

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0929347	(X3) Date Survey Completed 08/12/2024
Name of Provider or Supplier Physicians Stat Lab Inc	Street Address, City, State 4290 S Hwy 27, Suite 204, Clermont, 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 CLIA complaint survey was conducted at Physicians Stat Lab from 06/09/2024 to 08/12/2024. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Conditions were cited: D3000 - Facility Administration 493.1100 D5200 - General Laboratory Systems 493.1230 D5300 - Preanalytic Systems 493.1240 D5400 - Analytic Systems 493.1250 D5800 - Postanalytic Systems 493.1290 D6000 - Moderate Complexity Laboratory Director 493.1403
D3000	<p>FACILITY ADMINISTRATION CFR(s): 493.1100</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on observation, record review, and interview, the laboratory failed to have available, patient records and instrument printouts from January 2022 to 9/27/2023 (See D3031) and the laboratory failed to retain proficiency testing records for 2023 and 2024 (See D3037).</p>
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p>

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 observation, record review and interview, the laboratory failed to have patient records and instrument printouts available from January 2022 to 9/27/2023. Findings Included: On 6/27/2024 at 11:01 AM, tour of the lab revealed Alinity ci-series and Cell Dyn Ruby in use for Chemistry and Hematology testing. Cell Dyn Ruby had access to Hematology results from 9/28/2023 to 6/19/2024. Cell Dyn Ruby did not store any Hematology instrument results from 1/1 /2022 to 9/27/2023. Alinity ci-series had access to Chemistry results from 9/28/2023 to 6/19/2024. Alinity ci-series did not have any stored Chemistry results from 1/1/ 2022 to 2/9/2023. On 6/24 /2024 at 11:08 AM, the Administration Assistant stated the laboratory had changed their laboratory management system from Avalon to Osmeir. They stated it was not possible to gain access to Avalon records. The patient information records from 1/1 /2022 to 1/1/2024 could not be pulled in Avalon system. Review of record retention policy effective date 6/10/2020 read "testing record: 1. Instrument printouts (not interfaced/LIS) and worksheets Retention period 2 years. 2. Patient results and reports, including original and corrected reports and referral laboratory reports Retention period 2 years." On 6/27/2024 at 11:01 AM, the Technologist stated older instrument data could not be pulled from Cell Dyn Ruby and Alinity ci-series.

D3037

RETENTION REQUIREMENTS

CFR(s): 493.1105(a)(4)

Proficiency testing records. Retain all proficiency testing records for at least 2 years.

This STANDARD is not met as evidenced by:

Based on review of American Proficiency Institute (API) and College of American Pathologists (CAP) proficiency testing (PT) records, and interview, the laboratory failed to retain proficiency testing records for 2023 and 2024. Findings Included: The laboratory used API for PT in 2023. Review of the API 2023 Chemistry - Core Remedial PT revealed the instrument printouts were missing. Review of the API 2023 Chemistry - Core PT 2nd event revealed the instrument printouts were missing. Review of the API 2023 Chemistry - Miscellaneous PT 1st event revealed the instrument printouts for microalbumin, sex hormone binding globulin, testosterone (free) and testosterone (total) were missing. Review of the API 2023 Chemistry - Miscellaneous PT 2nd event revealed the instrument printouts for microalbumin, sex hormone binding globulin, testosterone (free) and testosterone (total) were missing. Review of the API 2023 Hematology / Coagulation PT 1st event revealed the instrument printouts were missing for hematology testing. Review of the API 2023 Hematology / Coagulation PT 2nd event revealed the instrument printouts were missing for hematology and urinalysis testing. Review of the API 2023 Immunology / Immunochemistry PT 1st event and the 3rd events revealed the instrument printouts were missing. The laboratory used CAP for PT in 2024. Review of the CAP 2024 Hemoglobin A1c PT 1st event revealed the instrument printouts were missing. Review of the CAP 2024 Diagnostic Immunology PT 1st event revealed the instrument printouts were missing. On 06/27/24 at 11:38 AM, Testing Person A acknowledged the instrument printouts were missing.

D5200

GENERAL LABORATORY SYSTEMS

CFR(s): 493.1230

Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, 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 general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:

Based on observation, review of records and procedures, and interview, the laboratory failed to ensure confidentiality of patient information from August 23, 2023 to June 19, 2024 (See D5201), and the laboratory failed to follow written policies and procedures that ensured 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. (See D5203).

D5201

CONFIDENTIALITY OF PATIENT INFORMATION

CFR(s): 493.1231

The laboratory must ensure confidentiality of patient information throughout all phases of the total testing process that are under the laboratory's control.

