

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0707800	(X3) Date Survey Completed 02/22/2021
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 announced recertification survey was conducted on 02/08/2021 to 02/22/2021 at American Health Associates. The laboratory was not in compliance with 42 CFR 493, Requirements for Clinical Laboratories. Based on the survey findings, an Immediate Jeopardy situation was identified and the laboratory was notified at 2:45 PM on 02/19/2021. The laboratory failed to follow manufacturers' instructions (MI) for storing Ammonia quality control and patient specimens, failed to run quality control per MI, failed to monitor COVID 19 pooled specimens, and failed to validate instruments prior to reporting patients (See D5300 and D5400). The following Conditions were not met: D5300 - Preanalytic Systems 493.1240 D5400 - Analytic Systems 493.1250 D6141 - General Supervisor 493.1459 D6168 - Testing Personnel 493.1487 D6076 - Laboratory Director 493.1441
D3005	<p>FACILITIES CFR(s): 493.1101(a)(3)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review, observation and interview, the laboratory failed to have a closed uni-directional flow system for their molecular COVID-19 PCR(Polymerase Chain Reaction) testing as of 2/22/2021. Finding included: During an observation on 02/12/2021 at 11:00 AM, a molecular technologist held a 96 well plate and walked through an Accession room for microbiology, blood cultures and urine and then walked into the PCR reading room to test the 96 well plate. Review of Molecular Testing Diagram revealed that molecular technologists have to go across an accessioning room to reach the PCR reading room. Review of Lyra Direct SARS-CoV-2 Assay package insert states, "Proper workflow planning is essential to minimize contamination risk. Always plan laboratory workflow in a uni-directional</p>

manner, beginning with pre-amplification and moving through amplification and detection." During an interview on 2/22/2021 at 6:00 PM, the molecular supervisor confirmed no uni-directional flow existed for molecular technologists to pass through an accessioning area with COVID-19 and 96 well plates to reach the PCR reading room.

D3011

FACILITIES
CFR(s): 493.1101(d)

Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.

This STANDARD is not met as evidenced by:
Based on observations, record review, and interview with the Laboratory Manager, the laboratory failed to properly use the flammable cabinet, and failed to store 1 gallon of 100% alcohol and 12 gallons of Methyl alcohol in a flammable cabinet. Findings Included: Observation taken on tour that was conducted on 02/08/2021 at 1:45 PM revealed, multiple papers and folders stored on the top shelf of the flammable cabinet. In the Microbiology department a 1 gallon container of 100% alcohol was observed sitting on a shelf. In the storage room 3 boxes with 4 - 1 gallon containers of Methyl alcohol was observed stacked against a shelf. Review of the Safety Data Sheet revealed, both the 100% alcohol and the Methyl alcohol were to be stored in an approved Flammable Liquids storage area. During an interview on 02/08/2021 at 2:30 PM, the Laboratory Manager confirmed that the containers of alcohol were supposed to be stored in the flammable cabinet and the papers should not have been put in the flammable cabinet.

D3031

RETENTION REQUIREMENTS
CFR(s): 493.1105(a)(3)

Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.

This STANDARD is not met as evidenced by:
Based on record review and interview, the laboratory failed to retain calibration records for at least two years. Findings included: Review of the procedure titled, "Record Retention Policy" signed and dated by the Laboratory Director on 08/11/2020, noted the Calibration and Calibration verification records, and Equipment maintenance and function check records be retained for two years. 1. The laboratory has three Beckman Coulter DXH900 hematology instruments that were validated in January 2020. Review of the calibration records for the DXH900 hematology instruments showed that the instrument print outs for the calibration performed on 07/07/2020 were missing for the hematology instrument S/N BC50900. During an interview on 02/09/2021 at 1:51 PM, the General Supervisor - C stated, she was unable to locate the missing instrument printouts. 2. The laboratory used two Beckman Coulter DXH800 hematology instruments in 2019. Review of the calibration records for the DXH800 hematology instruments were not available for review. During an interview on 02/10/2021 at 4:10 PM, the General Supervisor - C stated, she was unable to locate the missing calibration record for the DXH800 used in

	<p>2019. 3. Review of the maintenance for the Arkray Aution Max AX-4030 instruments used for urine chemistry testing showed the maintenance from 01/01/2020 to 08/31 /2020 was not available for review at the time of the survey. During an interview on 02 /13/2021 at 12:50 PM, the General Supervisor - C stated, the maintenance records were missing.</p>
<p>D3033</p>	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)(i)</p> <p>In addition, the laboratory must retain records of test system performance specifications that the laboratory establishes or verifies under 493.1253 for the period of time the laboratory uses the test system but no less than 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to maintain the raw data used for their IQCP (Individualized Quality Control Plan) on Microbiology plates. Findings Included: Review of the IQCP for Microbiology plates revealed, no raw data that was used for the Quality Control part. The IQCP was originally established 10/11 /16 and was last signed by the Laboratory Director on 08/11/20. Interview on 02/12 /21 at 4:00 PM with the Microbiology Supervisor confirmed, the raw data was not available.</p>
<p>D5209</p>	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to perform competency assessment for 2 (TP 1 and 2) out of 21 (TP 1 to TP 21) testing personnel (TP) and did not follow the Employee Competency policy for 2 out of 2 years reviewed (2019-2020). Findings included: 1) Review of the Personnel Policy revealed, the policy failed to include that when Supervisors also have the role as testing personnel they are required to have a competency assessment as TP. 2) Review of the CMS 209 Laboratory Personnel Report dated and signed by the Laboratory Director (LD) on 02/09/2021 revealed, there were 22 TP. TP 1 and 2 also are GS (General Supervisors). During an interview on 02/09/2021 at 11:30 AM, with GS 1, she confirmed that the laboratory failed to perform competency assessment for the TP of reference.</p>
<p>D5217</p>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to have a policy to</p>

perform the accuracy verification study on the primary method for testing SARS COVID 19 RT PCR (Severe Acute Respiratory Syndrome Coronavirus Disease 2019 Real Time Polymerase Chain Reaction) patients since 7/1/2020. Findings included: Review of Policy Number 6-102.15M for proficiency testing (PT) revealed, the laboratory failed to define that the PT is required for only the primary method for patient testing. Record review revealed, the laboratory has been running COVID 19 patient testing with the Lyra method since 07/01/2020. Review of the College of American Pathologists (CAP) revealed, the laboratory performed the PT for the Taq-Path COVID 19. This method is not the method used in the daily patient testing. Review of a comparative sample study performed in December 2020 for the COVID 19 Lyra method revealed, the laboratory did not have the raw data for the 2 laboratories involved to support their results. During an interview on 02/08/21 at 2:30 PM, the General Supervisor confirmed, the laboratory failed to have a policy to perform accuracy verification for the COVID 19 Lyra method since 07/01/2020.

