

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2048957	(X3) Date Survey Completed 08/28/2023
Name of Provider or Supplier Auspicious Laboratory Inc	Street Address, City, State 3707 Westcenter Dr # 100, Houston, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	Based on an announced validation inspection performed on 8/28/23 and 8/29/23, the laboratory was found out of compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780. The condition not met was: D5300 - 42 C.F.R. 493.1240 Condition: Preanalytic systems; Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility representatives were given an opportunity to provide evidence of compliance with noted deficiencies and no such evidence was provided prior to survey exit.
D5209	<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 a review of the laboratory's submitted CMS 209 form, the laboratory's personnel records, and staff interview, the laboratory failed to have documentation of a competency assessment for one of one general supervisor and one of two technical supervisors in 2021 and 2022. Findings include: 1. A review of the laboratory's submitted CMS 209 form revealed the laboratory identified 1 general supervisor and 2 technical supervisors. 2. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of a competency assessment for the general supervisor and technical supervisor #2 in 2021 and 2022. 3. An interview with technical supervisor #1 (as indicated on the CMS 209 form) on 8/28/23 at 10:49 a.m. in the office, after review of the records, confirmed the above findings.</p>
D5300	<p>PREANALYTIC SYSTEMS CFR(s): 493.1240</p>

Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as specified in 493.1249 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:

Based on a review of the laboratory's policies, the laboratory's records, surveyor observation, and staff interview, the laboratory failed to meet the requirements for the preanalytical systems. Findings include: 1. The laboratory failed to have a mechanism in place to ensure the temperature of patient's specimens were maintained during transport to the laboratory for testing. (Refer to D5311 I) 2. The laboratory failed to ensure patient specimens were labeled with two patient identifiers for samples observed. (Refer to D5311 II) 3. The laboratory failed to provide the required conditions for urine specimen collection and transportation for Sexually Transmitted Infection (STI) pathogen testing to their clients. (Refer to D5317)

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:

I. Based on a review of the laboratory's Client Services Manual, the laboratory's records, and staff interview, the laboratory failed to have a mechanism in place to ensure the temperature of patient's specimens were maintained during transport to the laboratory for testing for 16 of 16 months from January 2022 to May 2023. Findings include: 1. A review of the laboratory's 'Client Services' manual revealed the following: "Specimen Transport: Clients that are serviced by Auspicious couriers should contact the laboratory according to the arrangements made at the time of enrollment. The laboratory should complete a Shipping Log with each shipment that includes the number of specimens in the shipment, the temperature condition at which the specimens were stored, the date of the pickup, along with the initials of the individual completing the form. A copy of this form is included at the end of this manual. The laboratory courier will transfer the specimens to a cooler containing ice packs for transport to the laboratory. Specimens that are transported via FedEx should be frozen prior to shipping. Once the available specimens are ready for shipment, they should be packaged in the FedEx Temp-Assure packaging to ensure the integrity of the specimens during transit. Follow the instructions provided by FedEx when packaging the specimens. Specimen Rejection: - Specimens received at temperatures higher than 8C" 3. Surveyor observation of the laboratory's accessioning area on 8/28 /23 at 10:10 a.m. revealed the laboratory personnel did not have a mechanism in place for determining the temperature of the specimens that were being received into the laboratory. 4. A review of the laboratory's records from January 2022 to May 2023