This STANDARD is not met as evidenced by:

Based on observation, review of building floor plan and the laboratory's lease agreement, and interview, the laboratory failed to ensure confidentiality of patient information from August 23, 2023 to June 19, 2024. The laboratory failed to prevent the sharing of passwords for office staff and access to a referral laboratory's laboratory management system (LIS) which exposed patient information and test results to any staff member in the office or laboratory. Findings Included: On 06/19/2024 at 3:30 PM, a room next to the laboratory was found to have a broken door frame and the door would not remain closed. Observation of Suite 201 revealed the room was used for histopathology testing and currently used for storage. Review of the building floor plan showed the room was accessible to anyone entering the second floor of the building. Review of the Lease Agreement noted the suites numbers leased to the tenant (laboratory) and a diagram of the space leased (Exhibit B) in the Lease Agreement was signed and dated by a representative of the tenant on 08/23/2023. The Lease Agreement stated the "Landlord, subject to the terms hereof and in consideration of the obligations and conditions set forth hereafter, does hereby lease to Tenant; and Tenant, in consideration of those obligations and conditions, does hereby lease from Landlord the property located at Suite 201/ Smart Space 8, Suite 204, Suite 205. and Suite 206, . . ." Review of the Lease Agreement Exhibit B showed diagram of the lay out of the second floor and which suites were included in the Lease Agreement. Examination of the room revealed the room contained 30 plastic containers with the laboratory's patient requisitions, 176 boxes of patient tissue blocks, and 52 boxes of histology slides. Review of the contents of the black containers revealed the containers were filled with the laboratory's patient requisitions. The patients' requisitions listed patients' names, dates of birth, addresses, phone numbers, diagnosis or diagnosis code, Medicaid/Medicare numbers, social security numbers, and copies of drivers licenses. The histology slides and tissue

blocks were labeled with patients' names and/or case numbers. There was one patient consult report on a counter which included the name, date of birth and diagnosis of the patient. On 06/25/2024 at 11:50 AM, the Administrator stated the door broke sometime in July or August 2023. On 06/19/2024 at 6:00 PM, Suite 201 was secured so that no one could enter the room through that door. On 6/21/2024 at 4:57 PM, tour of the lab revealed the Technologist, Administration Assistant, Lab Assistant and Operations Manager's passwords were stored in all laboratory computers and anyone had access to it. The Operations Manager, Administration Assistant and Lab Assistant had access to change patient results in laboratory management system. The Operations Manager and Administration Assistant had access to one for their referral laboratory's Osmeir laboratory management system. The Operations Manager and Administration Assistant could accession, see patient results, patient demographics for anyone tested in referral laboratory's LIS system. Review of LIS policy revealed no policy for shared passwords and access to referral laboratory's LIS to protect patient information. On 6/24/2024 at 11:32 AM, the Administration Assistant and Lab Assistant confirmed they had access to LIS for referral laboratory and passwords were shared in the laboratory

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 observation, review of the laboratory's procedure manual, review of documents, and interview, it was determined the laboratory failed to follow written policies and procedures that ensured 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. Findings Include: A) Review of the procedure titled, Specimen Collection, Handling, and Transporting approved by the Lab Director 5/24/24 noted the following: 1) specimens must be properly labeled or they will not be processed. Labels should contain patients names and second identifier (date of birth), body source of specimen, date, time collected and initials of collector. 2) reject criteria for coagulation studies, Serology, and Hematology specimens stated reject criteria included aged beyond reliable time limits; for Urinalysis un-refrigerated specimens, Specimens should be refrigerated if not tested with 2 hours of collection. and 3) Specimen Preparation for Transportation read, when appropriate, the specimen is placed into a third rigid container (cooler) which is also a climate controlled environment. This helps to protect the integrity of the specimen until it reached the laboratory. 4) Specimen temporary Storage-specimens shall be stored for a specified time, and at conditions that ensure stability of sample properties. 4) handwritten labels (salvageable) missing date and time of collection. On 6/24/24 at the clinical lab at 11:45 AM, Testing Personnel A and Accessioner A stated they were not aware of written instructions for handling of patient samples for the laboratory or for Reference Lab A for patient samples to ensure positive identification and integrity was maintained. B) At the off site Draw Station, a plastic bin with three urine samples in cups was observed on 6/24/24 at 8:17 AM. The bin had a sign instructing for drop off only and to label with FULL name and birth date. Draw Station phlebotomist A stated on 6/24/24 at 8:30 AM, the patient urine samples in the bin were dropped off from patients