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:
42115 Based on observation, record review and interview, the laboratory failed to ensure the test requisitions are received from an authorized person for 1 (#2) out of 6 (#1, #2, #3, #4, #5, & #6) test requisitions. The laboratory failed to ensure 10 out of 10 (C-1, C-2, C-3, C-4, C-5, C-6, C-7, C-8, C-9, & C-10) chemistry test requisitions were signed by an authorized person (See D5301). The laboratory failed to ensure the test requisitions solicits the time of collection (See D5305), failed to follow their policy to ensure temperatures of COVID-19(Coronavirus 2019) specimen delivered on 2/10/2021 for the Lyra Direct SARS-COV-2 (Severe Acute Respiratory Syndrome Coronavirus 2) Assay were in acceptable ranges for testing; Failed to ensure the stability of Ammonia samples since 02/2019 (See D5311); and Failed to document collection dates and times for 4 out 4 COVID-19 patients tested for Lyra Direct SARS-CoV-2 Assay. (See D5313).

D5301

TEST REQUEST
CFR(s): 493.1241(a)

The laboratory must have a written or electronic request for patient testing from an authorized person.

This STANDARD is not met as evidenced by:
Based on record review and interview, the laboratory failed to ensure the complete blood count with differential test requisitions for 1 (#2) out of 6 (#1, #2, #3, #4, #5, #6) are received from an authorized person and failed to ensure 10 out of 10 (C-1, C-2, C-3, C-4, C-5, C-6, C-7, C-8, C-9, and C-10) chemistry test requisitions were signed by an authorized person. Findings Included: Review of test requisitions for

hematology patients showed that 1 (#2) out of 6 (#1, #2, #3, #4, #5, #6) failed to include the name of the physician who ordered the complete blood count with differential. Review of test requisitions for chemistry patients showed that 10 out of 10 (C-1, C-2, C-3, C-4, C-5, C-6, C-7, C-8, C-9, and C-10) chemistry test requisitions were not signed by an authorized person. During an interview on 02/10/19 at 2:40 PM, the General Supervisor - C stated, the test requisition didn't provide the ordering physician's name for the complete blood count with differential patients and did not have an authorized signature on the test requisition for the chemistry tests.

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 record review and interview, the laboratory failed to ensure the test requisitions solicits the time of collection. Findings Included: Review of Test requisitions for Hematology patients showed that 2 (#5, #6) out of 6 (#1, #2, #3, #4, #5, #6) failed to include the collection time. Review of Test requisitions for Coagulation patients showed that 5 (#1, #2, #3, #4, #11) out of 11 (#1, #2, #3, #4, #5, #6, #7, #8, #9, #10, #11) failed to include the collection time. Review of Test requisitions for Urinalysis patients showed that 1 (#6) out of 6 (#1, #2, #3, #4, #5, #6) failed to include the collection time. During an interview on 02/12/21 at 4:30 PM, the General Supervisor - C stated, the missing collection times were across the board in all areas of testing.

D5311

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

The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.

This STANDARD is not met as evidenced by:
Based on observation, record review and interview, the laboratory failed to follow their policy to ensure temperatures of COVID-19 (Coronavirus 2019) specimen

delivered on 2/10/2021 for the Lyra Direct SARS-COV-2 (Severe Acute Respiratory Syndrome Coronavirus 2) Assay were in acceptable ranges for testing and failed to ensure the stability of Ammonia samples since 02/2019. Findings Included: During an observation on 2/10/2021 at 2:25 pm, a courier brought in a COVID-19 specimen in a plastic bag without documentation of temperature or collection dates. Then the accessioning technician measured the temperature of the plastic bag of the specimen with a laser temperature gauge and recorded that as the constant temperature of the COVID-19 specimen. Review of the Lyra Direct SARS-CoV-2 Assay package insert states, "Nasal, nasopharyngeal, or oropharyngeal swab specimens should be collected and placed in a clean, dry transport tube. Specimens should be transported and tested as soon as possible after collection. Specimens are stable for up to 48-hours at room temperature or up to 72-hours when stored at 2(C) Celsius to 8C. If specimens cannot be tested within 72 hours of collection, they should be frozen at -70C or colder until tested. Stability at-70C was assessed up to 8 days from collection." Review of COVID-19 Testing Protocol (dated 12/06/2020) states, once collected, specimens must be refrigerated and subsequently transported in a thermal cooler to maintain temperature between 2 and 8 degrees C. During an interview on 2/10/2021 at 2:25 pm, the accessioning technician confirmed, the temperatures of the COVID-19 specimen in the plastic bag were not monitored before arrival. Observations during a tour of the accession area at 1:45 PM on 02/08/2021 revealed, Ammonia samples were stored in a frost free freezer until tested. Review of the policy and procedure manual (Last reviewed by the Lab Director on 09/23/2020) revealed, Ammonia specimens were stable for 3 hours at 2-8 degrees Celsius and stable for 24 hours when frozen less than or equal to - 20 degrees Celsius. Review of the temperature charts for the freezer where the Ammonia samples were stored prior to testing from 02/2019 until 02/2021 revealed, no temperature less than or equal to -20 degrees Celsius. Interview with the Laboratory Manager on 02/08/2021 at 2:00 PM confirmed, the freezer was used to store Ammonia specimens until tested. There were 1,661 Ammonia samples tested in 2019; 2,090 tested in 2020; and 231 tested in 2021.

