

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D0982952	(X3) Date Survey Completed 06/06/2019
Name of Provider or Supplier Semans Dermatopathology Service	Street Address, City, State 101 E Main Street, Rochester, IL	
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
D5601	<p>HISTOPATHOLOGY CFR(s): 493.1273(a)(f)</p> <p>(a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the laboratory director (LD); the laboratory failed to document reactivity of hemotoxylin and eosin (H&E) staining for 5 of 5 patient test report dates reviewed. Findings Include: 1. Review of the laboratory procedure, "Quality Control Statement for Histotechnologists", stated H&E staining quality is check on a daily basis and logged on the "Daily Physician evaluation for grossing and histotchnologist" log. 2. Review of the "Daily Physician evaluation for grossing and histotchnologist" logs found the laboratory failed to document H&E staining acceptability on the in 2017 through the date of survey, 6-6-2019. 3. A review of 5 of 5 patient testing dates found the laboratory failed to document H&E staining acceptability. Patient Identification Date P1 08-24-2017 P2 12-21-2017 P3 04-04-2018 P4 10-16-2018 P5 02-14-2019 4. Interview on 06-06-2019, at 12:50 pm, the LD confirmed the facility failed to document the H&E staining acceptability each time of use in 2017 through the date of survey (6-6-2019).</p>
D6128	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9)</p> <p>The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually</p>

after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

This STANDARD is not met as evidenced by:

Based on review of laboratory records and interview with the laboratory director (LD); the LD failed to ensure annual competency assessments were completed for 1 of 1 high complexity testing personnel (TP) in 2017 and 2018 performing grossing for histopathology testing. Findings Include: 1. Review of the laboratory's policy and procedure manual identified the policy, "Grosser Laboratory, Competency Assessment Policy", which stated the following: "The grosser is assessed for competency in technical skills, problem solving, and procedural knowledge. This assessment is recorded initially after six months and annually thereafter as part of the performance review process. A copy of the results will be kept in their employee file." 2. Review of employee competency assessment records found the LD failed to ensure annual competency assessments were completed for TP #2 in 2017 and 2018. 3. On survey date 06-06-2019, at 12:50 pm, the LD confirmed competency assessments were not performed in 2017 and 2018 for TP#2.