

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2032918	(X3) Date Survey Completed 06/22/2023
Name of Provider or Supplier Sagis, Pllc	Street Address, City, State 4131 Directors Row, 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	<p>The laboratory was found out of compliance with the CLIA regulations. The condition not met was: D6141 - 42 C.F.R. 493.1459 Condition: Laboratories performing high complexity testing; general supervisor 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.</p>
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies and staff interview, it was revealed that the laboratory failed to define the acceptability criteria for specimens transported at 'ambient temperature' for six of six Cytology and Histology services performed. Findings include: 1. A review of the laboratory's policy titled 'Cytology Services' revealed the following: "Routine Cytology Store specimens at room temperature (15 to 30C), Transport ambient temperature" 2. A review of the laboratory's policy titled 'Histology Services' revealed the following: "Routine Histology Store specimens at room temperature (15 to 30C), Transport ambient temperature" "Special Stains Store specimens at room temperature (15 to 30C), Transport ambient temperature" "Immunohistochemistry Store specimens at room temperature (15 to 30C), Transport ambient temperature" "In-situ Hybridization Store specimens at room temperature (15 to 30C), Transport ambient temperature" "Direct Immunofluorescence Store</p>

specimens at room temperature (15 to 30C), Transport ambient temperature" 3. An interview with the laboratory manager on 6/22/23 at 3:10 p.m. in the conference room, after review of the records, confirmed that the laboratory does not have a defined acceptability criteria for 'ambient temperature'. Key: C = Degrees Celsius

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 surveyor's observations in the laboratory, review of manufacturer's Technical Memos, laboratory's policies/procedures, documentation for validation of controls, patient test records and staff interview, the laboratory failed to have a procedure to define and document validation of 3 of 17 Special Stain controls used by the laboratory, the commercially prepared Spirochete, Acid Fast Bacteria (AFB) and Amyloid control slides. Findings included: 1. On 06/21/2023 at 0910 hours during initial tour of the laboratory, the Laboratory Director indicated the laboratory validated each batch of controls for each stain by staining and reviewing the first and last cut/slide of each batch. 2. Surveyor's observations on 06/22/2023 at 1425 hours in the laboratory revealed the laboratory used in-house and commercially prepared control slides for its 17 special stains. Further observations revealed the following 3 commercially prepared control slides did not have documentation of the date of receipt or opening of the boxes: Newcomer Supply Spirochete, Animal Control Slides (98 slide/set) Newcomer Supply Acid Fast Bacteria (AFB), Animal Control Slides (98 slide/set) Newcomer Supply Amyloid, Animal Control Slides (98 slide/set) 3. Review of manufacturer's Technical Memos (Part 4660 Revised August 2021, Part 4011 Revised January 2020 and Part 4031 Revised January 2021) for the above control slides revealed: "Reactivity: guaranteed product specific reactivity for one year from date of receipt. Revalidate after one year to verify continued reactivity." 4. Review of the laboratory's procedure "Manual Special Stain Batch Control" (Number 5024, adopted 08/30/2021) revealed there was no mention of validation of in-house or commercially prepared control slides. 5. Review of the laboratory's procedure "Control Validation- Immunohistochemistry" (Number 4005, adopted 01/18/2017) revealed: "Each test or appropriate group of tests should have a running Control Validation Log sheet, kept in a Control Log notebook." And, "Once the pathologist has approved both the first and last cuts as appropriate, the remaining cuts may be put into service as control tissue." Note: The Policy/procedure did not address validation of commercially prepared controls. 6. Review of documentation for validation of controls revealed: a. Spirochete Control slides were last validated on 08/30/2019 b. AFB Control slides were last validated on 07/13/2021 c. Amyloid Control Slides were last validated on 09/20/2020 7. Review of patient test records for 2022 revealed: a. 28 patient samples were tested for Spirochete reactivity in 2022 b. 513 patient samples were tested for AFB reactivity in 2022 c. 136 patient samples were tested for Amyloid reactivity in 2022 8. In an interview on 06/22/2023 at 1435 hours in the conference room the laboratory's Testing Person number 41 (as indicated on submitted form CMS 209), after review of the data, confirmed the findings. Key: CMS - Centers for Medicare and Medicaid

