

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2044865	(X3) Date Survey Completed 12/10/2020
Name of Provider or Supplier Sagis	Street Address, City, State 1033 La Posada Dr Ste 306, Austin, 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
D5473	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, quality control records, patient test results and interview, the laboratory failed to document the negative and positive intended reactivity of quality control slides for Hematoxylin & Eosin (H&E) each day of patient testing. Findings follow. 1. Review of the laboratory's procedure Examination of histologic Slides and Reporting of Results, version 1, effective date 3 /31/2016, on page 2 under Quality Control stated, "Documentation should be kept daily on quality of routine slides to be graded as excellent, acceptable, or unacceptable with type of staining protocol reported on the QA log. If at any time, a grade of "unacceptable" is assigned, the type of corrective action must be included." 2. QA logs were requested but not provided at the time of the survey. 3. Review of the patient test reports showed 6 of 7 were lacking the comment "Positive control and appropriate negative control (internal) have been reviewed and react appropriately" as listed by accession number: a. SD20-082816 b. SD20-037507 c. SD20-037418 d. SD20-31170 e. SD19-001392 f. SD19-001117 Interview with the Laboratory Director on the CMS form 209 on December 10, 2020 at 1020 hours confirmed he did not use a QA log to document the stain quality, and he did not document the H&E stain quality on the patient test report.</p>