page 1 under notes: "This stability study is performed at Curative Labs, DC and the results extended to all Curative labs sites." Further review found on page 1 of 7 under the heading SCOPE: "This document applies to the use of the Abbott Molecular transport Buffer (09N77) to preserve patient specimens over the course of 5.5 days. Comparative clinical performance was assessed by measuring agreement between the results obtained from the 1.5-day old samples and the results obtained from the same samples after four additional days. This study was executed at the DC Curative Lab Division located in Washington DC using equipment and software representative of the San Dimas, Washington DC, and Texas Laboratories." On page 4 under the heading CONCLUSIONS: " The Laboratory Director has reviewed these data and report and has determined it is acceptable to store nasal samples suspended in Abbott Molecular Transport Buffer (09N77) over an extended period of time (up to 136 + 2 hours) at room temperature (15 - 25 C)." 4. Surveyor observation of samples received by the laboratory on February 23, 2022 at 7:00 PM revealed the laboratory received 20 cardboard boxes (various sizes and manufacturers) containing samples picked up at the airport by the courier and brought to the laboratory. There was not a mechanism in place to ensure the samples did not exceed the laboratory's defined acceptable temperatures as defined by its stability studies. The boxes contained samples placed in biohazard bags with no means of monitoring the temperature during the transport process. 5. Review of Specimen accessioning records for February 23, 2022 between 10:00 AM and 8:00 PM found the laboratory accessioned 6228 patient specimens to be tested for SARS-CoV-2. 6. Interview of the Laboratory Director conducted February 23, 2022 at 7:14 PM confirmed that the laboratory did not validate all shipping box configurations. Any box chosen for shipment would be acceptable as long as the box itself was labeled with the correct information.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, 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 analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.

	This CONDITION is not met as evidenced by: Based on manufacturer's labeling of the Abbott Alinity Pipette Tips, Abbott Alinity Transport Tubes, and Abbott Alinity Transport Tube Pierceable Caps, temperature charts, laboratory's instrumentation list, establishment study records, patient test records, the laboratory's submitted Form CMS-116, Abbott Alinity SARS-CoV-2 assay instructions for use (IFU), laboratory policies and procedures, quality control (QC) documents, patient reports, and interview with facility personnel: 1) The laboratory failed to ensure supplies used for the Abbott Alinity m PCR SARS-CoV-2 test had not exceeded manufacturer's temperature requirements for 24 out of 123 days (refer to D5413). 2) The laboratory failed to include interfering substances in analyte specificity studies for the laboratory developed test (LDT) for SARS-CoV-2(refer to D5423-A). 3) The laboratory failed to establish analyte specificity, to include interfering substances for Abbott Alinity SARS-CoV-2 assay in use for six out of six months after making an off-label specimen stability modification (refer to D5423-B). 4) The laboratory failed to evaluate all patient test results since the last acceptable external control after QC failures for four of four QC failures reviewed for two weeks of January 2022 for the Alinity M SARS-CoV-2 test (refer to D5783).
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, temperature charts, observation, and interview, the laboratory failed to ensure supplies used for the Abbott Alinity m PCR SARS-CoV-2 test had not exceeded manufacturer's temperature requirements for 24 out of 123 days. Findings follow. A. Review of the manufacturer's label on the box and case of the Abbott Alinity Pipette Tips, Abbott Alinity Transport Tubes, and Abbott Alinity Transport Tube Pierceable Capped showed the required storage temperature of 15 - 30 degrees Celsius. B. Review of the continuous monitoring room temperature chart for the warehouse "Freezer Cage", showed 24 out of 123 days where the temperature exceeded 15-30 degrees Celsius from October 