who had not been able to provide a urine sample at the time of blood draw. The phlebotomist A confirmed there were no written directions provided to patients on how to properly collect and store samples until dropped off at the lab. The phlebotomist A confirmed there was no way to know date, time, and storage of samples collected by patients prior to drop off at the draw station. There was no client service manual or any specific written instructions provided for review for collection, processing, storage, and transport of patient samples while at the draw station and transport from the lab draw station. confirmed on 06/24/24 at 08:17 AM and 07/05/24 at 10:30 AM there was be no client service manual or any specific written instructions provided to staff for collection, processing, storage, and transport of patient samples for the lab or reference lab A. On 7/5/24 at 10:15 AM, phlebotomist A said Accessioner A from the main lab verbally instructed the draw station staff to hold patient samples from 7/3/24 until 7/5/24. Phlebotomist A stated samples would be shipped to Reference Lab A via transport company at 1:00 PM and that all patient samples from 7/03/24 and 7/05/24 would be put in one box with no ice pack. The transport label for the patient sample box address was not the address of Reference Lab A. On 06/24/24 at 8:20 AM, and 7/5/24 at 10:20 AM, the patient sample storage refrigerator/freezer did not have a thermometer to monitor the temperature of the refrigerator or the freezer compartment, the two centrifuges were pre-set for time and speed (unknown what settings were). On 06/24/24 at 8:20 AM, and 07/05/24 at 10:30 AM, phlebotomist A stated there was no monitoring of temperatures of the refrigerator /freezer or the room temperatures to ensure integrity of patient samples and the temperature requirements were not known to the staff. On 06/24/24 at 8:20 AM, phlebotomist A there was no way to adjust the time and speed of centrifuges for specific test requirements and did not know what the required time and speed setting of the centrifuges should be. On 7/5/24 at 10:40 AM, the following patient samples were observed in the laboratory refrigerator in a transport bag: 15 serum separator tubes (SST), 11 lavender top vacutainers tubes, 2 blue top vacutainers tubes, 3 red top vacutainers tubes, 2 green top vacutainers tubes, and 3 urinalysis cups. On 7/5 /24 at 10:40 AM, phlebotomist A said the samples in the transport bag were all the patient samples from 7/3/24 and were listed on the Laboratory Specimen Log. Review of the Laboratory Specimen Log dated 7/3/24 documented the date, time received, patient name, under test ordered the type of collection tube or if urine, and initials. The Laboratory Specimen Log for 7/3/24 did not include one of the patient urine samples, which was confirmed by phlebotomist A on 7/5/24 at 10:40 AM.

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 observation, record review, and interview, the laboratory failed to have established and followed written policies and procedures for specimen storage and preservation, conditions for specimen transportation, specimen acceptability and rejection, and specimen referral, (See 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, it was determined the laboratory failed to have established and followed written policies and procedures for specimen storage and preservation, conditions for specimen transportation, specimen acceptability and rejection, and specimen referral. Findings Included: Review of the policy titled, Specimen Collection Handling and Transporting reviewed and approved by the Lab Director on 05/24/2024 showed rejection criteria for Hematology Test. The policy included if specimens aged beyond reliable time limits and specimens not meeting stability chart, for Coagulation Studies if specimens aged beyond reliable time limits, and for Urinalysis un-refrigerated specimens if not tested within 2 hours. The policy did not indicate what the aged beyond time limits were for Hematology and Coagulation, what the stability chart limits were, and what the temperature limits for refrigerated specimens were for storage. Review of Reference Lab #A's document titled Sample Collection Requirement, provided to surveyors as client instructions for referral of laboratory samples, noted for Coagulation, submit frozen citrated plasma if storage exceeds 24 hours and under storage requirements to be refrigerated, and for Hematology and Urinalysis specimen storage requirements were to be refrigerated. There was no written instructions provided if there were any time limits for Hematology, Coagulation or Urinalysis specimens, if specimens required centrifugation, what speed and time was required for specimen processing, what was acceptable temperature limits for refrigerated and frozen specimens were. On 6/24/24 at the clinical lab at 11:45 AM, Testing Personnel A and Accessioner A stated they were not aware of written instructions for handling of patient samples for the laboratory or for Reference Lab A for patient samples to ensure positive identification and integrity was maintained including specimen storage and preservation, conditions for specimen transportation, specimen acceptability and rejection, and specimen referral. On 06/24/24 at 8:20 AM, and 7/5/24 at 10:20 AM, the patient sample storage refrigerator/freezer did not have a thermometer to monitor the temperature of the refrigerator or the freezer compartment. The two centrifuges were pre-set for time and speed (unknown what settings were). On 06/24/24 at 8:20 AM, and 07/05/24 at 10:30 AM, phlebotomist A said there was no monitoring of temperatures of the refrigerator /freezer or the room temperatures to ensure integrity of patient samples and the temperature requirements were not known to the staff. Phlebotomist A confirmed on 06/24/24 at 8:20 AM, there was no way to adjust the time and speed of centrifuges for specific test requirements and the phlebotomist did not know what the required time and speed setting of the centrifuges should be. On 7/5/24 at 10:40 AM, the following patient samples were observed in the laboratory refrigerator in a transport bag: 15 serum separator tubes (SST), 11 lavender top vacutainer tubes for Hematology testing, 2 blue top vacutainers tubes for Coagulation testing, 3 red top vacutainers tubes, 2 green top vacutainers tubes, and 3 urinalysis cups. On 7/5/24 at 10:40 AM, phlebotomist A stated the samples in the transport bag were all the patient samples from 7/3/24 and were listed on the Laboratory Specimen Log. The specimens were to

