

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D1089250	(X3) Date Survey Completed 10/31/2022
Name of Provider or Supplier Agendia Inc	Street Address, City, State 22 Morgan, Irvine, CA	
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
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 the number and severity of the deficiencies cited herein, the Condition: Facility Administration was not met. These findings include: 1. Based on the surveyors' observation of the preanalytic/analytic areas for histopathology and interviews with the laboratory director (LD), technical supervisor (TS), and the director of operations (DOO) on October 31, 2022, at approximately 12:45 p.m., it was determined that the laboratory lacked a system to ensure its ventilation system properly removes vapors, fumes, and excessive heat, when appropriate, for the type of testing done in the laboratory. See D3001. 2. Based on the surveyor's observation during the laboratory tour and interview the laboratory director (LD), technical supervisor (TS), and director of operations (DOO) on October 31, 2022, it was determined that the laboratory failed to minimize cross-contamination of patient specimens, equipment, and materials used during specimen processing and the polymerase chain reaction (PCR) preparation of reagents (master mix and controls) used on Agendia's laboratory developed test "Mama Print and Blue Print for determining breast cancer metastasis risk" procedure. 3. Based on direct observation of the facilities layout, observation of the laboratory developed test (LDT) Mama</p>

Print and Blue print testing for determining breast cancer metastasis risk by the polymerase chain reaction (PCR) testing, and interviews with the laboratory director (LD) technical supervisor (TS) and director of operations (DOO) on October 31, 2022 on its molecular amplification procedure, it was determined that the laboratory failed to ensure that the PCR procedures which are not contained in closed systems have a unidirectional flow with separate areas for specimen preparation, master mix and reagents preparation, amplification, and product detection. See D3005. 4. Based on the surveyor's observation, review of records, and interviews with the (TS) and (DOO), it was determined that the histopathology laboratory lacks a monitor to measure the amounts xylene and formaldehyde (chemical) exposure the testing personnel receive on a daily and cumulative basis by processing biopsy samples preserved in formalin and daily staining using xylene as a clearing agent. The laboratory failed to observe safety procedures to ensure protection from chemical materials. See D3011.

D3001

FACILITIES
CFR(s): 493.1101(a)(1)

The laboratory must be constructed, arranged, and maintained to ensure the space, ventilation, and utilities necessary for conducting all phases of the testing process.

This STANDARD is not met as evidenced by:
Based on the surveyors' observation of the preanalytic/analytic areas for histopathology and interviews with the laboratory director (LD), technical supervisor (TS), and the director of operations (DOO) on October 31, 2022, at approximately 12:45 p.m., it was determined that the laboratory lacked a system to ensure its ventilation system properly removes vapors, fumes, and excessive heat, when appropriate, for the type of testing done in the laboratory. The findings include: 1. During the laboratory tour on October 31, 2022, at approximately 12:45 p.m. the surveyor observed that the ventilation in the histopathology sample processing room was not adequate for the testing personnel working in this area. a. During the tour of the histopathology sample processing and staining area, the surveyor was overwhelmed by the strong chemical fumes the moment the door leading to the histopathology laboratory was opened by the TS. b. The surveyor continued the tour to the processing and staining area and started feeling noxious and dizzy while in room where processing and staining of samples was taking place. The surveyor's dizziness developed in a headache which lasted 24 hours after the tour. 2. During interviews on October 31, 2022, at approximately 1:30 p.m., the TS and DOO confirmed poor ventilation in the histopathology area and were informed of the dizziness the surveyor had experienced after entering the poorly ventilated area. 3. The laboratory's testing declaration form, signed by the LD on October 31, 2022, stated that the laboratory performs 22,800 histopathology tests annually.

D3003

FACILITIES
CFR(s): 493.1101(a)(2)

The laboratory must be constructed, arranged, and maintained to ensure contamination of patient specimens, equipment, instruments, reagents, materials, and supplies is minimized.

This STANDARD is not met as evidenced by:

Based on the surveyor's observation during the laboratory tour and interview the laboratory director (LD), technical supervisor (TS), and Director of Operations (DOO) on October 31, 2022, it was determined that the laboratory failed to minimize cross-contamination of patient specimens, equipment, and materials used during specimen processing for molecular testing and the polymerase chain reaction (PCR) preparation of reagents (master mix and controls). The findings include: 1. During the laboratory tour on October 31, 2022, at approximately 1:00 p.m., the surveyor observed in the area assigned for molecular testing that sample processing and preparation of the PCR reagents to be in the same area/room, just a few feet separating the two sections. 2. Preparation of the master mix, positive controls, negative control, and addition of template took place in the same Biosafety Cabinet (BSC) right next to the molecular testing sample processing area ("dirty room"). There was not a designated "Clean" area or room for the preparation of PCR reagents and controls and addition of sample template. 3. During an interview on October 31, 2022, at approximately 1:00 p.m. the LD and DOO confirmed that the laboratory failed to have separate areas/room for molecular testing sample processing and preparation of PCR reagents to minimize cross-contamination. 4. The laboratory's testing declaration form, signed by the laboratory director on October 31, 2022, stated that the laboratory performs 42,264 PCR tests annually, Monday through Friday 8:00 a.m. to 5:00 p.m.

