

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0707800	(X3) Date Survey Completed 09/25/2020
Name of Provider or Supplier American Health S Llc DbA American Health	Street Address, City, State 15712 Sw 41 St Suite 16, Davie, FL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	An unannounced complaint survey (#2020013583) conducted on 9/23/2020 - 9/25/2020, found that American Health Associates clinical laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following Conditions were not met : 5300-Preanalytic Systems
D5300	<p>PREANALYTIC SYSTEMS CFR(s): 493.1240</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on observation, record review and interview, the laboratory failed to follow Quidel Lyra Direct SARS-CoV-2 RT - PCR manufacturer's storage and rejection procedures for COVID-19 specimen testing from July 20, 2020 to Sept. 23rd 2020. (see 5311)</p>
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>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.</p>

This STANDARD is not met as evidenced by:
 Based on observation, record review and interview, the laboratory failed follow Quidel Lyra Direct SARS-CoV-2 RT - PCR manufacturer's storage and rejection procedures for COVID-19 specimen testing from 7/20/2020 to 9/23/2020. Findings Included: Review of Quidel Lyra Direct SARS-CoV-2 RT - PCR Assay manual revealed COVID-19 specimen are stable for up to 24 hours at room temperature or up to 72 - hours when stored at 2 degree Celsius (C) to 8 C. If specimens cannot be tested within 72 hours of collection, they should be stored at -70 C or colder until tested. Review of COVID-19 Testing Protocol stated once collected COVID-19 specimens must be refrigerated and subsequently transported in a thermal cooler to maintain temperature between 2 C and 8 C. Review COVID-19 specimen rejection policy revealed no rejection log for COVID-19 specimen not stored properly at room temperature at 24 hours, 2 C to 8 C at 72 hours or -70 C after 72 hours. Based on Observation of the COVID-19 specimen receiving area revealed COVID -19 specimen sitting in boxes at room temperate without a time log indicating 24 hours. There was no thermometer in shipping boxes to indicate if the COVID-19 specimen were at 2-8 C during transportation. COVID-19 specimen for retest were stored in a refrigerator at 6.7 C. Shipping boxes with COVID-19 specimen are place in refrigerator without review of collection time. A review of Patients requisitions revealed Patients: 26316352,26316354 ,26316358, 26316357, 26316362 had a collection date of 7/15/20 and receiving date of 7/20/20. There was no documentation of patient samples being store in a -70C after 72 hours. A review of COVID-19 Patients log revealed 146,532 patients have been tested for COVID-19 RT-PCR from 7 /20/2020 to 9/23/2020. During an interview on 9-24-2020at 9:30 am , the supply manager confirmed specimen were received in a shipping box without a temperature gauge, COVID-19 specimen were kept in a refrigerator with a temperature of 6.7 degrees C and bins without review of collection dates and time frames .

D5313

SPECIMEN SUBMISSION, HANDLING, AND REFERRAL
 CFR(s): 493.1242(b)

The laboratory must document the date and time it receives a specimen.

This STANDARD is not met as evidenced by:
 Based on record review and interview, the laboratory performed Quidel Lyra Direct SARS-CoV-2 RT-PCR testing on 5 (26394877, a3875663, a3875667 ,26316343, 26316339) out of 5 patient requisitions no collection date and time for COVID-19 specimen in 7/20/2020, 8/21/2020 and 8/22/2020. Finding Included: Review of Quidel Lyra Direct SARS-CoV-2 RT - PCR Assay manual revealed COVID-19 specimen are stable for up to 24 hours at room temperature or up to 72 - hours when stored at 2 degree Celsius (C) to 8 C. If specimens cannot be tested within 72 hours of collection, they should be stored at -70C or colder until tested. A review of Patients requisitions revealed 5 (26394877, a3875663, a3875667, 26316343, 26316339) out of 5 patients had COVID-19 specimen no collection dates and time in 7/20/2020, 8/21/2020 and 8 /22/2020. A review of final reports revealed the lab had placed their own collection times and dates for patients: 26394877, a3875663, a3875667,26316343, 26316339. During an interview on 9/25/2020 at 10:00am, the co-owner, general manager and lab manager confirmed collection dates and time were missing from 5 out 5 patient requisitions in 7/20/2020, 8/21/2020 and 8/22/2020.