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 observation, record review, and interview revealed that the laboratory failed to follow their policy to document collection dates and times for 4 out 4 COVID-19 (Coronavirus 2019) patients tested for Lyra Direct SARS-CoV-2 (Severe Acute Respiratory Syndrome Coronavirus 2) Assay. Findings Included: A Review of COVID-19 Patient Record revealed, 4 (26957803, 26956292, 26956294, and 26956295) out 4 patients requisitions had no collection date and time and order date and time. Review of the Lyra Direct SARS-CoV-2 Assay package insert states, "Nasal, nasopharyngeal, or oropharyngeal swab specimens should be collected and placed in a clean, dry transport tube. Specimens should be transported and tested as soon as possible after collection. Specimens are stable for up to 48-hours at room temperature or up to 72-hours when stored at 2C to 8C. If specimens cannot be tested within 72 hours of collection, they should be frozen at -70C or colder until tested. Stability at-70C was assessed up to 8 days from collection." During an observation on 2/10/2021 at 2:25 pm, an accessioning technician placed a collection date of 2/10 /2021 in the accessioning system for 4 (26957803, 26956292, 26956294, and 26956295) out 4 patients requisitions without collection dates and times. Review of

the COVID-19 Collection Policy (signed by the Laboratory Director 12/06/2020) states, we must have the patient full name, collection date and time on every requisition and sample. Failure to provide this information can and will result in your specimen being rejected. During an interview on 2/10/2021 at 2:25pm with the Accessioning Technician confirmed, the laboratory failed to document the collection date and time of 4 out of 4 COVID-19 patients tested for Lyra Direct SARS-CoV-2 Assay.

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:

42115 Based on record review and interview, the laboratory failed to have policies that reflected what was being performed in Microbiology and did not have a policy on how to contact providers when a redraw was necessary (See D5403). Based on record review, observation and interview, the laboratory failed to have a COVID-19 pooling policy for mixing several COVID-19 (Coronavirus 2019) samples together in a batch or pooled sample, then testing the pooled COVID-19 samples with a Lyra Direct SARS-COV-2 (Severe Acute Respiratory Syndrome Coronavirus 2) Assay and TaqPath COVID-19 Combo Kit as of 1/1/2021 to 2/11/2021 and failed to store Ammonia controls per the manufacturer's instructions since 02/2019 (See D5411). Based on record review and interview, the laboratory failed to perform a validation of the iQ Series Automated Urinalysis System and the Iris iChem Velocity instruments. (See D5421) Based on record review and staff interview, the laboratory failed to complete a validation for the Sofia 2 SARS Antigen and Sofia 2 Flu + SARS Antigen FIA for uses of an unauthorized nasal swabs before testing from 9/7/2020 to present. The laboratory failed to complete a validation for Lyra Direct SARS-CoV-2 Assay and TaqPath COVID-19 Combo Kit from before testing from 6/3/2020 to present. The laboratory failed to complete a validation for the use of the Applied Biosystems COVID 19 Interpretive Software with Lyra Direct SARS-CoV-2 Assay before testing from 6/25/2020 to present. (See D5423) Based on record review and interview, the laboratory failed to document the maintenance performed on the Beckman Coulter DXH900 hematology instruments, the Sysmex CS-2500 coagulation instruments, and the iQ Series Automated Urinalysis System and the Iris iChem Velocity instruments. (See D5429) Based on record review and interview, the laboratory failed to follow manufacturer's instructions by not performing calibrations on the Arkray Aution Max AX-4030 urine chemistry analyzer monthly from 01/01/20 to 02/28/21. (See D5437) Based on observation, record review and interview, the laboratory failed to establish documentation and monitoring of external quality control(QC) for the unvalidated high complexity use of Sofia 2 Flu + SARS Antigen and Sofia 2 Flu + SARS Antigen from 9/7/2020 to present. (See D5441) Based on record review and interview, the laboratory failed to perform quality control per the laboratory's IQCP (Individualized Quality Control Plan) on 5 out of 5 Labpro Microscan Walkaway Microbiology instruments, and failed to perform quality control daily when in use on the Autoscan Walkaway instrument for 2 of 2 years (02/2019-02/2021) reviewed (See D5445).

Based on record review and interview, the laboratory failed to perform quality control lot to lot comparisons from 02/08/2019 to 02/08/21 for hematology controls. (See D5469) Based on record review and interview the laboratory failed to document the physical characteristics of the media for 2 out of 2 (02/2019-02/2021) years reviewed (See D5477). Based on record review and interview, the laboratory reported patients without 2 levels of controls being acceptable for 13 days (01/05/21, 11/13/20, 10/21/20, 04/05/20, 03/09/20, 03/21/20, 12/14/19, 07/07/19, 07/11/19, 06/27/19, 06/02/19, 06/01/19, and 02/23/19) for Hemoglobin A1C, 1 day (06/23/19) for Free T4, 1 day (09/16/20) for Creatinine, 3 days for Vitamin D (09/22/20, 09/23/20, and 09/24/20), and 2 days for Ammonia (09/24/20 and 09/25/20) (See D5481). Based on record review and interview, the laboratory failed to have a system that twice a year evaluates and defines the relationship between test results using the different methodologies and instruments (See D5775). Based on record review and interview, the laboratory failed to ensure accurate and reliable tests results for 1 (#8) out of 11 (#1, #2, #3, #4, #5, #6, #7, #8, #9, #10, #11) coagulation patients (See D5779).

