

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D0413340	(X3) Date Survey Completed 04/22/2024
Name of Provider or Supplier Coagulation Consultants Lab	Street Address, City, State 1640 Elk Blvd, Des Plaines, IL	
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
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on review of laboratory records, lack of documentation, and interview with the technical supervisor (TS); the laboratory failed to enroll in an approved Centers for Medicare and Medicaid Services (CMS) proficiency testing (PT) program for one regulated SARS-CoV-2 virology analyte in 2022 through the date of survey, 04/22/2024, affecting more than 2642 patient tests performed. Findings include: 1. Review of laboratory records revealed the laboratory performed regulated virology analyte testing of SARS-CoV-2 utilizing the "iAMP COVID-19 Detection Kit" assay from the month of May 2022 to the date of survey, 04/22/2024, affecting more than 2642 patient tests performed. 2. Review of laboratory records revealed no documented evidence of PT enrollment in an approved CMS program for the SARS-CoV-2 virology analyte. 3. On 04/22/2024, at 2:30 p.m., the TS confirmed the above findings.</p>
D3000	<p>FACILITY ADMINISTRATION CFR(s): 493.1100</p> <p>Each laboratory that performs nonwaived testing must meet the applicable</p>

requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe.

This CONDITION is not met as evidenced by:
Based on surveyor's direct observation, laboratory documentation, and interview with the technical supervisor (TS); the laboratory failed to provide a uni-directional workflow for molecular amplification procedures to minimize contamination of patient specimens, equipment, instruments, reagents, materials, and supplies. (Refer to D3005).

D3005

FACILITIES
CFR(s): 493.1101(a)(3)

Molecular amplification procedures that are not contained in closed systems have a uni-directional workflow. This must include separate areas for specimen preparation, amplification and product detection, and, as applicable, reagent preparation.

This STANDARD is not met as evidenced by:
Based on surveyor's direct observation, laboratory documentation, and interview with the technical supervisor (TS); the laboratory failed to maintain a uni-directional workflow for molecular amplification procedures to prevent potential cross-contamination in specimen processing, preparation, amplification, and detection for SARS-CoV-2 in 2022 through date of survey 04/22/2024, affecting more than 2642 patient tests. Findings Include: 1. Review of the manufacturer's "iAMP COVID-19 Detection Kit INSTRUCTIONS FOR USE" stated the following information: "QUALITY CONTROL Due to the sensitivity of iAMP COVID-19 reaction, these assays should be conducted using strict quality control and quality assurance procedures. Following the guidelines below will help minimize chance of false-positive or false-negative amplification. General Considerations o Personnel must be familiar with the protocol and equipment/instruments used. o Maintain separate areas and dedicated equipment (e.g., pipettes, microcentrifuges) and supplies (e.g., microcentrifuge tubes, pipette tips, gowns and gloves) for assay reagent setup and handling of processed samples. o Workflow must always be from the clean area to the dirty area ... o Do not bring processed samples or reaction products into the assay setup area." 2. On 04/22/2024 at 10:00 a.m., direct observation of the TS demonstrating the testing procedures for the "iAMP COVID-19 Detection Kit" assay revealed the laboratory failed to follow the quality control and general considerations outlined in the manufacturer's instructions for use in 2022 through date of survey 04/22/2024, affecting more than 2642 patient tests. a. The preparation of extraction buffer reagent, the transfer of patient samples to the patient testing plates, and the addition of positive and negative control samples to the patient testing plates all performed in one biosafety cabinet ("SAS SENTRY AIR SYSTEMS, INC., Serial No: 6FA1711040, MODEL NO: 11236BBC86"). b. One set of pipettes and pipette tips utilized for the preparation of extraction reagents, the transfer of patient samples to the patient testing plates, and the addition of positive and negative control samples

to the patient testing plates. 3. Direct observation on 04/22/2024 at 10:35 a.m., revealed the "Azure Cielo Real-Time PCR System, S/N: QI6-1380" located on a benchtop directly adjacent to the "SAS biosafety cabinet, Serial No: 6FA1711040" identified above in Finding 2a. 4. On 04/22/2024, at 10:36 a.m., the TS confirmed the above findings.

D5217

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(c)(1)

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.

This STANDARD is not met as evidenced by:
Based on review of laboratory records, lack of documentation, and interview with the laboratory director (LD); the laboratory failed to verify the accuracy of one hematology analyte (Platelet Aggregation) testing at least twice annually before reporting patient results in 2022 through the date of survey, 04/22/2024, affecting more than 821 patient tests. Findings include: 1. Review of laboratory records revealed a procedure manual marked "Platelet Aggregation" which detailed the process of platelet aggregation testing. 2. Review of laboratory records revealed no documented evidence of the verification of hematology analyte Platelet Aggregation accuracy testing performed at least twice a year in 2022 through the date of survey, 04/22/2024, affecting more than 821 patient tests. 3. On 04/22/2024, at 11:33 a.m., the LD confirmed the above findings.