be referred to Reference Lab A. Review of the Laboratory Specimen Log dated 7/3/24 documented the date, time received, patient name, under test ordered the type of collection tube or if urine, and initials. There was no indication of the Coagulation specimens older than 24 hours had been or would be frozen during storage and transport as required by the Sample Collection Requirement, provided as client instructions for referral of laboratory samples provided to the surveyors. There was no process or mechanism to transport specimens to the clinical lab or referral lab per the indicated temperature requirements for refrigerator or frozen. On 06/24/24 at 8:20 AM, and 07/05/24 at 10:30 AM, phlebotomist A said there was no process or mechanism to transport specimens to the clinical lab or referral lab refrigerated or frozen, all samples put together in a bag/box for transport.

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 document review, and interview, the laboratory failed to run hepatitis C virus (Anti- HCV), hepatitis B(HbsAg), Antibody to Hepatitis A Virus, IgM (HAV-IgM) and homocysteine test (Homc-undil) with unexpired reagents before patient testing (See D5417), the laboratory failed to demonstrate accuracy prior to reporting patient test results for Hematology testing on the Cell Dyn Ruby instrument before reporting patient test results (See D5421), the laboratory failed to run positive and negative controls for the following analytes: TPO antibodies (Anti-TPO), thyroxine test (Free T4) and Folate before patient testing (See D5449), the laboratory failed to document all corrective actions taken for hematology testing from 02/13/24 to 02/21 /2024 (See D5781), and the laboratory failed to have accurate test reports and identity who performed the test (See D5787).

D5417

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

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:
Based on record review, and interview, the laboratory failed to run hepatitis C virus (Anti-HCV), hepatitis B (HbsAg), Antibody to Hepatitis A Virus, IgM (HAV-IgM) and homocysteine test (Homc-undil) with unexpired reagents before patient testing. Findings Included: Review of Results list report released with code flag expired reagents (EXP) revealed the following: A. 1 patient was tested for Anti -HCV with expired reagents on 5/6/2024. B. 6 patients were tested for HAV-IgM with expired reagents on 5/24/2024. C. 8 patients were tested for HbsAg with expired reagents on 5 /24/2024. D. 4 patients were tested for Homc-undil with expired reagents on 5/6/2024.

Review of Alinity ci-series LIS interface manual read, "Result abnormal Flags: EXP=expired material." Review of Quality Management and Quality Assurance Program with continuing Quality Improvement Plan revealed no documentation of a procedure for not testing expired material. On 6/26/2024 at 10:47 AM, the technologist confirmed expired materials were used.