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 record review and interview, the laboratory failed to perform quality control per the laboratory's IQCP (Individualized Quality Control Plan) on 5 out of 5 Labpro Microscan Walkaway Microbiology instruments, and failed to perform quality control daily when in use on the Autoscan Walkaway instrument for 2 of 2 years (02/2019-02/2021) reviewed. Findings Included: Review of Manufacturer's instructions on all 6 Walkaway instruments revealed, quality control can be ran weekly when an IQCP is developed. An IQCP was developed for the 5 Labpro Microscan Walkaway instruments that stated quality control would be ran weekly. No IQCP was developed for the Autoscan Walkaway instrument. Review of quality control for September 2020 revealed, that each of the 6 Walkaway instruments only had quality control performed once a month (Labpro 1A-09/24/20, Labpro 2A-09/30/20, Labpro 2B-09/02/20, Labpro 3A-09/10/20, Labpro 3B-09/08/20, and Autoscan 09/24/20). Interview on 02/13/21 at 11:45 AM with the Microbiology Supervisor revealed, she was told to alternate the weeks for quality control on the machine. She confirmed that they were not following their IQCP. Performing a rotating quality control was not included in the laboratory's IQCP. There were no manufacturers instructions provided to support rotating quality control.

D5403

PROCEDURE MANUAL
CFR(s): 493.1251(b)

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results.

(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to have policies that reflected what was being performed in Microbiology and did not have a policy on how to contact providers when a redraw was necessary. Findings Included: Review of the Microbiology policies and procedures revealed that they did not indicate an acceptable specimen, what plate used, how long to incubate the plate, what temperature to incubate, and what happened after incubation was done. Review of the policy on how and when to contact providers when redraw was necessary revealed that there was no procedure. Interview on 02/15/21 at 3:58 PM with the Laboratory Manager confirmed, the policies and procedures were lacking.

D5411

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(a)

Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

This STANDARD is not met as evidenced by:

Based on record review, observation, and interview, the laboratory failed to have a COVID-19 (Coronavirus 2019) pooling policy for mixing several COVID-19 samples together in a batch or pooled sample, then testing the pooled COVID-19 samples with a Lyra Direct SARS-CoV-2 (Severe Acute Respiratory Syndrome Coronavirus 2) Assay and TaqPath COVID-19 Combo Kit as of 1/1/2021 to 2/11/2021 and failed to store Ammonia controls per the manufacturer's instructions since 02/2019. Findings Included: During an observation on 02/11/2021 at 6:47 PM, a molecular technologist was pooling (4) 96 - well COVID - 19 PCR (Polymerase Chain Reaction) patients samples into (1) 96 well plate and then running 96 well plate on the unvalidated Quantstudio 12K, 7500 Fast Dx _1, 7500 Fast Dx _2 TaqPath and 7500 Fast Dx _3. Review of the COVID-19 Pooling Policy revealed, no documentation of a policy for pooling COVID-19 specimens and no documentation of what COVID-19 specimens were pooled in wells tested. During an interview on 02/10/2021 at 11:00 AM, the Chief Information Officer stated that 1,157,799 were tested for COVID-19 PCR. During an interview on 02/22/2021 at 6:00 PM, the Molecular Supervisor confirmed there was no documentation of a pooling policy for testing COVID-19 specimens with the Lyra Direct SARS-CoV-2 Assay and TaqPath COVID-19 Combo Kit. Observations during the tour of the laboratory on 02/08/2021 at 1:45 PM revealed, Level 1 and Level 3 Ammonia quality control stored in a freezer that was kept -10 to

-20 degrees Celsius. Manufacturer's instructions on the packaging stated that they should be stored at 2-8 degrees Celsius. Interview on 02/08/2021 at 2:00 PM with the Laboratory Manager confirmed, the Ammonia controls have been stored in the freezer since 02/2019.

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE

CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to perform a validation of the iQ Series Automated Urinalysis System and the Iris iChem Velocity instruments. Findings Included: Review of the laboratory's quality control documentation showed the laboratory did not have documentation for the validations on the iQ Series Automated Urinalysis System urine chemistry analysis instrument and the Iris iChem Velocity urine sediment analysis instrument. Review of the maintenance log showed the instruments were first used on 02/10/2020. The laboratory performed 29,914 urine chemistry analysis and 1,193 urine chemistry with sediment analysis in 2020, and 4,604 urine chemistry analysis and 196 urine chemistry with sediment analysis in 2021. During an interview on 02/13/2021 at 10:40 AM, the General Supervisor - C stated, when the instruments were installed the company didn't do a validation on the instrument, and the laboratory didn't do a validation on the instrument.

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 staff interview, the laboratory failed to complete a validation for the Sofia 2 SARS(Severe Acute Respiratory Syndrome) Antigen and Sofia 2 Flu + SARS Antigen FIA for uses of an unauthorized nasal swabs before testing from 9/7/2020 to present. The laboratory failed to complete a validation for Lyra Direct SARS-COV-2 Assay and TaqPath COVID-19(Coronavirus 2019) Combo Kit from before testing 6/3/2020 to present. The laboratory failed to complete a