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 direct observation of the facilities layout, observation of the of the laboratory developed test (LDT) Mama Print and Blue print testing for determining breast cancer metastasis risk by the polymerase chain reaction (PCR) testing, and interviews with the laboratory director (LD) technical supervisor (TS) and director of operations (DOO) on October 31, 2022 on its molecular amplification procedure, it was determined that the laboratory failed to ensure that the PCR procedures which are not contained in closed systems have a unidirectional flow with separate areas/rooms for specimen preparation, master mix and reagents preparation, amplification, and product detection. The findings included: 1. The laboratory performed PCR testing for their LDT test for determining breast cancer metastasis risk by PCR. 2. During the laboratory tour on October 31, 2022, at approximately 1:30 p.m., the surveyor observed that processing of the specimens, preparation of reagents, and sample template addition were all performed in the same open area without unidirectional flow. 3. The LD, TS, and DOO confirmed by interview on 10/31/2022 that the laboratory's molecular PCR testing for the presumptive detection of metastatic breast cancer risk was not set up in a unidirectional flow area. 4. Based on laboratory records, the laboratory performed and reported approximately 42,264 Real Time PCR molecular diagnostic tests annually.

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 the surveyor's observation during the laboratory tour, review of records, and interview with the technical supervisor (TS) and director of operations (DOO), it was determined that the histopathology laboratory lacked established, accessible, and observed procedures to measure the amount of chemical exposure testing personnel (TP) receive on a daily and cumulative basis by processing biopsy samples preserved in formaldehyde and daily staining using xylene as a clearing agent. It was also observed during the tour of the molecular testing section under multiple biosafety cabinets (BSC) in the polymerase chain reaction (PCR) processing and amplification rooms, unlabeled clear bags filled to the rim with used disposable pipette tips. The laboratory failed to observe safety procedures to ensure protection from physical and chemical materials. The findings included: 1. On the day of the survey October 31, 2022, at approximately 12:45 p.m. the surveyor observed that the histopathology TP processing samples room in the laboratory lacked a xylene and formaldehyde exposure monitor. a. There was no fumes detection system in place in the histopathology laboratory to measure daily levels of xylene, formaldehyde, or other chemicals used in histopathology laboratory. b. There were no chemical exposure badges worn by the TP on the daily basis. 2. On the day of the survey October 31, 2022, at approximately 1:15 p.m., the surveyor observed under the BSCs located in various areas of the PCR testing procedures non-biohazard bags filled to the top with used pipette tips. 3. The TS and DOO affirmed: a. The lack of a chemical exposure monitoring device when processing histopathology samples daily or exposure badges to measure cumulative levels of xylene, formaldehyde, or other chemicals worn by the TP. A single xylene exposure test had been performed only for one day in the last 2 years. b. The clear plastic bags overfilled with used pipette tips under multiple BSCs in the PCR testing processing areas. 4. Based on the laboratory testing volume declaration submitted on October 31, 2022, the laboratory processes and reports 42,264 molecular (PCR) test and 22,800 histopathology tests annually.

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 the laboratory's procedure manual, lack of documentation, observation, and interview with the technical supervisor and director of operations (DOO); it was determined that the laboratory failed to perform and document maintenance and calibration as defined by the manufacturer and with at least the frequency specified by the manufacturer for the laboratory's small equipment such as vortexes and microcentrifuges. The findings included: 1. The laboratory's standard operating procedure (SOP) indicated that maintenance and calibration be performed according to manufacturer's requirements on all equipment used in the laboratory. 2. The TS and DOO confirmed on October 31, 2022, at approximately 1:00 p.m. that the laboratory failed to follow the manufacturer's instructions on preventive maintenance and

calibration of small equipment used in the laboratory. 3. According to the test volume declared by the laboratory on 10/31/2022 the laboratory performs approximately 65,064 diagnostic tests annually.

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 the lack of the laboratory's procedures to minimize the risk factors of molecular testing cross-contamination, unidirectional workflow when performing molecular amplification procedures that are not contained in a closed system, safety procedures to ensure protection for the testing personnel in histopathology sample processing area of chemical materials, preventive maintenance and calibration procedures and records for small equipment, and interviews with the laboratory's director, technical supervisor, and director of operations on October 31, 2022; it was determined that the laboratory director failed to ensure that several aspects of the preanalytic, analytic, and postanalytic phases of laboratory testing were performed and monitored. D3003, D3005, D3011, and D5429.

D6083

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(2)

The laboratory director must ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed.

This STANDARD is not met as evidenced by:

Based on the surveyor's observation, lack of ventilation in the histopathology laboratory on October 31, 2022, and interviews with the technical supervisor and director of operations; the laboratory failed to provide a system to ensure its ventilation system properly removes vapors, fumes, and excessive heat, when appropriate, for the type of testing done in the laboratory. The findings include: See D3001.