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's equipment maintenance records, operator's manuals, laboratory's policies/procedures and staff interview, the laboratory failed to document daily cleaning of the Leica Cryostat as per manufacturer requirements for 31 of 61 days reviewed. Findings included: 1. Review of laboratory's equipment maintenance records for the Leica Cryostat from November 2022 to January 2023 revealed "Daily Clean" was not documented for 31 of 61 reviewed days as follows: 11/01/2022 11/03/2022 11/08/2022 11/10/2022 11/11/2022 11/15/2022 11/16/2022 11/17/2022 11/22/2022 11/29/2022 11/30/2022 12/01/2022 12/06/2022 12/08/2022 12/13/2022 12/14/2022 12/15/2022 12/20/2022 12/21/2022 12/22/2022 12/27/2022 12/28/2022 12/29/2022 01/05/2023 01/10/2023 01/12/2023 01/17/2023 01/19/2023 01/24/2023 01/26/2023 01/31/2023 2. Review of the "Leica Biosystems Instructions for use CM1860 /CM1860 UV- Cryostat" (V1.6 Revi-10/2016) revealed: "Cleaning -Remove frozen section waste from the cryostat with a cold brush every day." 3. Review of laboratory's procedure "Leica Cryostat - CM1860" (Number 5021, adopted 03/12/2018) revealed the procedure did not define the frequency of performance for cleaning, disinfection and how to address documentation for the days the instrument was not in use. 4. In an interview on 06/22/2023 at 1415 hours in the conference room, the laboratory's Testing Person number 41 (as indicated on the submitted form CMS 209), after review of the data, confirmed the findings Key: CMS - Centers for Medicare and Medicaid

D5473

CONTROL PROCEDURES

CFR(s): 493.1256(e)(2)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's stain quality control records, patient sample's slide staining tallies and staff interview, the laboratory failed to document Hematoxylin and Eosin (H&E) stain reactivity acceptability for 4 of 65 reviewed days the stain was in use. Findings included: 1. Review of the laboratory's stain quality control records from January to March 2023 revealed the following 4 of 65 days the H&E stain was used the stain's reactivity was not documented: 01/06/2023 01/20/2023 02/14/2023 03/09/2023 2. Review of patient sample's slide staining tallies revealed the following number of patient sample slides were processed using the H&E on the days stain's reactivity was not documented: Date: Slides processed: 01/06/2023 1730 01/20/2023 2177 02/14/2023 1505 03/09/2023 2567 3. In an interview on 06/22/2023 at 1540

hours in the conference room the laboratory's Testing Person number 41 (as indicated on submitted form CMS 209), after review of the data, confirmed the findings. Key: CMS - Centers for Medicare and Medicaid

D5645

CYTOLOGY
CFR(s): 493.1274(d)(3)

(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(3) The laboratory must maintain records of the total number of slides examined by each individual during each 24-hour period and the number of hours spent examining slides in the 24-hour period irrespective of the site or laboratory.

This STANDARD is not met as evidenced by:
Based on review of laboratory's policies, a random review of the Cytology Prep Quality and Workload reports from October 2022 to March 2023, and staff interview, it was revealed that the laboratory failed to ensure seven of twenty Cytology Prep Quality and Workload reports reviewed included the total number of slides that were screened and/or the total number of hours the technical supervisor spent screening non-gynecologic cytology slides during each 24-hour period. Findings include: 1. A review of the laboratory's policy titled 'Cytology Workload Tracking' revealed the following: "Individual screening workload maximum limits will be set at 100 cytology slides per 24 hours for pathologists as an initial workload limit." 2. A random review of the Cytology Prep Quality and Workload reports from October 2022 to March 2023 revealed the following 7 reports failed to include the total number of slides that were examined and/or the total time the technical supervisor spent screening the cytology slides: Date: 10/21/22 Report was missing the screening time for case numbers GC22-946, GC22-947, GC22-948 Date: 12/16/22 Report was missing the total number of slides screened and the screening time for case number GC22-1276 Date: 1/20/23 Report was missing the total number of slides screened for case numbers GC23-113, GC23-114, GC23-115, GC23-116, GC23-117 Report was missing the screening time for case numbers GC23-110, GC23-111, GC23-112, GC23-113, GC23-114, GC23-115, GC23-116, GC23-117 Date: 2/6/23 Report was missing the screening time for case numbers GC23-624, GC23-625, GC23-623, GC23-207, GC23-214, GC23-215, GC23-216, GC23-218, GC23-219, GC23-220, GC23-221 Date: 2/21/23 Report was missing the screening time for case numbers GC23-316, GC23-317, GC23-318, GC23-319, GC23-320, GC23-321, GC23-322 Date: 3/24/23 Report was missing the total number of slides screened and the screening time for case numbers GC23-519, GC23-520, GC23-521, GC23-522, GC23-523, GC23-524, GC23-525 Date: 3/30/23 Report was missing the total number of slides screened and the screening time for case numbers GC23-1632, GC23-554, GC23-555, GC23-556, GC23-557, GC23-558, GC23-559, GC23-548, GC23-549, GC23-550, GC23-551, GC23-552, GC23-553, GC23-1602 3. An interview with the laboratory director on 6/22/23 at 4:15 p.m. in the conference room, after review of the records, confirmed the above findings.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The

laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's Cytology Prep Quality and Workload reports from January and February 2023 and staff interview, it was revealed that the laboratory's quality assessment program failed to ensure patient's case numbers on the reports were documented correctly for twenty three days reviewed from January and February 2023. Findings include: 1. A review of the laboratory's Cytology Prep Quality and Workload reports revealed a column for the technical supervisor to document the case numbers screened each day. All case numbers begin with GC and the last two numbers of the calendar year, followed by a unique patient number. 2. A review of the laboratory's Cytology Prep Quality and Workload reports from January and February 2023 revealed the following 23 days where the patient's case numbers were documented as GC22- (from calendar year 2022) and not GC23- (from calendar year 2023): 1/3/23 1/4/23 1/5/23 1/6/23 1/9/23 1/10/23 1/12/23 1/13/23 1/16/23 1/17/23 1/18/23 1/19/23 1/20/23 1/23/23 1/24/23 1/25/23 1/26/23 1/27/23 1/30/23 2/1/23 2/2/23 2/3/23 2/6/23 3. An interview with the laboratory director on 6/22/23 at 4:20 p. m. in the conference room, after review of the records, confirmed that the report forms were not changed out at the beginning of the new year.

D6079

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(a)(b)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's CMS 209 Personnel report, personnel records and confirmed in an interview, the laboratory director failed to employ of personnel qualified as a General Supervisors in histopathology speciality. Refer to D6143.

D6141

GENERAL SUPERVISOR

CFR(s): 493.1459

The laboratory must have one or more general supervisors who are qualified under 493.1461 of this subpart to provide general supervision in accordance with 493.1463 of this subpart.

This CONDITION is not met as evidenced by:

Based on review of the laboratory's CMS 209 Personnel report, personnel records and confirmed in an interview, the laboratory failed to meet the requirements to qualify two of four General Supervisors in histopathology speciality. Refer to D6143.