validation for the use of Applied Biosystems COVID 19 Interpretive Software with Lyra Direct SARS-COV-2 (Severe Acute Respiratory Syndrome Coronavirus 2) Assay before testing 6/25/2020 to present. Findings Included: Review of Sofia 2 SARS Antigen Instructions for Use stated, "When collecting a nasal swab sample, use the Nasal Swab supplied in the kit." Review of Sofia 2 Flu + SARS Antigen Instructions for Use stated, "When collecting a nasal swab sample, use the Nasal Swab supplied in the kit." During an interview on 2/10/2021 at 11 am, the lab aide confirmed that they were using Nasal Swabs not from the Sofia SARS Antigen and Sofia Flu + SARS Antigen kits for COVID-19 sample collections. Review of the Supplies Purchase Record showed purchases of Sterile nasal swabs without a breaking point of polyester material in 1/6/2021. Review of the Sofia SARS Antigen Validation showed no documentation of a validation. Review of the Sofia 2 Flu + SARS Antigen Validation showed no documentation of a validation. Review of the Sofia 2 instrument 2 revealed, instrument use from 9/7/2020 to 2/8/2021 with the Sofia 2 Flu + SARS Antigen and Sofia 2 Flu + SARS Antigen. Review of the Sofia 2 instrument 3 revealed, instrument use from 9/15/2020 to 2/8/2021 with Sofia 2 Flu + SARS Antigen and Sofia 2 Flu + SARS Antigen. Review of the COVID-19 PCR Instruments revealed: 1. Quantstudio 12K was in use from 6/27/2020 to present with the Lyra Direct SARS-CoV-2 Assay. 2. 7500 Fast Dx _1(serial 275031618) was in use from 7/2/2020 to present with the Lyra Direct SARS-CoV-2 Assay and 6/3/2020 to present with TaqPath COVID-19 Combo Kit. 3. 7500 Fast Dx _2(serial 275031639) was in use 6/25/2020 to present with the Lyra Direct SARS-CoV-2 Assay and 6/3/2020 to present with the Taq Path COVID-19 Combo Kit. 4. 7500 Fast Dx _3(serial 27503218) was in use 10/27/2020 to present with the Lyra Direct SARS-CoV-2 Assay. Review of 7500 Fast Dx _1 Lyra Direct SARS-CoV-2 Assay validation revealed no documentation of instrument data printouts indicating the validation test runs and Applied Biosystems COVID 19 Interpretive Software. There was no instrument documentation of a comparison study with another laboratory. Review of 7500 Fast Dx _2 Lyra Direct SARS-CoV-2 Assay validation revealed no documentation of instrument data printouts indicating the validation test runs. No documentation of a validation of Applied Biosystems COVID- 19 Interpretive Software use present onsite. Review of 7500 Fast Dx _3 Lyra Direct SARS-CoV-2 Assay validation revealed no documentation of instrument data printouts indicating the validation test runs. There was no documentation of a validation of Applied Biosystems COVID-19 Interpretive Software use present onsite. Review Quantstudio 12K Lyra Direct SARS-CoV-2 Assay Bridging study validation revealed no documentation of instrument data printouts indicating the validation test runs. There was no documentation of a validation of Applied Biosystems COVID 19 Interpretive Software use present onsite. Review of the Lyra Direct SARS-CoV-2 Assay Instructions for Use revealed, the assay has been validated using Applied Biosystems 7500Fast Dx software version 1.4, or later, Applied Biosystems Standard software version 2.0.6, or later, Roche LightCycler 480 Instrument II, software version 1.5.0.39 or later, Roche Cobas z480 Instrument, software version 1.5.1.62 SP2- or later, Qiagen Rotor-Gene Q software version 2.0.2.4 or later, Bio-Rad CFX96 Touch, software version 3.1 or later and Thermofisher QuantStudio 7 Pro software version 2.4 or later. Review of the 7500 Fast Dx _1 TaqPath COVID-19 Combo Kit Validation revealed, there was no documentation of COVID-19 sample validation test runs with instrument printouts. Review of the 7500 Fast Dx _2 TaqPath COVID-19 Combo Kit Validation revealed, there was no documentation of COVID-19 sample validation test runs with instrument printouts. During an interview on 2/10/2021 at 11am, the software technician stated that 1,157,799 were tested for COVID-19 PCR and 4,206 were tested for COVID-19 Antigen. During an interview on 2/22/2021 at 6pm, the owner and molecular supervisor confirmed the laboratory failed to complete

a validation for the Sofia 2 SARS Antigen, Sofia2 Flu + SARS Antigen Lyra Direct SARS-CoV-2 Assay, TaqPath COVID-19 and Applied Biosystems COVID 19 Interpretive Software for the Lyra kit.

D5429

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to document the maintenance performed on the Beckman Coulter DXH900 hematology instruments, the Sysmex CS-2500 coagulation instruments, and the iQ Series Automated Urinalysis System and the Iris iChem Velocity instruments. Findings included: 1. Review of the procedure titled, "Beckman Coulter Unicel DxH Series Operations", signed and dated by the Laboratory Director on 08/11/2020 noted, "Daily, Weekly, Monthly and As Needed Maintenance must be performed." Review of the maintenance logs titled, "Manual Shutdown DxH Slidemaker/Stainer Maintenance Log: showed that every six months "Cleaning the STM" (Specimen Transport Module) is to be performed. The maintenance log showed that the cleaning of the STM had not been performed from 02/08/2019 to 02/08/2021. During an interview on 02/09/2021 at 4:05 PM, the General Supervisor - C stated, that the cleaning of the STM was not checked off. 2. Review of the Hematology Microscope maintenance log noted, "Supervisor review and Initial Monthly." Review of the microscope maintenance log for hematology showed that the maintenance was reviewed for 3 months (October 2019, November 2019, and December 2019) out of 25 (February 2019 to January 2021). During an interview on 02/09/2021 at 4:15 PM, the General Supervisor - C stated, General Supervisor B had not signed off on the review of the hematology microscope maintenance log. 3. Review of the policy titled, "General Laboratory Policies", signed and dated by the Laboratory Director on 08/11/2020, noted "All scheduled maintenance must be performed on time according to the Manufacturers specifications." Review of the Daily Maintenance for the Sysmex CS-2500 Coagulation instrument used for D-Dimer testing showed the following dates the maintenance was not documented. Daily Maintenance Rinse Probe - 04/05/2020, 06/28/2020, 06/29/2020, 07/05/2020, 07/18/2020, 11/15/2020. Discard used cuvettes - 02/15/2020, 03/06/2020, 04/05/2020, 04/11/2020, 06/28/2020, 06/29/2020, 07/02/2020, 07/05/2020, 07/18/2020, 08/15/2020. Dispose of waste - 02/15/2020, 03/06/2020, 04/05/2020, 04/11/2020, 06/28/2020, 06/29/2020, 07/02/2020, 07/05/2020, 7/18/2020, 8/15/2020. Check and discard trap chamber - 02/15/2020, 03/06/2020, 04/05/2020, 04/11/2020, 06/28/2020, 06/29/2020, 07/02/2020, 07/05/2020, 07/18/2020, 08/15/2020. Shutdown 04/05/2020, 06/28/2020, 06/29/2020, 07/05/2020, 07/18/2020, 11/15/2020. Weekly Maintenance Clean the instrument - between 06/02/2020 to 06/18/2020. Rinse the Rinse Tank - between 02/20/2020 to 03/03/2020, 05/15/2020 to 05/25/2020, 06/03/2020 to 06/15/2020, 06/26/2020 to 07/08/2020, 07/24/2020 to 08/05/2020, 08/15/2020 to 08/30/2020. During an interview on 02/12/2021 at 9:35 AM, the General Supervisor - C stated, not all the maintenance was recorded. 4. Review of the policy titled, "General Laboratory Policies", signed and dated by the Laboratory Director on 08/11/2020, noted "All scheduled maintenance must be performed on time according to the Manufacturers specifications." Review of the Daily Maintenance for the Sysmex CS-2500 Coagulation instrument used for Pro-Time, INR (International

