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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 10D2160877 | (X3) Date Survey Completed 05/29/2019 |
| Name of Provider or Supplier Digestive Disease Consultants Llc | Street Address, City, State 870 Kingsley Avenue, Orange Park, 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 |
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| D5609 | <p>HISTOPATHOLOGY CFR(s): 493.1273(e)(f)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to maintain complete Histopathology quality control documentation of reagent lot numbers and expiration dates for 3 of 3 months reviewed in 2019. Findings Included: Record review of quality control documentation showed there was no record of lot numbers and expiration dates for the Hematoxylin and Eosin (H&E) staining reagents that were used on patient skin sample histopathology slides during processing. Interview with the office staff on 5/29/19 at 6:30 PM confirmed that the laboratory had not kept any quality control reagent logs showing documentation of the lot number and expiration dates for the H&E staining reagents.</p> |