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 review of laboratory records, lack of documentation and interview with the technical supervisor (TS); the laboratory failed to monitor and evaluate the overall quality of virology (SARS-CoV-2) and hematology (prothrombin time (PT) / partial thromboplastin time (PTT), Factors VIII, IX and XI, Platelet Aggregation, Heparin / PF 4 Platelet Antibody (ELISA), and TTI Method Lupus Anti-Coagulant Screen and DRVVT Method Lupus Anti-Coagulant Screen) testing in 2022 through 2024. Findings include: 1. The laboratory failed to follow the manufacturer's storage instructions for the "iAMP COVID-19 Detection Kit". (Refer to D5413). 2. The laboratory failed to document of the establishment of performance specifications for the "Azure Cielo Real-Time PCR System, S/N: QI6-1380" test system utilizing the "iAMP COVID-19 Detection Kit" assay before reporting one SARS-CoV-2 virology analyte in 2022 through the date of survey, 04/22/2024, affecting more than 2642 patient tests performed. (Refer to D5423). 3. The laboratory failed to document the instrument maintenance for one of four hematology test systems (LabSystems Multiskan Plus) for testing hematology analyte Heparin / PF 4 Platelet Antibody

(ELISA) as defined by the manufacturer on 1 of 12 test dates reviewed, 04/01/2023. (Refer to D5429). 4. The laboratory failed to document the instrument maintenance to ensure accurate test results for hematology and virology testing in 2022 through 2024. (Refer to D5433).

D5413

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

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on review of laboratory records, direct observation, and interview with the technical supervisor (TS); the laboratory failed to follow the manufacturer's instructions for the storage of one of one "iAMP COVID-19 Detection Kit" utilized for testing SARS-CoV-2 in 2024. Findings Include: 1. Review of the manufacturer's "iAMP COVID-19 Detection Kit INSTRUCTIONS FOR USE" revealed the following information: "KIT STORAGE INFORMATION All kit reagents (COVIDBM, COVIDPM, COVIDRM, COVIDNC, COVIDPC, COVID6XSBA, and COVID-30XSBB) should be stored at -20C freezer for long time storage. Shelf life of the kit is currently assigned as 1 year and the open kit stability is 6 months when kit is properly stored." 2. Direct observation on 04/22/2024, at 10:23 a.m., revealed the "iAMP COVID-19 Detection Kit, LOT: COVID20231218, EXPIRATION: 2024-11, TEMPERATURE RANGE: -25C to -15C, opened 4.22.24" stored at -70C in the freezer marked, "ScienTemp Adrian, Michigan U.S.A". 3. Review of the manufacturer's storage information and direct observation revealed the laboratory failed to follow the manufacturer's storage instructions for the "iAMP COVID-19 Detection Kit" identified in Finding 2. 4. On 04/22/2024, at 10:23 a.m., the TS confirmed the above findings.

D5423

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(2)

Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.

This STANDARD is not met as evidenced by:

Based on review of laboratory records, lack of documentation, and interview with the

technical supervisor (TS); the laboratory failed to establish performance specifications for the "Azure Cielo Real-Time PCR" test system utilizing the "iAMP COVID-19 Detection Kit" assay before reporting one SARS-CoV-2 virology analyte in 2022 through the date of survey, 04/22/2024, affecting more than 2642 patient tests performed. Findings include: 1. Review of the manufacturer's "iAMP COVID-19 Detection Kit - REF- iAMP-COVID19-100 Instructions For Use - Rx Only - For use under an Emergency Use Authorization (EUA) only" stated the following information: "EQUIPMENTS & MATERIALS REQUIRED BUT NOT SUPPLIED with the kit ... 2. One of the following validated Real-time PCR system with FAM /HEX fluorescence channels: Biorad CFX96 Real-Time System, Roche LightCycler 480 Instrument II, Atila PowerGene 9600 Plus Real-Time PCR System, and Applied Biosystems 7500 Real-Time PCR Systems." 2. Direct observation on 04/22/2024 at 10:35 a.m., revealed the "Azure Cielo Real-Time PCR System, S/N: QI6-1380" in use for SARS-CoV-2 testing utilizing the "iAMP COVID-19 Detection Kit" assay. 3. Review of the "azure biosystems COVID19VALIDATION042822, DATE: 4/22/2024 12:25:00 AM" revealed no documentation of the establishment of performance specifications for the "Azure Cielo Real-Time PCR System, S/N: QI6-1380" test system utilizing the "iAMP COVID-19 Detection Kit" assay before reporting one SARS-CoV-2 virology analyte in 2022 through the date of survey, 04/22/2024, affecting more than 2642 patient tests performed. 4. On 04/22/2024, at 2:17 p.m., the TS confirmed the above findings.