Normalized Ratio), and Partial Thromboplastin Time testing showed the following dates the maintenance was not documented. Daily Maintenance Rinse Probe - 02/23/2020, 04/14/2020 to 04/30/2020, 07/05/2020, 08/29/2020. Discard used cuvettes - 02/15/2020, 04/14/2020 to 04/30/2020, 05/16/2020, 06/05/2020, 06/06/2020, 06/30/2020, 07/05/2020, 08/22/2020, 11/10/2020, 01/08/2021. Dispose of waste - 02/15/2020, 04/14/2020 to 04/30/2020, 05/16/2020, 06/05/2020, 06/06/2020, 06/30/2020, 07/05/2020, 08/22/2020, 11/10/2020, 01/08/2021. Check and discard trap chamber - 02/15/2020, 04/14/2020 to 04/30/2020, 05/16/2020, 06/05/2020, 06/06/2020, 06/30/2020, 07/05/2020, 08/22/2020, 11/10/2020, 01/08/2021. Shutdown - 02/23/2020, 04/14/2020 to 04/30/2020, 07/05/2020, 08/29/2020. Weekly Maintenance Clean the instrument - between 02/29/2020 to 03/08/2020, 04/13/2020 to 04/30/2020. Rinse the Rinse Tank - between 02/28/2020 to 03/08/2020, 04/07/2020 to 04/30/2020, 05/15/2020 to 05/27/2020, 06/05/2020 to 06/14/2020, 08/17/2020 to 08/30/2020. During an interview on 02/12/2021 at 9:35 AM, the General Supervisor - C stated, not all the maintenance was recorded. 5. Review of the iQ Series Operators Manual, showed that the manual provided a log for the instrument. Review of the maintenance log for the Beckman Coulter iQ Series Automated Urinalysis System instrument used for urine chemistry analysis showed the following dates the maintenance was not documented. IQ Series Maintenance Log Daily Check Lamina Supply - 02/10/2020 to 02/22/2020, 02/27/2020 to 02/28/2020, 03/30/2020, 04/20/2020, 04/21/2020, 05/15/2020, 05/16/2020, 05/18/2020, 05/19/2020, 05/20/2020, 08/14/2020, 08/15/2020, 08/16/2020. Monthly Perform Instrument Calibration - 02/01/2020 to 02/28/2020, 07/01/2020 to 07/31/2020, 09/01/2020 to 09/30/2020, 10/01/2020 to 12/31/2020 Perform Backup - 02/2020 to 07/31/2020, 09/01/2020 to 01/31/2021. During an interview on 02/13/2021 at 11:03 AM, the General Supervisor - C stated, not all the maintenance was recorded. 6. Review of the iChem Velocity Operators Manual, showed that the manual provided a log for the instrument. Review of the maintenance log for the Beckman Coulter Iris iChem Velocity instrument used for urine sediment analysis showed the following dates the maintenance was not documented. iChem Velocity Maintenance Log Weekly Clean the Strip Conveyor Module - 01/01/2021 to 01/31/2021. Monthly Clean the Wash Station Bath - 01/01/2021 to 01/31/2021. Quarterly Perform Reflective CalChek - 2/10/2020 to 7/28/2020. Perform SG/CC CalChek - 2/10/2020 to 7/28/2020. TOSOH G8 Hemoglobin A1C. Six month maintenance (of replacing fluid supply) records reviewed from 02/2021 to 07/2019 - only done 02/2020. During an interview on 02/13/2021 at 11:03 AM, the General Supervisor - C stated, not all the maintenance was recorded.

D5437

CALIBRATION AND CALIBRATION VERIFICATION
CFR(s): 493.1255(a)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to follow the manufacturer's instructions by not performing calibrations on the Arkray Aution Max AX-4030 urine chemistry analyzer monthly from 01/01/2020 to 02/28/21. Findings Included: Review of the manufacturer's operations manual noted, "Perform S.G. calibration of the instrument once a month using low and high S.G. standard solutions and a urinometer." Review the quality control documents for the Arkray Aution Max AX-4030 showed the documentation for the calibrations was missing from 01/01/2020 to 02/28/21. During an interview on 02/13/2021 at 1:30 PM, the General Supervisor - C stated, she could not find the documentation and did not know if the calibrations were done. Word Key: S.G. = specific gravity

D5441

CONTROL PROCEDURES
CFR(s): 493.1256(a)(b)(c)(g)

(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on observation, record review, and interview, the laboratory failed to establish documentation and monitoring of external quality control (QC) for the unvalidated high complexity use of Sofia 2 Flu + SARS (Severe Acute Respiratory Syndrome) Antigen and Sofia 2 Flu + SARS Antigen from 9/7/2020 to present. Findings Included: Review of Sofia 2 SARS Antigen controls showed no documentation of external positive and negative controls from 09/07/2020 to 02/08/2021. Review of Sofia 2 Flu + SARS Antigen controls showed no documentation of external positive and negative controls from 09/07/2020 to 02/08/2021. See D5423 for unvalidated instrument During interview on 02/11/21 at 11:21 PM, the Serology Technologist confirmed that external QC was not documented for unvalidated high complexity use of Sofia 2 Flu + SARS Antigen and Sofia 2 Flu + SARS Antigen from 9/7/2020 to present.