revealed no documentation of the laboratory ensuring the temperature of the patient's specimens were maintained during transport to the laboratory. 5. Further review of the laboratory's records revealed the laboratory estimated performing 120,000 patient tests annually. 6. An interview with technical supervisor #1 (as indicated on the CMS 209 form) on 8/29/23 at 12:10 p.m. in the office, after review of the records, confirmed the above findings. Key: C = Degrees Celsius II. Based on a review of the laboratory's Client Services Manual, surveyor observation, a review of patient test records, and staff interview, the laboratory failed to ensure eight of eight patient specimens were labeled with two patient identifiers for samples observed on August 29, 2023. Findings include: 1. A review of the laboratory's 'Client Services' Manual revealed the following: "Proper Identification of Specimens Specimen labels: ALL specimens should be labeled at the time of collection with at least two patient identifiers written on the container and not the lid. 1) Patient's legal name (full first name, and full last name) 2) Second patient identifier may be one of the following: - Physician office specimen label that includes patient name and date of birth - Practice ID number - Auspicious control number (6-digit number)" 2. Surveyor observation of the laboratory on 8/29/23 at 11:00 a.m. revealed the following 8 patient specimens that failed to include two patient identifiers: - 3 buccal swabs for LC-MS (Liquid Chromotography- Mass Spectrometry) testing only included the patients' first and last names (Patient IDs: 06231988, 04011964, 04211992) - 4 urine samples for LC-MS (Liquid Chromotography- Mass Spectrometry) testing only included the patients' first and last names (Patient IDs: 03051944, 05101978, 08191963, 11131975) - 1 urine sample for STI (Sexually Transmitted Infection) pathogen testing did not include any patient information (Patient ID: 10021983) 3. A review of the test records from August 29, 2023 revealed the 8 above listed patient's samples were used for testing. 4. An interview with technical supervisor #1 (as indicated on the CMS 209 form) on 8/29/23 at 11:12 a.m. in the office, after review of the records, confirmed the above findings.

D5317

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

If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section.

This STANDARD is not met as evidenced by:
Based on a review of the laboratory's policies, the laboratory's client service manual, and staff interview, the laboratory failed to provide the required conditions for urine specimen collection and transportation for Sexually Transmitted Infection (STI) pathogen testing to their clients. Findings include: 1. A review of the laboratory's policy titled 'Determination of Sexually Transmitted Infection Pathogens (STI) using Real-Time Polymerase Chain Reaction (RT-PCR)' revealed the following: "- Using a sterile, plastic, preservative-free collection container, collect the initial 5-10 mL segment of the first morning void. If the first morning void cannot be obtained, collect a 5-10 mL voided specimen at least one hour from the previous void. Do not overfill the collection container. - Use the urine vacutainer tube containing preservative (Greiner Bio-one GmbH-Ref-454486) to transfer 4 mL of urine from collection container as described by manufacturer. - The VACUETTE Urine CCM tubes with additive used in this protocol stabilizes the bacterial count and parameters for up to 72 hours at room temperature. The urine specimen thus does not require refrigeration." 2. Further review of the laboratory's 'Determination of Sexually Transmitted Infection

Pathogens (STI) using Real-Time Polymerase Chain Reaction (RT-PCR)' policy revealed the laboratory failed to define the acceptability criteria for "room temperature". 3. A review of the laboratory's 'Client Services' manual revealed no documentation of the required conditions for urine specimen collection and transportation for STI RT-PCR testing. 4. An interview with technical supervisor #1 (as indicated on the CMS 209 form) on 8/28/23 at 2:00 p.m. in the office, after review of the records, confirmed the above findings.

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 a review of the laboratory's policies, the laboratory's records, and staff interview, the laboratory failed to follow its policy by ensuring a Quality Control (QC) plate was run weekly for Sexually Transmitted Infection (STI) pathogen Real-Time Polymerase Chain Reaction (RT-PCR) testing on the QuantStudio 5 system for 14 of 14 weeks reviewed between March 1, 2023 and June 1, 2023. Findings include: 1. A review of the laboratory's policy titled 'Determination of Sexually Transmitted Infection Pathogens (STI) using Real-Time Polymerase Chain Reaction (RT-PCR)' revealed the following: "Once a week, a QC plate (containing all the validated molecular assays on that instrument) will be run to confirm the stability of the chemistry and all analytical systems for all assays. Acceptability of results for the entire analytical system is dependent upon the agreement of the Ct values +/- 20% (80% - 120%) as determined through quality control continual charting." 2. A review of the laboratory's records from March 1, 2023 and June 1, 2023 revealed no documentation of a QC plate being run weekly for STI RT-PCR testing on the QuantStudio 5 system per the laboratory's policy. 3. An interview with technical supervisor #1 (as indicated on the CMS 209 form) on 8/29/23 at 9:18 a.m. in the office, after review of the records, confirmed the above findings.