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 document review, and interview, the laboratory failed to demonstrate accuracy prior to reporting patient test results for Hematology testing on the Cell Dyn Ruby instrument before reporting patient test results. The laboratory failed to perform performance specifications for accuracy, precision, and reportable ranges for thyroid peroxidase antibody (Anti-TPO), Hepatitis C (Anti-HCV), hepatitis A virus-specific antibody (HAV-IgM), hepatitis B (HbsAg) for Alinity instrument before patient testing. Findings Included: Review of the Validation/Verification of Test Methods procedure reviewed and approved by the Lab Director on 6/23/2020, noted accuracy of test method may be verified by comparing laboratory results with a reference method. The method comparison is performed by analyzing 10-29 patients, analyze all samples by both methods, and determine bias by statistical methods. All documented data must be reviewed by the Medical Director (Lab Director) prior to initiating patient testing. Review of Validation Study form documented the Cell Dyn Ruby instrument was installed 10/3/2023 with Validation approved by Lab Director on 10/16/23 with the date of Two Instrument Comparison 10/16/23 performed. There were further documented reviews by Lab Supervisor on 5/10/24 and Medical Director on 6/11/24 on the same Validation Study form. The Two Instrument Comparison study provided documented the study was performed 2/23/24 between the same model of Cell Dyn Ruby instruments at the lab identified as Y and Reference Lab A identified as X. It was documented the study passed and was signed as performed by Technical Consultant #1 on 5/10/24 and approved by the Lab Director on 6/11/24. Review of the instrument data and final reports used for the Two Instrument Comparison from Reference Lab A did not match. The Two Instrument Comparison included 10 patient samples for Complete Blood Count (CBC) testing at each lab (#36115, 36107, 36105, 36006, 36116, 36114, 36113, 36112, 36110, and 36109). Seven (#36115, 36105, 36116, 36114, 36113, 36112, and 36110) of the 10 patient comparison samples instrument printouts and final reports from Reference Lab A did not match. The data entered for the calculation of comparison was from the final reports. The analytes reviewed for Whole Blood Count (WBC) was measured as $10e3$ /uL, Red Blood Cells (RBC) as $10e6$ /uL, Hemoglobin (HGB) as g/dL, Hematocrit (HCT) as %, and Platelet (PLT) as $10e3$ /uL. The discrepancies from the instrument printouts and final reports were as follows: For #36115 results from instrument printout for WBC=3.22 but the final report was 4.2; results from instrument printout for RBC=4.38 but the final report was 4.79; results from instrument printout for

HGB=13.5 but the final report was 14.2; results from instrument printout for HCT=42.3 but the final report was 41; and results from instrument printout for PLT was 219 but the final report noted 223.1. For #36105 results from instrument printout for RBC was 3.96 but the final report was 4.15 and results from instrument printout for PLT noted 217 but the final report was 242.9. For #36116 results from instrument printout for WBC was 5.84 but the final report was 6.9; results from instrument printout for RBC was 3.84 but the final report was 3.95; results from instrument printout for HCT noted 34.6 but the final report was 35.9; and results from instrument printout for PLT was 279 but the final report was 286.9. For #36114 results from instrument printout for WBC was 5.86 but the final report was 6.8; results from instrument printout for RBC noted 4.73 but the final report was 4.87; results from instrument printout for HGB showed 13.8 but the final report was 14.5; results from instrument printout for HCT was 43.4 but the final report was 44.8; and results from instrument printout for PLT noted 221 but the final report was 241. For #36113 results from instrument printout for WBC noted 5.02 but the final report was 6.4; results from instrument printout for RBC was 4.02 but the final report was 4.11; results from instrument printout for HGB showed 12.0 but the final report was 11.9; and results from instrument printout for HCT was 38.1 but the final report was 37.6. For #36112 results from instrument printout for WBC noted 3.82 but the final report was 5.8 and results from instrument printout for PLT showed 209 but the final report was 222.1. For #36110 results from instrument printout for WBC was 4.24 but the final report was 5.8; results from instrument printout for RBC noted 4.79 but the final report was 4.9; results from instrument printout for HCT showed 46.2 but the final report was 45.6; and results from instrument printout for PLT was 239 but the final report was 230.1. Technical Consultant A confirmed on 6/21/24 at 2:45 PM the comparison data for the Two Instrument Comparison from Reference Lab A instrument data and final report data did not match and therefore the comparison calculations were not accurate and should not have been approved. No explanation was provided as to why the instrument data which was interfaced to Reference Lab A's laboratory information system (LIS) did not match. On 6/19/2024 at 2:00PM, a laboratory tour revealed Abbott Alinity ci-series was in use for patient testing. Review of Abbott Alinity ci-series Results List Report revealed the following: a. 30 patients were tested for HbsAg on the following dates: 4/25/2024, 5/17/2024, 5/24/2024, 5/16/2024, 5/10/2024 and 5/9/2024. b. 37 patients were tested for Anti-TPO on the following dates: 5/10/2024 c. 24 patients were tested for Anti-HCV on the following dates: 4/25/2024, 5/24/2024, 5/16/2024, 5/10/2024 and 5/9/2024, 5/3/2024. d. 14 patients were tested for HAV-IgM on the following dates: 4/25/2024, 5/24/2024, 5/16/2024, and 5/10/2024. Review of performance specifications for Alinity ci-series revealed the following: a. No documentation for accuracy, precision, and reportable ranges for HbsAg b. No documentation for accuracy, precision, and reportable ranges for Anti-TPO c. No documentation for accuracy, precision, and reportable ranges for Anti-HCV d. No documentation for accuracy, precision, and reportable ranges for HAV-IgM On 6/29/2024 at 11:51 AM, located in the fridge were controls for HbsAg, Anti-HCV and HAV-IgM. On 6/29/2024 at 11:25 AM, the lab technologist confirmed patient testing was performed for Anti-TPO Anti-HCV, HAV-IgM, and HbsAg on Alinity instrument.