D5469

CONTROL PROCEDURES
CFR(s): 493.1256(d)(10)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials

having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to perform quality control lot to lot comparisons from 02/08/2019 to 02/08/21 for hematology controls. Findings Included: The laboratory used two Beckman Coulter DXH800 hematology instruments used in 2019 until the Beckman Coulter DXH900 hematology instruments that were validated. The laboratory has three Beckman Coulter DXH900 hematology instruments that were validated on 01/30/2020. Review of the "Quality Control (Internal) - Selection, Setup and Review" policy noted "New lot numbers of controls will be tested in parallel with current lot numbers to establish or to verify assay mean and standard deviation." Review of the quality control documentation showed that there was no lot to lot comparisons of the hematology controls. During an interview on 02/10/21 at 10:12 AM, the General Supervisor - B stated, the laboratory did not perform lot to lot comparisons of the hematology controls.

D5477

CONTROL PROCEDURES

CFR(s): 493.1256(e)(4)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to document the physical characteristics of the media for 2 out of 2 (02/2019-02/2021) years reviewed. Findings Included: Review of the Microbiology documentation revealed, there was no documentation of the physical characteristics of the media since 02/2019. Interview on 02/15/21 the Laboratory Manager confirmed that the physical characteristics of the media was not being documented.

D5481

CONTROL PROCEDURES

CFR(s): 493.1256(f)(g)

(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory reported patients without 2 levels of controls being acceptable for 13 days (01/05/21, 11/13/20, 10/21/20, 04/05/21, 03/09/20, 03/21/20, 12/14/19, 07/07/19, 07/11/19, 06/27/19, 06/02/19, 06/01/19, and 02/23/19) for Hemoglobin A1C, 1 (06/23/19) day for Free T4, 1 day (09/16/21) for Creatinine, 3 days for Vitamin D (09/22/20, 09/23/20, and 09/24/20), and 2 days for Ammonia (09/24/20 and 09/25/20). Findings Included: Review of quality control

for Hemoglobin A1C revealed, that on 01/05/21 Level I was not acceptable with 178 patients ran, on 11/13/20 Level II was not acceptable with 156 patients ran, on 04/05/2020 there was no Level I or II ran with 23 patients ran, on 03/21/20 Level I was not acceptable with 47 patients ran, on 03/23/19 Level 1 was not acceptable and there were 53 patients ran, and on 10/21/20-03/09/20-12/14/19-07/07/19-07/11/19-06/27/19-06/02/19-and 06/01/19 had quality control that was not acceptable, however the laboratory did not provide how many patients were ran on those days. Review of the quality control for Free T4 revealed on 06/23/19 both levels of control was not acceptable. There were 28 patients reported on 06/23/19. Review of the quality control for Creatinine revealed, on 09/16/20 Level 2 was not acceptable and there were 238 reported. Review of the quality control for Vitamin D revealed, on 09/22/20 Level 2 was not ran with 24 patients reported. On 09/23/20 level 2 was not ran with 68 patients reported, and on 09/24/20 Level 2 was not ran with 34 patients reported. Review of quality control for Ammonia revealed, that Level 2 was not ran on 09/24/20 and Level 2 was not acceptable on 09/25/20. The laboratory did not provide how many patients were reported on those 2 days. Interview on 02/09/21 at 6:00 PM the Laboratory Manager confirmed the aforementioned quality control was not acceptable and patients were reported.

D5775

COMPARISON OF TEST RESULTS

CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to have a system that twice a year evaluates and defines the relationship between test results using the different methodologies and instruments. Findings Included: 1. The laboratory used two Beckman Coulter DXH800 hematology instruments used in 2019 until the Beckman Coulter DXH900 hematology instruments that were validated. The laboratory has three Beckman Coulter DXH900 hematology instruments that were validated on 01/30/2020. Review of the quality control documentation showed that there was no documentation comparing the automated WBC (White Blood Cell) differential performed on the Beckman Coulter DxH 800 Hematology analyzer to the manual microscopic WBC differential from 02/08/2019 to 01/30/2020. Review of the quality control documentation showed that there was no documentation comparing the automated WBC differential performed on the Beckman Coulter DxH 900 Hematology analyzer to the manual microscopic WBC differential from 01/30/2020 to 02/08/2021. During an interview on 02/10/21 at 10:34 PM, the General Supervisor - C stated, they don't perform a method to method comparison for WBC differentials. 2. The laboratory used two Beckman Coulter DXH800 hematology instruments used in 2019 until the Beckman Coulter DXH900 hematology instruments that were validated. The laboratory has three Beckman Coulter DXH900 hematology instruments that were validated on 01/30/2020. Review of the quality control documentation showed that there was no documentation of an instrument to instrument comparison of the two Beckman Coulter DxH 800 Hematology instruments from 02/08/2019 to 01/30/2020. Review of the calibration records for the Beckman Coulter DxH 900 Hematology instruments showed that a comparison of the

three analyzers was performed at the time of the initial calibration dated 01/30/2020. Review of the quality control documentation showed that there was no documentation of an instrument to instrument comparison of the three Beckman Coulter DxH 900 Hematology instruments from 02/01/2020 to 02/08/2021. During an interview on 02/09/21 at 3:51 PM, the General Supervisor - B stated, they don't perform an instrument to instrument comparison. 3. The laboratory used the Iris iChem Velocity (automated sediment analysis) instrument to perform urine sediment analysis from 02/10/2020 to 02/13/2020. Review of the quality control documentation showed that there was no documentation of a method to method comparison of the automated sediment analysis to the manual microscopic sediment analysis from 02/10/2020 to 02/13/2020. During an interview on 02/15/21 at 11:25 AM, the General Supervisor - C stated they don't perform a method to method comparison for sediment analysis. 4. The laboratory used the Arkray Aution Max AX-4030 instrument to perform urine chemistry analysis from 02/08/2019 to 02/13/2020. The laboratory used the Iris iQ Series Automated Urinalysis System instrument to perform urine chemistry analysis from 02/10/2020 to 02/13/2020. Review of the quality control documentation showed that there was no documentation of a method to method comparison of the two urine chemistry instruments from 02/10/2020 to 02/13/2020. During an interview on 02/15/21 at 11:25 AM, the General Supervisor - C stated, they don't perform an instrument to instrument comparison. 5. The laboratory used 2 Quidel Solanas to perform C. difficile testing from 02/08/2019 to 02/15/2021. Review of the quality control documentation showed that there was no documentation of an instrument to instrument comparison of the 2 Solanas. During an interview on 02/15/21 at 3:58 PM the Laboratory Manager confirmed, that no instrument to instrument comparison had been done on the Quidel Solanas. 5. The laboratory used 5 Microscan microbiology instruments since 02/08/2021. Review of the quality control documentation showed that there was no documentation of an instrument to instrument comparison of the 5 Microscans. During an interview on 02/15/21 at 3:58 PM the Laboratory Manager confirmed, that no instrument to instrument comparisons had been done on the 5 Microscans.