2021 - January 2022: 1. The following dates in October 2021 with the temperature in Celsius - a. 1: 31.70 b. 2: 33.18 c. 3: 33.13 d. 4: 32.50 e. 5:32.25 f. 6: 32.63 g. 7: 33.90 h. 8: 34.10 i. 9: 33.10 j. 10: 32.85 k. 11: 31.73 l. 13: 31.10 m. 15: 31.08 n. 21: 30.85 o. 22: 30.68 p. 23: 31.30 q. 24: 31.05 r. 25: 32.18 s. 26: 30.85 2. The following dates in January 2022 with the temperature in Celsius - a. 2: 12.4 b. 21: 13.1 3. The following dates in February 2022 with the temperature in Celsius - a. 3: 11.9 b. 4: 11.0 c. 5: 14.1 C. Surveyor observed on February 24, 2022 at 1130 hours in the warehouse of the administration building, the following cases of supplies: 1. Abbott Alinity Pipette Tips, 50 uL, in quantities of 12 x 480 (5,760) per case: a. Lot 1003926, manufactured 2021-08-09 178 cases b. Lot 1003927, manufactured 2021-08-11 58 cases c. Lot 0753493, manufactured 2021-07-06 21 cases d. Lot 1009042, manufactured 221-09-09 84 cases e. Lot 1009043, manufactured 2021-09-11 71 cases 2. Abbott Alinity

	Pipette Tips, 1000 microliter (uL), in quantities of 8 x 480 (3,840) per case: a. Lot 1019011, manufactured 2021-10-26 88 cases b. Lot 1025517, manufactured 2021-12-15 70 cases 3. Abbott Alinity Transport Tube, in quantities of 1600 per case: Lot ATT046, expiration 2026-06-01 11 cases 4. Abbott Alinity Transport Tube, Pierceable Capped, in quantities of 6 x 25 x 10 (1500) per case: Lot ATP027, expiration 2026-05-25 6 cases Surveyor observation on February 24, 2022 at 1300 hours in the warehouse showed some cases with the storage requirement had been received as early as September 27, 2021. D. Interview with the warehouse manager on February 24, 2022 at 1145 hours in the warehouse acknowledged when the supplies were purchased directly from Hamilton, they had no storage requirements, but the repackaged Hamilton supplies by Abbott have the 15 -30 [degrees Celsius] requirement. It was his understanding the temperature requirement was for when the supplies were in use. Interview with the Quality Specialist 1 on February 24, 2022 at 1155 in his cubicle acknowledged the laboratory's upper limit of acceptability was set at 40 degrees Celsius for the operation of the refrigerators in use in the warehouse, and they just recently started storing supplies for the Alinity in the warehouse.
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: A. Based on review of the laboratory's instrumentation list, establishment study records, patient test records, the laboratory's submitted Form CMS-116, and confirmed in interview of laboratory personnel, the laboratory failed to provide documentation of completing studies for interfering substances for 1 of 1 laboratory developed test (LDT) for SARS-CoV-2. The findings included: 1. A review of the laboratory's equipment list for its 1 of 1 LDT for SARS-CoV-2 listed the following equipment and serial numbers for 10 of 10 Bio-Rad Thermal Cycler CFX384 PCR instruments: Equipment Base Head/Optics In Use Number SN SN Date EQ-00970 CT046187 786BR05988 08-19-2021 EQ-00968 CT046194 786BR05980 08-16-2021 EQ-00976 CT052609 786BR06542 08-01-2021 EQ-01857 CT055989 786BR06362 08-01-2021 EQ-00978 CT053673 786BR06498 08-04-2021 EQ-00979 CT053635 786BR06598 08-01-2021 EQ-00971 CT047828 786BR06128 10-06-2021 EQ-00974 CT050239 786BR06428 10-07-2021 EQ-00975 CT052676 786BR06543 10-07-2021 EQ-01750 CT056013 786BR06768 10-07-2021 2. A review of the laboratory's establishment studies for its laboratory developed test (LDT) for SARS-CoV-2 found the laboratory failed to have documentation of performing or verifying studies for interfering substances using the listed 10 of 10 Bio-Rad Thermal Cycler CFX384 instruments. 3. Review of patient test records from September 2021, November 2021, and December 2021 found the following random sample of patient results that were performed when the laboratory had not performed complete establishment studies