D5449

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(ii)(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--
At least once a day patient specimens are assayed or examined perform the following

for-- Each qualitative procedure, include a negative and positive control material; (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 run positive and negative controls for the following analytes: TPO antibodies (Anti-TPO), thyroxine test (Free T4) and Folate before patient testing Findings Included: Review of Results list report released with code flag control (CNTL) revealed the following: A. 37 patients were tested for Anti -TPO with no passed positive and negative controls on 5 /10/2024. B. 2 patients were tested for Free T4 with no passed positive and negative controls on 9/29/2023. C. 37 patients were tested for Folate with no passed positive and negative controls on 10/11/2023. Review of Alinity ci-series LIS interface manual read, "Result abnormal Flags: CNTL=Results produced after a control had a Westgard failure rating or control results outside range." Review of Quality Control effective on 8/24/2021 read, "Daily QC (Quality Control) must be run as follows: "8. Out of range QC values should be evaluated using Westgard rules. B. Testing must be ceased for any values outside of 3 sd. Troubleshooting steps may include recalibration, freshly prepared control repeated run, fresh reagents or diluents."

D5781

CORRECTIVE ACTIONS
CFR(s): 493.1282(b)(1)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b) (1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on document review, and interview, the laboratory failed to document all corrective actions taken for hematology testing from 02/13/24 to 02/21/2024. Findings Included: Review of the Cell Dyn Ruby QC and Maintenance Monthly Logs for February 2024 documented the instrument was not in use from 02/13/24 to 02/21 /2024. Review of the Hematology proficiency documents for first event 2024 documented receipt of proficiency specimens on 02/15/2024 with written note "Instrument Down 02/19/24 Report to CAP (College of American Pathologist) and on the attestation form signed by the Lab Director (date unknown) "Test not performed Inst (instrument) down". The Cell Dyn Ruby QC Monthly Log for February 2024 had no corrective action(s) documented from 02/13/24 to 02/21/2024 as to why the instrument was not available for testing or what action(s) was performed prior to resuming testing on 2/21/2024. The Cell Dyn Ruby QC Monthly Log for February 2024 had initials and date line on the bottom for documenting Technical Supervisor monthly review which was blank. On 6/21/24 at 11:50 AM, Technical Consultant #1 confirmed there was no documented corrective action addressing the reason for the instrument not being available for hematology testing from 02/13/24 to 02/21/2024.

D5787

TEST RECORDS

CFR(s): 493.1283(a)

The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).

This STANDARD is not met as evidenced by:

Based on review of patient test records, and interview, the laboratory failed to ensure accurate date and time of the specimen receipt into the laboratory was documented and failed to include the identity of personnel who performed the tests in 10 out of 10 patient test records reviewed. Findings Included: Review of 10 patient test records revealed the following: Patient #1- patient specimen was collected at a draw station 84 miles from the laboratory on 09/11/2023. The test report noted the specimen was collected on 09/11/2023 at 12:43 PM, received by the laboratory on 09/11/2023 at 12:43 PM and reported on 09/13/2023 at 2:48 PM. Patient #2- patient specimen was collected at a draw station 84 miles from the laboratory on 09/01/2023. The test report showed the specimen was collected on 09/01/2023 at 9:14 AM, received by the laboratory on 09/01/2023 at 9:14 AM and reported on 09/04/2023 at 12:06 PM. Patient #3- patient specimen was collected at a draw station 84 miles from the laboratory on 09/01/2023. The test report read the specimen was collected on 09/01/2023 at 6:18 AM, received by the laboratory on 09/01/2023 at 6:18 AM and reported on 09/05/2023 at 4:50 PM. Patient #4- patient specimen was collected at a draw station 84 miles from the laboratory on 09/08/2023. The test report revealed the specimen was collected on 09/08/2023 at 9:15 AM, received by the laboratory on 09/08/2023 at 9:15 AM and reported on 09/08/2023 at 5:00 PM. Patient #5- patient specimen was collected at a draw station 84 miles from the laboratory on 09/05/2023. The test report noted the specimen was collected on 09/05/2023 at 11:43 AM, received by the laboratory on 09/05/2023 at 11:17 AM and reported on 09/13/2023 at 10:08 AM. Patient #6- patient specimen was collected at a draw station 84 miles from the laboratory on 10/02/2023. The test report showed the specimen was collected on 10/02/2023 at 7:39 AM, received by the laboratory on 10/02/2023 at 7:39 AM and reported on 10/03/2023 at 8:10 PM. Patient #7- patient specimen was collected at a draw station 84 miles from the laboratory on 09/29/2023. The test report revealed the specimen was collected on 09/29/2023 at 8:29 AM, received by the laboratory on 09/29/2023 at 8:29 AM and reported on 10/02/2023 at 6:47 AM. Patient #8- patient specimen was collected at a draw station 84 miles from the laboratory on 09/28/2023. The test report read the specimen was collected on 09/28/2023 at 6:54 AM, received by the laboratory on 09/28/2023 at 6:54 AM and reported on 10/02/2023 at 8:31 AM. Patient #9- patient specimen was collected at a draw station 84 miles from the laboratory on 09/28/2023. The test report showed the specimen was collected on 09/28/2023 at 6:29 AM, received by the laboratory on 09/28/2023 at 06:29 AM and reported on 09/29/2023 at 4:45 PM. Patient #10- patient specimen was collected at a draw station 84 miles from the laboratory on 09/08/2023. The test report noted the specimen was collected on 09/08/2023 at 9:15 AM, received by the laboratory on 09/08/2023 at 9:15 AM and reported on 09/05/2023 at 5:00 PM. On 06/24/2024 at 11:00 AM, the Technical Consultant confirmed there was no documentation to identify who performed the tests. On 06/25/2024 at 4:30 PM, the Accessioning personnel confirmed the 10 patients samples were drawn at a draw station 84 miles away and it was not possible to have the same collection day and time and receipt in laboratory

day and time. She explained that she was not documenting the actual day and time received in the laboratory in the computer- it was actually the day and time of collection.

D5800

POSTANALYTIC SYSTEMS
CFR(s): 493.1290

Each laboratory that performs nonwaived testing must meet the applicable postanalytic systems requirements in 493.1291 unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7) that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the postanalytic systems and correct identified problems as specified in 493.1299 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:

Based on record review, and interview, the laboratory failed to document the date, time, test results, and person to whom the test results were reported in 15 out of 24 critical laboratory results reported from 08/2023 to 05/2024 (See D5813).

D5813

TEST REPORT
CFR(s): 493.1291(g)

The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values.

This STANDARD is not met as evidenced by:

Based on record review, and interview, the laboratory failed to document the date, time, test results, and person to whom the test results were reported in 15 out of 24 critical laboratory results reported from 08/2023 to 05/2024. Findings Included: Review of the laboratory's policy, "Reporting Critical Values" (Effective 05/03/2021) revealed "The documented call must have this comment, Results Called to and Read back by (person receiving the result) on (time/date) by (Tech's name)." "If the laboratory staff is unable to communicate a critical value appropriately during the regular laboratory hours, she/he should document that she/he made three (3) attempts but get no response and notify the supervisor of the department or the Medical Director. The Sales person in-charge of the facility that the laboratory is trying to call a critical result and that they should call the laboratory ASAP (as soon as possible)." Review of the critical call logs from 08/07/2023 to 05/06/2024 revealed the following: Patient C-1- On 08/07/2023 did not document who the critical value was called to and the time. Did not document who from the laboratory made the call. Patient C-2- On 08/07/2023 only documented that 1 message was left and not that the critical value was reported to anyone. Did not document who from the laboratory made the call. Patient C-5- On 08/29/2023 only documented that 1 message was left and not that the critical value was reported to anyone. Did not document who from the laboratory made the call. Patient C-6- On 09/07/2023 did not document who the critical value was reported to. Did not document who from the laboratory made the call. Patient C-10- On 10/13/2023 only documented that 1 message was left and not that the critical value was reported to anyone. Did not document who from the laboratory made the call. Patient C-11- No date documented and only documented that 1 message was left and not that the critical value was reported to anyone. Did not document who from the laboratory