D5779

CORRECTIVE ACTIONS

CFR(s): 493.1282(a)

Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to ensure accurate and reliable tests results for 1 (#8) out of 11 (#1, #2, #3, #4, #5, #6, #7, #8, #9, #10, #11) coagulation patients. Findings included: Review of the policy titled, "Quality Management Plan" signed and dated by the Laboratory Director on 08/11/2020, noted the Test Management Assessment "is used to assure that the laboratory system performs according to specification and provides accurate and reliable test requests, result entry, result transmittal and correct charging." Review of the test report for coagulation patients #8 showed the test report for a Prothrombin Time (PT) of 90.0 sec and International Normalized Ratio (INR) of 8.00. Review of the instrument printout on 01/14/2021 showed PT results of greater than 90.0 seconds and and INR results of greater than 8.00 seconds. The laboratory performed 38,394 PT/INR test in

2020 and 3,172 PT/INR tests from 01/01/2021 to 02/12/2021. During an interview on 02/10/21 at 2:40 PM, the General Supervisor - B stated, the test report didn't indicate greater than for the PT and INR results.

D5805

TEST REPORT
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:
Based on record review and interview, the laboratory failed to give 2 out of 2 COVID-19 (Coronavirus 2019) final patient reports listing TaqPath COVID-19 Combo Kit as the PCR (Polymerase Chain Reaction) test performed. Findings Included: Review of the Wet Plate Map revealed patients (26841815 and 26841816) were tested for COVID-19 PCR using the TaqPath COVID-19 Combo Kit on 01/06/2021. Review of the Patient Final reports revealed patients 26841815 and 26841816 were tested for COVID-19 PCR using the Lyra Direct SARS-CoV-2 Assay on 01/06/2021. During an interview on 02/22/2021 at 6:00 PM, the Owner and Molecular Supervisor confirmed the laboratory failed to have final reports that accurately indicated the method of testing on the 2 (26841815 and 26841816) patient reports that should have stated TaqPath COVID-19 Combo Kit as the test performed.

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 record review and interviews, the Laboratory Director failed to provide oversight in the laboratory and failed to delegate duties (See D6079) and failed to establish or have a quality assurance program (See D6094).

D6079

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(a)(b)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and

493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:
Based on observations, record review, and interviews, the Laboratory Director failed to assign a delegation of duties for duties that were being performed by someone else in the laboratory for 1 of 1 (02/2020-02/2021) year and failed to ensure overall compliance of the Laboratory for 2 out of 2 years(02/2019-02/2021) reviewed. Findings Included: Review of the delegation of duties signed by the Laboratory Director revealed signed copies for previous employees but none signed for the General Supervisor who has been there for the last year. Interview on 02/12/21 at 10:13 AM, the Laboratory Director confirmed that he has not signed a delegation of duties to the new General Supervisor. For overall compliance of the Laboratory see D5300 and D5400.

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 the lack of documentation and interview, the Laboratory Director failed to establish or maintain a quality assurance program to ensure the quality of laboratory services provided and to identify failures in quality as they occur for the preanalytic, analytic, and postanalytic phases of testing for 2 out of 2 (02/2019-02/2021) years reviewed. Findings Included: Review of laboratory records revealed no quality assurance policy or documentation for the 2 year period reviewed 02/2019-02/2021. Interview on 02/12/2021 at 10:13 AM, the Laboratory Director revealed that he did not have an established quality assurance program. Interview on 02/15/2021 at 3:58 PM, the Laboratory Manager confirmed that there were no quality assurance documents available.

D6168

TESTING PERSONNEL
CFR(s): 493.1487

The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493.1495 of this subpart for the volume and complexity of testing performed.

This CONDITION is not met as evidenced by:
Based on record review and interview with laboratory personnel, the laboratory was not in compliance with state requirement that testing personnel (TP) is required to have a Florida License that includes the specialty for the type of tests this TP is performing since 9/20/2020 for 2 (M1 and M2) out of 5 TP (M1, M2, M3, M4, and M5) performing the test (See D6170).

D6170

TESTING PERSONNEL QUALIFICATIONS

CFR(s): 493.1489(a)

Each individual performing high complexity testing must possess a current license issued by the State in which the laboratory is located, if such licensing is required.

This STANDARD is not met as evidenced by:

Based on record review and interview with laboratory personnel, the laboratory was not in compliance with state requirement that testing personnel (TP) are required to have a Florida License that includes the specialty for the type of tests the TP is performing since 9/20/2020 for 2 (M1 and M2) out of 5 TP (M1, M2, M3, M4, and M5) performing the test. Findings included: Patient testing records revealed the laboratory started performing the Sofia SARS (Severe Acute Respiratory Syndrome) Antigen Fluorescent Immunoassay (FIA) for SARS COVID 19 (Coronavirus 2019) antigen testing since 09/15/2020. Review of personnel files for 5 TP performing Sofia SARS antigen testing revealed that 2 TP (M1 and M2) failed to have the specialty of Microbiology on their Florida License. Florida Administrative Rule 64B3-5.003 revealed that Laboratory Personnel must be licensed in the specialty performing testing. During an interview on 02/01/2021 at 10:00 AM the Supervisor of Molecular confirmed that those TP were performing the test of reference and it was classified as Virology under the specialty of Microbiology.