prior to patient testing: Requisition Number: 46460294 Release Date: 09-13-2021 SARS-CoV-2 Result: Negative Requisition Number: 49441318 Release Date: 11-23-2021 SARS-CoV-2 Result: Negative Requisition Number: 49413735 Release Date: 11-23-2021 SARS-CoV-2 Result: Negative Requisition Number: 49398397 Release Date: 11-23-2021 SARS-CoV-2 Result: Negative Requisition Number: 49468541 Release Date: 11-24-2021 SARS-CoV-2 Result: Negative Requisition Number: 49482787 Release Date: 11-24-2021 SARS-CoV-2 Result: Positive Requisition Number: 49426231 Release Date: 11-23-2021 SARS-CoV-2 Result: Negative Requisition Number: 51253999 Release Date: 12-27-2021 SARS-CoV-2 Result: Positive Requisition Number: 49402604 Release Date: 11-23-2021 SARS-CoV-2 Result: Negative Requisition Number: 49445447 Release Date: 11-23-2021 SARS-CoV-2 Result: Negative Requisition Number: 49465659 Release Date: 11-24-2021 SARS-CoV-2 Result: Negative Requisition Number: 49668313 Release Date: 12-02-2021 SARS-CoV-2 Result: Negative Requisition Number: 49413642 Release Date: 11-23-2021 SARS-CoV-2 Result: Negative Requisition Number: 49418334 Release Date: 11-23-2021 SARS-CoV-2 Result: Negative Requisition Number: 49484819 Release Date: 11-24-2021 SARS-CoV-2 Result: Negative Requisition Number: 49360656 Release Date: 11-24-2021 SARS-CoV-2 Result: Negative Requisition Number: 49313306 Release Date: 11-23-2021 SARS-CoV-2 Result: Negative 4. Review of the laboratory's submitted Form CMS-116 approved by the laboratory director on February 23, 2022 listed a SARS-CoV-2 testing volume of 5 million tests annually. 5. An interview with the laboratory director on February 24, 2022 at 14:27 hours in the conference room confirmed the findings. When asked where the study for interfering substances was performed, he stated, "San Dimas." This confirmed the findings. Key: SARS - Severe Acute Respiratory Syndrome SN - serial number CMS - Centers for Medicare and Medicaid Services 45469 . B. Based on review of the Abbott Alinity SARS-CoV-2 assay instructions for use (IFU), laboratory documents, instrument establishment records, the Centers of Medicare and Medicaid Services (CMS) form 116, and confirmed in interview, the laboratory failed to establish analyte specificity for the SARS-CoV-2 assay which was modified from the emergency use authorization (EAU) to include interfering substances for six out of six months as evidence by: 1. Review of the EUA for the Alinity SARS-CoV-2 AMP Kit (ref 09N78-095) section "Specimen Collection, Storage, And Transport To The Test Site" stated: "Transport and store transport tube at 2 to 25 (degrees) Celsius (C) for up to 48 hours. If delivery and processing exceed 48 hours, specimens should be transported on dry ice and once in laboratory frozen at -70(degrees) C or colder. 2. Review of the laboratory document titled "Patient Sample Stability Within Abbott Molecular Transport Buffer (09N77), performed at a laboratory in the District of Colombia (DC), effective and signed by the laboratory director 9/2/2021, section 9.0 "Conclusions", subsection 9.2 has an off-label assay modification stating the following: "The Laboratory Director has reviewed these data and report has determined it is acceptable to store nasal samples suspended in Abbott Molecular Transport Buffer (09N77) over an extended period of time (up to 136 +/- 2 hours at room temperature (15-25 (degrees) C)." 3. Review of the laboratory policy for the Abbot Alinity titled "Detection of SARS-CoV-2 Using the Abbot Alinity m SARS-CoV-2 Assay Kit" signed by the laboratory director 12/22/2021, section 9.0 "Specimen Requirements" subsection 9.2 stated: "The specimen may be transported and stored at 2 - 25 (degrees) C for up to 136 +/- 2 hours." 4. The laboratory made an off-label specimen stability modification from the manufacturer instructions provided in the EUA. Any time a laboratory implements modification of the manufacturer's instructions that could affect performance specifications establishing studies must be performed. Review of the validation and qualification reports titled "Verification Plan for Abbott Alinity m SARS-CoV-2 Assay", with an effective date of 6/24/2021, did not include a study

	establishing analytic specificity, to include interfering substances. 5. Review of the CMS116 section VIII:Non-Waived Testing, lists an estimated annual test volume of 5,000,000 for the specialty microbiology. 6. In an interview on 2/24/2022 at 14:46 in the conference room, the laboratory director confirmed that there was no establishment study done for interfering substances after the change in specimen handling was implemented on 9/2/2021. .
