Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D2166075	11/21/2019
Name of Provider or Supplier	**Street Address, City, State**	
Sagis	701 Metairie Road, Suite 2a205-S, Metairie, LA	

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	An Initial survey was performed on November 21, 2019 at Sagis, PLLC, CLIA ID # 19D2166075. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to establish complete personnel competency policies. Findings: 1. Review of the laboratory's personnel competency policy did not include how personnel competency will be assessed. 2. In interview on November 21, 2019 the Laboratory Director confirmed the laboratory's competency policy did not include how competency will be assessed.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6)

	The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to include complete quality control procedures in their policy and procedure manual. Findings: 1. Review of the laboratory's "Quality Control" policy under the "Controls" section revealed the following: a) "Positive and negative controls will be reviewed daily for all hematoxylin and eosin, special stains, immunohistochemistry, and immunofluorescent studies." b) "Documentation of positive and negative control review on all histology order slides will be done DAILY by the ordering pathologist or technical supervisor before patient sample interpretation." 2. Further review of the "Quality Control" policy revealed the policy did not include the testing personnel's responsibility and acceptability criteria. 3. In interview on November 21, 2019, the Laboratory Director confirmed the laboratory's policy did not include the identified information.
D5609	HISTOPATHOLOGY CFR(s): 493.1273(e)(f) (e) The laboratory must use acceptable terminology of a recognized system of disease nomenclature in reporting results. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to ensure testing personnel documented the stain quality for Hematoxylin and Eosin (H&E) stains. Findings: 1. Review of the laboratory's CMS 209 form (Laboratory Personnel Report) revealed the Laboratory Director serves as the testing personnel. 2. Review of random selection of patients and quality control (QC) records from August 2019 through November 2019 revealed the laboratory did not have documented QC assessment performed by the testing personnel identified on the laboratory's CMS 209 form for the following dates: Report Date: August 20, 2019 Patient: SD19-096034 Report Date: September 4, 2019 Patient: SD19-103619 Report Date: September 24, 2019 Patient: SD19-113618 Report Date: October 21, 2019 Patient: SD19-127252 Report Date: November 1, 2019 Patient: SD19-132939 3. In interview on November 21, 2019 at 9:38 am, the Laboratory Director stated she does not document the QC at the Metairie location. The Laboratory Director further stated the QC is documented at the Houston location, where slides are processed. 4. Review of the laboratory's test menu revealed the laboratory performs 2,500 H&E stains annually.
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 record review and interview with personnel, the laboratory failed to follow their established written quality assessment policy and procedures for three (3) of three (3) months reviewed. Findings: 1. Review of the laboratory's Quality Assessment (QA) records revealed the laboratory had "Monthly Quality Assessment Checklist" forms that included the following monitors: a) "Complaints /Communication Errors" b) "Proficiency Testing" c) "Quality Control" d) "Reagents /Specimens" e) "Maintenance and Function Checks" f) "Lab Safety and Competency Training" g) "Patient Test Management and Confidentiality" h)" Procedure Manual" i)"Lab Changes" j)" Miscellaneous/Comments" 2. Further review of the laboratory's "Monthly Quality Assessment Checklist" forms for August 2019 through October 2019 revealed the laboratory did not have documented assessments of each monitor for the following three (3) months: August 2019 September 2019 October 2019 3. Further review of the identified "Monthly Quality Assessment Checklist" forms revealed the Laboratory Director's signature was included on the identified forms; however, the date for each month was "5/15/19." 4. In interview on November 21, 2019 at 9:43 am, the Laboratory Director confirmed she did not document the QA for August 2019 through October 2019.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure that a quality control program was established to assure the quality of laboratory testing. Refer to D5609.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was maintained to assure the quality of laboratory services provided. Refer to D5791.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13)

	The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure complete policies and procedures were established for assessing personnel competency. Refer to D5209.