GENERAL SUPERVISOR QUALIFICATIONS

CFR(s): 493.1461

(a) The general supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and (b) The general supervisor must be qualified as a-- (b)(1) Laboratory director under 493.1443; or (b)(2) Technical supervisor under 493.1449. (c) If the requirements of paragraph (b)(1) or paragraph (b)(2) of this section are not met, the individual functioning as the general supervisor must-- (c)(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; and (c)(1)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing; or (c)(2)(i) Qualify as testing personnel under 493.1489(b)(2); and (c)(2)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing; or (c)(3)(i) Except as specified in paragraph (3)(ii) of this section, have previously qualified as a general supervisor under 493.1462 on or before February 28, 1992. (c)(3)(ii) Exception. An individual who achieved a satisfactory grade in a proficiency examination for technologist given by HHS between March 1, 1986 and December 31, 1987, qualifies as a general supervisor if he or she meets the requirements of 493.1462 on or before January 1, 1994. (c)(4) On or before September 1, 1992, have served as a general supervisor of high complexity testing and as of April 24, 1995-- (c)(4)(i) Meet one of the following requirements: (c)(4)(i)(A) Have graduated from a medical laboratory or clinical laboratory training program approved or accredited by the Accrediting Bureau of Health Education Schools (ABHES), the Commission on Allied Health Education Accreditation (CAHEA), or other organization approved by HHS. (c)(4)(i)(B) Be a high school graduate or equivalent and have successfully completed an official U.S. military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician). (c)(4)(ii) Have at least 2 years of clinical laboratory training, or experience, or both, in high complexity testing; or (c)(5) On or before September 1, 1992, have served as a general supervisor of high complexity testing and-- (c)(5)(i) Be a high school graduate or equivalent; and (c)(5)(ii) Have had at least 10 years of laboratory training or experience, or both, in high complexity testing, including at least 6 years of supervisory experience between September 1, 1982 and September 1, 1992. (d) For blood gas analysis, the individual providing general supervision must-- (d)(1) Be qualified under 493.1461(b)(1) or (2), or 493.1461(c); or (d)(2)(i) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (d)(2)(ii) Have at least one year of laboratory training or experience, or both, in blood gas analysis; or (d)(3)(i) Have earned an associate degree related to pulmonary function from an accredited institution; and (d)(3)(ii) Have at least two years of training or experience, or both in blood gas analysis. (e) The general supervisor requirement is met in histopathology, oral pathology, dermatopathology, and ophthalmic pathology because all tests and examinations, must be performed: (e)(1) In histopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(1)(1); (e)(2) In dermatopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(1) or (2); (e)(3) In ophthalmic pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(1)(3); and (e)(4) In oral pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(m).

This STANDARD is not met as evidenced by:

A. Based on the review of CMS 209 Personal report, personnel records, and confirmed in an interview, the laboratory failed to meet the requirements to qualify two of four General Supervisors (GS) in histopathology speciality. The findings were: 1. Review of the CMS 209 personnel report, signed by the laboratory director on 6/20/2023, revealed four GS for histopathology speciality. 2. Review of personnel records for four GS revealed two of four GS did not meet the requirements to qualify as a general supervisor in histopathology speciality. GS#3 Hire Date: 4/3/2018 GS#4 Hire Date: 1/25/2021 3. An interview with the laboratory supervisor on 06/22/2023 at 9:38 a.m. in a conference room confirmed the above findings. Key: CMS=Centers for Medicare and Medicaid Services 44698 B. Based on review of the laboratory's patient test records, specimen progress audits and staff interview, the laboratory failed to ensure physical examinations/descriptions (grossing) of tissue were reviewed by qualified personnel (technical supervisor) within 24 hours of grossing completion for 6 of 8 random patients' test records reviewed. Findings included: 1. Review of random laboratory's patient test records for January 2023 and corresponding specimen progress audits revealed the following 6 of 8 reviewed patients' samples did not have review of grossing by qualified personnel within 24 hours of grossing completion: Sample Accession: SP23-001646 Grossing Completed: 01/19/2023 at 23:10 Final Report Signed (grossing reviewed): 01/23/2023 at 10:39 Elapsed time: approximately 83 hours Sample Accession: SP23-001609 Grossing Completed: 01/19/2023 at 23:06 Final Report Signed (grossing reviewed): 01/23/2023 at 10:29 Elapsed time: approximately 83 hours Sample Accession: SD23-016523 Grossing Completed: 01/20/2023 at 00:13 Final Report Signed (grossing reviewed): 01/22/2023 at 17:16 Elapsed time: approximately 41 hours Sample Accession: SD23-016321 Grossing Completed: 01/19/2023 at 22:40 Final Report Signed (grossing reviewed): 01/23/2023 at 06:26 Elapsed time: approximately 80 hours Sample Accession: SD23-015655 Grossing Completed: 01/19/2023 at 13:57 Final Report Signed (grossing reviewed): 01/22/2023 at 17:03 Elapsed time: approximately 51 hours Sample Accession: SD23-015826 Grossing Completed: 01/19/2023 at 13:04 Final Report Signed (grossing reviewed): 01/23/2023 at 14:50 Elapsed time: approximately 50 hours 2. In an interview on 06/22/2023 at 1120 hours in the conference room the laboratory's Testing Person number 41 (as indicated on submitted form CMS 209), stated that each pathologist (technical supervisor) reviewed grossing at time of final report entry. This confirmed the findings. Key: CMS - Centers for Medicare and Medicaid