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on laboratory policy, quality control (QC) documents, patient reports, and confirmed in interview, the laboratory failed to have a mechanism in place to evaluate all patient test results since the last acceptable external control after QC failures for four of four QC failures reviewed for two weeks of January 2022 for the Alinity M SARS-CoV-2 test. The findings include: 1. Review of the laboratory policy titled "Detection of SARS-CoV-2 Using the Abbott Alinity m SARS-CoV-2 Assay Kit" section 10.0 "Controls & Calibrations" had the following statement: Subsection 10.1.1.3 stated: "A set of Alinity m SARS-CoV-2 Negative and Positive controls should be tested at least once every 24 hours to establish a valid control record." 2. Review of quality control documents and laboratory handoff communications for the first 2 weeks of January 2022 lists the following QC failures that were resolved with the instrument being taken out of production and serviced by Alinity field service engineers (FSE): - 1/6/2022 - Analyzer E4 701 - Morning Shift Notes: "QC Failed twice, running for third time. Do not load until it passes." - 1/6/2022 - Analyzer B2 755 - PM Shift Note: "First QC had negative control fail as positive. Ran water samples and another QC to test for contamination. Otherwise, no issues" - 1/8/2022 - Analyzer C1 766 - Morning Shift Note: "QC Failed due to reactivity on negative control. Passed the second time, but FSE needs to examine." - 1/9/2022 - Analyzer D1 699 - Morning Shift Note: "Reactive negative control." 3. Review of patient testing records has the following number of patients tested on the above analyzers before a QC failure that required the analyzer to be taken out of production and serviced by Alinity field service engineers: - 1/6/2022 - Analyzer E4 701 - 149 Patients - 1/6/2022 - Analyzer B2 755 - 189 Patients - 1/8/2022 - Analyzer C1 766 - 764 Patients - 1/9 /2022 - Analyzer D1 699 - 167 Patients A sampling of 10 patients reported on analyzer E4 701 1/6/2022 include: Tube barcode number: A868633444734 A482195395772 A324884222673 A484014889784 A386013694104 A977548535443 A300633311126 A334469800837 A429528444314 A982511448364 4. In an interview on 2/23/2022 at 15:18 hours in the laboratory, the Alinity Supervisor stated that the only patient specimens evaluated after a QC failure are those specimens that were processed following the QC failure, as per the laboratory policy, and they did not have a mechanism in place to evaluate all patient tests resulted since the last acceptable external QC failure that could not be resolved with repeat testing.

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 surveyor observations, review of laboratory policies and procedures, laboratory environment wipe-test contamination records, biosafety cabinet records, review of laboratory policies and procedures, review of manufacturer instructions for specimen acceptability, temperature charts, laboratory's instrumentation list, establishment study documents, laboratory quality control records, patient records, and interview of facility personnel, the Laboratory Director failed to provide overall management and direction of the laboratory services. Refer to D6083, D6086, and D6106.
D6083	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(2) The laboratory director must ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed. This STANDARD is not met as evidenced by: Based on surveyor observations, review of laboratory policies and procedures, laboratory environment wipe-test contamination records, biosafety cabinet records, and interview with facility personnel, the Laboratory Director failed to ensure that contamination of patient specimens were minimized (refer to D3003), and failed to have a unidirectional workflow for the laboratory developed test (LDT) for SARS-CoV-2 (refer to D3005).
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 manufacturer's labeling of the Abbott Alinity Pipette Tips, Abbott Alinity Transport Tubes, and Abbott Alinity Transport Tube Pierceable Caps, temperature charts, laboratory's instrumentation list, establishment study records, patient test records, the laboratory's submitted Form CMS-116, Abbott Alinity SARS-CoV-2 assay instructions for use (IFU), laboratory policies and procedures, quality control (QC) documents, patient reports, and interview with facility personnel: 1) The Laboratory Director failed to ensure establishment studies included interfering substances in analyte specificity studies for the laboratory developed test (LDT) for SARS-CoV-2(refer to D5423-A), 2) The Laboratory Director failed to ensure

	establishment studies included analyte specificity, to include interfering substances for Abbott Alinity SARS-CoV-2 assay in use for six out of six months after making an off-label specimen stability modification (refer to D5423-B).
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 review of laboratory policy, manufacturer's instructions, laboratory environmental records, and confirmed in interview of laboratory personnel, the Laboratory Director failed to ensure the operating temperature range stated in its SOP met the manufacturer's operating temperature range for 5 of 5 months reviewed from October 2021 through January 2022. The findings included: 1. Review of the laboratory's policy titled, "Instrument Performance Qualification Report: Patient Sample Plating Using the Hamilton Liquid Handler (SN#E734) for SARS-CoV0-2 Multiplex Assay" (Document #PQ-042-TX, Rev. 1.0) approved by the laboratory director on August 1, 2021 under "4.0 Equipment and Materials" it stated: Equipment Description: Real-Time PCR System Manufacturer: Bio-Rad Model Number: CFX384 Touch Operating Conditions: 4 degrees Celsius - 100 degrees Celsius 2. Review of the manufacturer's instructions for the Bio-Rad CFX384 Touch Thermal Cycler (Chapter 2 Setting Up the C1000 Tough Thermal Cycler), under, "Operating Conditions" it stated, "15-31 degrees Celsius or 59-87 degrees Fahrenheit." 3. Review of the laboratory's environmental logs from October 2021 through January 2022 found the laboratory monitored the room temperature at a range from 15-30 degrees Celsius. 4. The operating temperature range listed in the SOP available to testing personnel did not match the manufacturer's instructions or the laboratory's current practice. 5. The findings were confirmed in interview with the laboratory director on February 24, 2022 at 15:00 hours in the conference room. Key: PCR - polymerase chain reaction SOP - standard operating procedure
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 site visit on 3/23/2022, the laboratory failed to allow the surveyor access to the laboratory testing area located at Clackamas Community College Harmony Campus, located at 7738 SE Harmony Rd., Portland, OR 97222. Refer to D8101.