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 the review of the manufacturer's User's guide, the laboratory's records in 2022, CMS 116 application, and confirmed in an interview, the laboratory failed to monitor and document humidity required by the manufacturer's system specification for 12 of 12 months reviewed. The findings were: 1. Review of the manufacturer's

user's guide titled AU480 Chemistry Analyzer (PN B28624AA December 2013) under 2.3.1 System Specifications revealed "3. Operating environments. Humidity 20 to 80% RH (with no condensation)." 2. Review of the laboratory's records in 2022 revealed no documentation of humidity for 12 of 12 months reviewed. 3. Review the laboratory's CMS 116 application signed by the laboratory director on 8/25/23 revealed the laboratory performed 100,000 toxicology tests annually. 4. An interview with TS#1 on 8/28/23 at 3:58 pm in the office confirmed the above findings. Key: CMS=Center of Medicare and Medicaid Services TS=Technical supervisor

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 a review of the laboratory's policies, the laboratory's establishment study, and staff interview, the laboratory failed to have documentation of a complete stability study for urine Sexually Transmitted Infection (STI) pathogen testing using Real-Time Polymerase Chain Reaction (RT-PCR). Findings include: 1. A review of the laboratory's policy titled 'Determination of Sexually Transmitted Infection Pathogens (STI) using Real-Time Polymerase Chain Reaction (RT-PCR)' revealed the following: "All stability determinations included samples prepared from at least two standard /control materials in clinical patient matrix, one below the LOD value and one at or above the LOD value." 2. A review of the laboratory's establishment study records revealed the laboratory did not include samples below and above the LOD (Limit of Detection) as part of the stability study performed in April 2022, as required by the laboratory's policy. - Stability study revealed the laboratory tested samples on 4/8/22 and 4/15/22. - Testing on 4/8/22 included only samples above the LOD 3. An interview with technical supervisor #1 (as indicated on the CMS 209 form) on 8/28/23 at 3:13 p.m. in the office, after review of the records, 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:
I. Based on a review of the TSQ Series Hardware Manual, the laboratory's maintenance and testing records, and staff interview, the laboratory failed to have documentation of performing the required maintenance procedures on two TSQ

