

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2048782	(X3) Date Survey Completed 06/08/2020
Name of Provider or Supplier Johnny Gurgen Do Pa	Street Address, City, State 1340 Citizens Blvd, Leesburg, FL	
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	A recertification survey was conducted on June 8, 2020. Johnny Gurgen DO PA clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to retain quality control (QC) records from June 8 - 30, 2018 and October 1 - 31, 2018. Findings: Review of the laboratory's histology QC records showed that there were not any records from June 8 - 30, 2018 and October 1 - 31, 2018. The following monthly QC records were missing: Slide Dryer/Oven Daily Maintenance QC, Flootation Bath Daily Maintenance QC, Manual H&E Stain Daily Maintenance QC, Microtome Daily Maintenance QC, Tissue Processor Daily Maintenance QC, and Embedding Center Daily Maintenance QC. Review of the Grossing Sheet for Specimens listed 173 patients specimens processed from June 8 - 30, 2018, and 225 patients specimens processed from October 1 - 31, 2018. During an interview on 6/8/20 at 12:10 PM, the Mohs Technician stated she did not know where the QC records for June 2018 and October 2018 were.</p>
D3039	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(5)</p> <p>Quality system assessment records. Retain all laboratory quality system assessment records for at least 2 years.</p>

This STANDARD is not met as evidenced by:
Based on record review and interview, the laboratory failed to retain quality assessment (QA) records from June through August 2018, October through December 2018 and January through June 2019. Findings: Review of the laboratory's histology QA records showed that there were not any records from June through August 2018, October through December 2018 and January through June 2019. The following monthly QA checklists were missing: Monthly Quality Assurance Checklist and Monthly Patient Quality Assurance Checklist. Review of the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification form signed by the Laboratory Director on 5/20/20 noted the estimated testing volume for histology biopsies was 4,320 per year. During an interview on 6/8/20 at 12:10 PM, the Mohs Technician stated she did not know where the QA records were.

D5217

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(c)(1)

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.

This STANDARD is not met as evidenced by:
Based on record review and staff interview, the laboratory failed to verify the accuracy of the reading and interpretation of the Hematoxylin and Eosin (H&E) stain at least twice annually in 2019. Findings: The laboratory used peer review to verify the accuracy of the reading and interpretation of H&E stains. Review of the laboratory's records for 2019 showed that all the peer reviews were signed and dated by the reviewing doctor on 9/19/19. During an interview on 6/8/20 at 11:30 AM, the Mohs Technician stated that peer review was performed only once during 2019.