D8101	BASIC INSPECTION REQUIREMENTS CFR(s): 493.1773(a) A laboratory issued a certificate must permit CMS or a CMS agent to conduct an inspection to assess the laboratory's compliance with the requirements of this part. A

	CLIA-exempt laboratory and a laboratory that requests, or is issued a certificate of accreditation, must permit CMS or a CMS agent to conduct validation and complaint inspections. This STANDARD is not met as evidenced by: Based on a complaint investigation onsite visit to Curative Temporary Testing site located at 7738 SE Harmony Road, Portland, OR 97222 on 3/23/2022, the laboratory failed to allow the surveyor access to the indoor patient testing areas, testing records, kit and reagent storage areas, including temperature logs, quality control records and testing personnel records. Findings included: 1 .A complaint investigation for Curative Labs was conducted on 3/23/2022, at approximately 2:00 pm at the address above. Upon arrival, the surveyor presented the letter of Authority to Enter to testing personnel (TP). Testing personnel #1 and #2 refused the surveyor entry into the temporary storage / testing container, stating "the Site Lead has to be present." 2. The Site Lead returned at approximately 2:15 pm, and also refused to allow the surveyor entry into the temporary storage / testing container. The letter of Authority to Enter was provided to the Site Lead. The Site Lead again refused entry, stating "we have to wait for the Manager at the Warehouse in Portland to arrive before entry is allowed."
D8201	INSPECTION OF COW OR PPMP LABS CFR(s): 493.1775(b) (b) If necessary, CMS or a CMS agent may conduct an inspection of a laboratory issued a certificate of waiver or a certificate for provider-performed microscopy procedures at anytime during the laboratory's hours of operation to do the following: (b)(1) Determine if the laboratory is operated and testing is performed in a manner that does not constitute an imminent and serious risk to public health. (b)(2) Evaluate a complaint from the public. (b)(3) Determine whether the laboratory is performing tests beyond the scope of the certificate held by the laboratory. (b)(4) Collect information regarding the appropriateness of tests specified as waived tests or provider-performed microscopy procedures. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the Curative Eugene Site Supervisor, the laboratory could not provide documentation of the laboratory's identification, correction, patient notification, and retention of discrepant COVID 19 patient results. Findings include: Site #1 Hult Center Eugene 1 Eugene Center, Eugene, Oregon 97401 CLIA # 45D2192800 1. The Oregon Health Authority (OHA) Electronic Laboratory Reporting Coordinator notified the Oregon CLIA program by email that she has had no cooperation from Curative Labs regarding missing results, incorrectly reported results as well as other demographic and clarification issues she and her team have submitted to Curative labs. Example # 1: Patient tested 11/19/2021, using ABBOTT BiNax Now rapid Antigen and received result of negative. Patient stated to Lane County Public Health "15 minutes after receiving the negative result, she received a second result of positive," which the patient then reported to Lane County Public Health. Lane County Public Health then contacted OHA Electronic Laboratory Reporting Coordinator. 2. Review of the Curative Standard Operating Procedure (SOP) for Correction of Laboratory reports for both the Rapid antigen test (Doc. # AG-002) and the rapid PCR test (Doc.# RP-002), page two (2) under Responsibilities states: "6.5 Rapid PCR testing personnel are responsible for notifying their Site Lead of results that need to be corrected." "6.6 Site Leads are responsible for

	documenting results that need to be corrected and notifying Customer Success of a request to correct a reported result." "6.8 Only trained Site Leads are authorized to correct or amend a reported result after the patient has been contacted." 3. As of 2/4 /2022, the laboratory has not provided documentation of corrected discrepant patient reports previously reported to the OHA electronic coordinator, as requested at the time of the onsite survey.