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 record review and interview, the laboratory failed to have logs identifying temperature ranges for refrigerators, freezers and room temperatures for COVID- 19 testing in molecular room from 6/28/2020 to 9/23/2020. Findings Included: Review of Quidel Lyra Direct SARS-CoV-2 RT- PCR Assay manual revealed PCR procedures need to be run at a controlled room temperature of 20 degree Celsius (C) to 25 C . Review of Temperature Room logs revealed no room temperature readings for molecular rooms from 6/28/2020 to 9/23/2020. Observation of Molecular room revealed no thermometer to record room temperature. Review of Freezers and Refrigerators temperature logs revealed freezers and refrigerators had no temperature ranges to identify the equipment was in or out of range and where it was located . Review of Freezer and Fridge manual revealed no manuals were available for review onsite. During an interview on 9-25-2020 at 10:00 am, the molecular supervisor confirmed no logs identifying the ranges temperature of for fridges and freezers and recording room temperature for COVID- 19 testing in molecular areas from 6/28/2020 to 9/23/2020.

D5415

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

CFR(s): 493.1252(c)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:

Based observation, record review and interview, the laboratory failed to store Tag Man Open Array Urinary Tract kit and Fast 96 - well Region of Interest Background plates according to manufacturer's guidelines. Findings Included: An observation of Molecular Reading room revealed an ultra - low freezer with a set temperature of -70 degrees Celsius (C). Located in the freezer were Tag Man Open Array Urinary Tract kit and Fast 96 - well Region of Interest. Fast 96 - well region of interest background plates and Tag Man Open Array Urinary Tract kit storage temperatures are -15 C to -25 C. Review of the ultra-freezer temperature logs revealed the freezer temperature at -70 C. During an interview on 9-25-2020 at 10 am, the molecular supervisor confirmed reagents and plates were stored in a freezer below the manufacturer's storage requirements.

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 record review and interview, the laboratory failed to validate threshold changes from 10,000 to 1,000 as acceptable for negative, positive and inconclusive results for COVID-19 patients for the Quidel Lyra Direct SARS-CoV-2 RT - PCR Assay from July 24,2020 to Sept 18th, 2020. Findings Included: Review of Quidel Lyra Direct Assay Verification Study revealed 10,000 threshold was used indicated if Covid-19 specimen were negative, positive or inconclusive . Review of Quidel Lyra Direct SARS-CoV-2 RT - PCR machine printouts displayed threshold changes from 10,000 to 1,000 from July 24, 2020 to Sept 18th, 2020. Review of COVID-19 Quidel Lyra PCR Patient Results showed a3875667 and a3875663 patients tested for PCR on August 22, 2020 with a threshold of 10,000 and resulted in two inconclusive results. The two patients samples were re-run with a threshold of 1,000 and both recieved negative results. During an interview on 9-25-2020 at 10am, the molecular supervisor confirmed threshold changes had been made for COVID-19 Quidel Lyra Direct Assay kit and was not validated.

D6086

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(3)(ii)

The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory director (LD) failed to ensure the validations and procedures for COVID-19 were approved and signed. Findings Included: Review of Quidel Lyra Direct Assay Verification Study For SARS-CoV-2 revealed the LD did not sign validation. Review Quidel Lyra Assay Bringing Study for Qualitative Detection of Verification Study For SARS-CoV-2 revealed no signature from LD. Review of COVID-19 procedure revealed LD had not signed the document . During an interview on 9-25-2020 at 10am, the molecular supervisor confirmed LD did not sign the validations and procedures for COVID-19.