Quantum Access Mass Spectrometers for four of 16 months reviewed from January 2022 to May 2023. Findings include: 1. A review of the TSQ Series Hardware Manual (Revision D, October 2010) revealed the following: "You are responsible for maintaining your system properly by performing the system maintenance procedures on a regular basis. - You must clean the two fan filters every four months." 2. A review of the laboratory's maintenance records for the two TSQ Quantum Mass Spectrometers (Serial numbers TQU00818 and TQU02655) from January 2022 to May 2023 revealed no documentation of the laboratory cleaning the fan filters every 4 months. 3. A review of the laboratory's testing records revealed the laboratory estimated performing 100,000 tests on the TSQ Quantum Mass Spectrometers annually. 4. An interview with technical supervisor #1 (as indicated on the CMS 209 form) on 8/29/23 at 9:47 a.m. in the office, after review of the records, confirmed the above findings. 44697 II. Based on the review of the manufacturer's User's guide, the laboratory's AU480 maintenance logs from June 2022 to May 2023, CMS 116 application, and confirmed in an interview, the laboratory failed to perform the maintenance required in instrument User's guide for 12 of 12 months reviewed for AU480 chemistry analyzer. The findings were: 1. Review of the manufacturer's user's guide titled AU480 Chemistry Analyzer (PN B28624AA December 2013) under Chapter 8 Maintenance revealed the following, " 8.3 Daily Maintenance 8.3.1 Inspect the Syringes for Leaks 8.3.2 Inspect the Wash Solution Roller Pump for Leaks 8.3.3 Inspect, Clean and Prime the Sample Probe, Reagent Probe, and Mix Bars 8.3.4 Inspect the Wash Solution and Replenish As Needed 8.3.5 Inspect the Printer and Paper 8.3.6 Replace the DI Water or Diluent in the Pre-dilution Bottle 8.3.7 Inspect the Stability of the Upper Cover 8.3.8 Prepare the Sample Probe Wash Solutions 8.4 Weekly Maintenance 8.4.1 Clean the Sample Probe and Mix Bars 8.4.2 Perform a W2 8.4.3 Perform a Photocal 8.4.4 Clean the Pre-dilution Bottle 8.5 Monthly Maintenance 8.5.1 Clean the Sample Probe and Reagent Probe Wash Wells 8.5.2 Clean the Mix Bar Wash Wells 8.5.3 Clean the Wash Nozzle Unit and Check the Tube Mounting joints 8.5.4 Clean the DI Water Tank, DI Filter, and Sample Probe Filter 8.6 Quarterly Maintenance 8.6.1 Clean the Air Filters 8.6.2 Inspect and if Needed, Replace the DI Water Filter, Sample Probe Filter, and Replace the O-ring 8.6.3 Replace the Wash Solution Roller Pump Tubing 8.7 6-Month Maintenance 8.7.1 Clean the Cuvettes and the Cuvette Wheel" 2. Review the laboratory's AU480 Chemistry Analyzer maintenance logs from June 2022 to May 2023 revealed the laboratory failed to document two of eight daily maintenance, one of four weekly maintenance, monthly, quarterly, and 6-month maintenance for 12 of 12 months reviewed. 8.3 Daily Maintenance 8.3.3 Inspect, Clean and Prime the Sample Probe, Reagent Probe, and Mix Bars 8.3.7 Inspect the Stability of the Upper Cover 8.4 Weekly Maintenance 8.4.1 Clean the Sample Probe and Mix Bars 3. Review the laboratory's CMS 116 application signed by the laboratory director on 8/25/23 revealed the laboratory performed 100,000 toxicology tests annually. 4. An interview with TS#1 on 8/29/23 at 11:16 am in the office confirmed the above findings. Key: CMS=Center of Medicare and Medicaid Services TS=Technical supervisor

D6082

LABORATORY DIRECTOR RESPONSIBILITIES
 CFR(s): 493.1445(e)(1)

The laboratory director must 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 a review of the laboratory's records and staff interview, the laboratory director failed to ensure preanalytic systems were followed to ensure quality testing. Findings include: 1. The laboratory failed to have a mechanism in place to ensure the temperature of patient's specimens were maintained during transport to the laboratory for testing. (Refer to D5311 I) 2. The laboratory failed to ensure patient specimens were labeled with two patient identifiers for samples observed. (Refer to D5311 II) 3. The laboratory failed to provide the required conditions for urine specimen collection and transportation for Sexually Transmitted Infection (STI) pathogen testing to their clients. (Refer to D5317)

D6102

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(12)

The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:
Based on a review of the laboratory's submitted CMS 209 form, the laboratory's personnel records, and staff interview, the laboratory director failed to ensure documentation of training for one of three testing personnel performing high complexity testing on the QuantStudio 5 system. Findings include: 1. A review of the laboratory's submitted CMS 209 form revealed the laboratory identified 3 testing personnel performing Real-Time Polymerase Chain Reaction (RT-PCR) testing on the QuantStudio 5 system. 2. A review of the laboratory's personnel records revealed testing person #3 had no documentation of training for RT-PCR testing on the QuantStudio 5 system. 3. An interview with technical supervisor #1 (as indicated on the CMS 209 form) on 8/29/23 at 9:20 a.m. in the office, after review of the records, confirmed the above findings.

D6115

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(2)

The technical supervisor is responsible for verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.

This STANDARD is not met as evidenced by:
Based on a review of the laboratory's records and staff interview, it was revealed that the technical supervisor failed to ensure establishment studies were complete prior to performing patient testing. (Refer to D5423)