made the call. Patient C-13- On 10/20/2023 only documented that 1 message was left and not that the critical value was reported to anyone. Did not document who from the laboratory made the call. Patient C-15- On 10/25/2023 only documented that 1 message was left and not that the critical value was reported to anyone. Did not document who from the laboratory made the call. Patient C-16- No date documented and only documented that 1 message was left and not that the critical value was reported to anyone. Did not document who from the laboratory made the call. Patient C-17- On 11/06/2023 only documented that messages were left and not the critical value was reported to anyone. Did not document who from the laboratory made the call. Patient C-18- On 11/07/2023 only documented that 1 message was left and not that the critical value was reported to anyone. Did not document who from the laboratory made the call. Patient C-20- On 02/22/2024 did not documented time and date the critical value was reported to. Patient C-22- On 04/18/2024 did not document what critical test result was being reported. Patient C-23- On 04/18/2024 did not document what critical test result was being reported. Patient C-24- On 05/06/2024 did not document what critical test result was being reported. On 06/25/2024 at 4:30 PM, the Accessioning personnel confirmed the policy was not being followed for reporting critical laboratory values.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR
CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:
Based on observation, record review, and interview, the previous Laboratory Director and current Laboratory Director failed to ensure quality laboratory services for all aspects of tests performed (See D6007) and the previous Laboratory Director and the current Laboratory Director failed to maintain quality of laboratory services from 01/2022 to 06/19/2024 (See D6021).

D6007

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(1)

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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (E) The laboratory director must-- (E)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;

This STANDARD is not met as evidenced by:
Based on observation, record review, and interview, the previous Laboratory Director and current Laboratory Director failed to ensure quality laboratory services for all aspects of tests performed. Findings Included: The previous Laboratory Director failed to ensure the laboratory retained patient records and instrument printouts from January 2022 to 09/27/2023. (See D3031) The previous Laboratory Director failed to

ensure the laboratory retained proficiency testing records for 2023 and 2024.(See D3037) The previous Laboratory Director failed to ensure the laboratory maintained confidentiality of patient information from August 23, 2023 to June 19, 2024. (See D5201) The previous Laboratory Director and current Laboratory Director failed to ensure the laboratory followed written policies and procedures that ensured 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. (See D5203) The previous Laboratory Director failed to ensure the laboratory established and followed written policies and procedures for specimen storage and preservation, conditions for specimen transportation, specimen acceptability and rejection, and specimen referral. (See D5311) The previous Laboratory Director failed to ensure the laboratory performed hepatitis C virus (Anti- HCV), hepatitis B(HbsAg), Antibody to Hepatitis A Virus, IgM (HAV-IgM) and homocysteine test (Homc-undil) with unexpired reagents before patient testing. (See D5417) The previous Laboratory Director and current Laboratory Director failed to ensure the laboratory demonstrated accuracy prior to reporting patient test results for Hematology testing on the Cell Dyn Ruby instrument before reporting patient test results. (See D5421) The previous Laboratory Director failed to ensure the laboratory performed positive and negative controls for the following analytes: TPO antibodies(Anti-TPO), thyroxine test (Free T4) and Folate before patient testing. (See D5449) The previous Laboratory Director failed to ensure the laboratory documented all corrective actions taken for hematology testing from 02/13/24 to 02/21/2024. (See D5781) The previous Laboratory Director failed to ensure the laboratory had accurate test reports and identity of who performed the test. (See D5787) The previous Laboratory Director failed to ensure the laboratory documented the date, time, test results, and person to whom the test results were reported in 15 out of 24 critical laboratory results reported from 08/2023 to 05/2024. (See D5813)

D6021

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(5)

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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:
Based on review of the procedure manual, the Monthly Quality Checklist, and the QA (Quality Assurance) Meeting document, the previous Laboratory Director and the current Laboratory Director failed to maintain quality of laboratory services from 01 /2022 to 06/19/2024. Finding Included: Review of the procedure titled, Quality Management and Quality Assurance Program with Continuing Improvement Plan noted, "At the end of every month the laboratory Supervisor/Assistant will do a quality assurance review and present it to the medical director. Any issues or concerns will be addressed immediately." The procedure also noted "The laboratory supervisor will sign the monthly QA form and forward to the laboratory medical director for review and signature." The laboratory's procedure manual contained a Monthly Quality Assurance Checklist. There were no checklists filled out and available for

review at the time of the survey. Review of the QA Meeting documents from the meeting on 06/18/2024, showed the participants for the meeting did not include the Laboratory Director or the Supervisor.