

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D2032918	<b>(X3) Date Survey Completed</b>  04/17/2018
<b>Name of Provider or Supplier</b>  Sagis, Pllc	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	<p>The laboratory was found to be out of compliance based on the following <b>CONDITION LEVEL DEFICIENCY: D6141 - 42 C.F.R. 493.1459 Condition:</b> General Supervisor Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility representative was given an opportunity to provide evidence of compliance with noted deficiencies and no such evidence was provided prior to survey exit. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider /supplier, the State Survey Agency (SA) should be notified immediately.</p>
<b>D5217</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's test menu, review of the laboratory's records, and staff interview, it was revealed the laboratory failed to have documentation of performing twice annual accuracy assessment for 31 of 31 special stains in 2017. The findings were: 1. A review of the laboratory's test menu revealed the laboratory utilized the following 31 special stains for histopathology: MART S100 MCK HMW CD3 CD4 CD5 CD8 CD20 CD30 CD68 CD117 SOX-10 HMB-45 KI-67 CK-8/18 CD34 CD1a Factor XIIIa Desmin CK20 Synaptophysin Chromogranin CK7 CD45 p63 EMA CEA CD31 T-PAP H. pylori 2. The laboratory was asked to provide documentation of performing twice annual accuracy assessment for the identified stains in 2017. No documentation was provided. 3. An interview with the laboratory</p>

supervisor on 04/17/2018 at 1222 hours in the office revealed the laboratory did not perform the required accuracy assessments. This confirmed the findings.

**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 submitted Form CMS 209, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of education to qualify 1 of 2 general supervisors (refer to D6143).

**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(l)(1); (e)(2) In dermatopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(l) or (2); (e)(3) In ophthalmic pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(l)(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:

Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of education to qualify 1 of 2 general supervisors. The findings were: 1. A review of the laboratory's submitted Form CMS 209 (signed by the laboratory director on 04/17/2018) revealed the laboratory identified 2 general supervisors. 2. A review of the laboratory's personnel records revealed general supervisor number 2 (as listed on Form CMS 209) highest education was an associates degree. 3. The laboratory was asked to provide documentation of a bachelor of science degree or higher to qualify general supervisor number 2. No documentation was provided. 4. An interview with the laboratory supervisor on 04/17/2018 at 1030 hours in the office - after her review of the records- confirmed the findings.