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 review of laboratory records, lack of documentation and interview with the technical supervisor (TS); the laboratory failed to document the instrument maintenance for one of four hematology test systems (LabSystems Multiskan Plus) for testing hematology analyte Heparin / PF 4 Platelet Antibody (ELISA) as defined by the manufacturer for the test date of 04/01/2023. Findings include: 1. Review of the "Multiskan Plus Operating Instructions" revealed the following information: "6. SERVICING 6.1 Maintenance - To guarantee the continuing reliability and accuracy of Mulitskan Plus avoid disturbing any components of the optical system. A misalignment of the light path affects measurements. Keep the optical system clean to ensure proper functioning and accurate results ... 6.2 Routine cleaning of the instrument Turn the power off and unplug the instrument. Use disposable gloves. Clean the instrument outside, the track (Fig.11:1) and the plate carrier (Fig.11:2) with a cloth dampened with water or mild detergent." 2. Review of laboratory records and patient test reports revealed no documentation of instrument maintenance performed for the hematology test system (LabSystems Multiskan Plus) for testing hematology analyte Heparin / PF 4 Platelet Antibody (ELISA) as defined by the manufacturer for the test date of 04/01/2023: a) Date: 04/01/2023 Test performed: Heparin / PF 4 Platelet Antibody (ELISA) Instrument: Labsystems Multiskan Plus No documentation of instrument maintenance performed. 3. On 04/22/2024, at 2:30 p.m., the TS confirmed the above findings.

D5433

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(b)(1)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

This STANDARD is not met as evidenced by:

Based on review of laboratory records, lack of documentation and interview with the technical supervisor (TS); the laboratory failed to establish instrument maintenance protocols for three of four hematology test systems (Amelung-GMBX CS 190 AMAX, Stago / ST4, and Bio-Data Corp Aggregometer) for testing eight hematology analytes, prothrombin time (PT) / partial thromboplastin time (PTT), Factors VIII, IX and XI, TTI Method Lupus Anti-Coagulant Screen and DRVVT Method Lupus Anti-Coagulant Screen (Lupus) and Platelet Aggregation; and one of one virology test system (Azure Cielo Real-Time PCR System) for testing one virology analyte, SARS-CoV-2, to ensure accurate and reliable test results in 2022 through 2024. Findings include: 1. Review of laboratory records and patient test reports revealed no documentation of established instrument maintenance protocols for three of four hematology test systems (Amelung-GMBX CS 190 AMAX, Stago / ST4, and Bio-Data Corp Aggregometer) to ensure accurate test results for eight hematology analytes prothrombin time (PT) / partial thromboplastin time (PTT), Factors VIII, IX and XI, TTI Method Lupus Anti-Coagulant Screen and DRVVT Method Lupus Anti-Coagulant Screen (Lupus) and Platelet Aggregation for the following six of six dates reviewed for hematology testing in 2022 through 2024: a) Date: 06/09/2022 Test performed: prothrombin time (PT) / partial thromboplastin time (PTT) Instrument: Amelung-GMBX CS 190 AMAX, Nr.:99Q50683 No instrument maintenance protocols on file; b) Date: 10/31/2022 Test performed: Factors VIII, IX, and XI Instrument: Amelung-GMBX CS 190 AMAX, Nr.:99Q50683 No instrument maintenance protocols on file; c) Date: 03/01/2024 Test performed: TTI Method Lupus Anti-Coagulant Screen and DRVVT Method Lupus Anti-Coagulant Screen Instrument: Stago / ST4 No instrument maintenance protocols on file; d) Dates: 03/28 /2022, 03/25/2023, and 01/16/2024 Test performed: Platelet Aggregation Instrument: Bio-Data Corp Aggregometer No instrument maintenance protocols on file. 2. Review of laboratory records and patient test reports revealed no documentation of an established instrument maintenance protocol for one virology test system (Azure Cielo Real-Time PCR System) to ensure accurate and reliable test results for one virology analyte SARS-CoV-2, for the following five of five dates reviewed for SARS-CoV-2 testing in 2022 through 2024: a) Dates reviewed: 06/12/2022, 10/26 /2022, 12/23/2023, 02/25/2023, and 04/22/2024 Test performed: SARS-CoV-2 Instrument: Azure Cielo Real-Time PCR System, S/N: QI6-1380 No instrument maintenance protocols on file. 3. On 04/22/2024, at 2:30 p.m., the TS confirmed the above findings.