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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 14D0415413 | (X3) Date Survey Completed 02/21/2019 |
| Name of Provider or Supplier Illinois Center For Digestive & Liver Health, The | Street Address, City, State 1710 N Randall Rd - Ste 280, Elgin, 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 |
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| D5203 | <p>SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232</p> <p>The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results.</p> <p>This STANDARD is not met as evidenced by: Based on review laboratory policies, procedures, testing logs, patients' test reports, patients' slides and interview with the laboratory director; the laboratory failed to establish and follow written policies and procedures that ensure positive identification and optimum integrity of patients' specimens form the time of collection or receipt of the specimen through completion of testing and reporting of results. Findings include: 1. Review of the laboratory's policies and procedures revealed that laboratory identifies the patients' slide (specimen) with a CPC master case number. In a section titled, "Receiving and Validating Histology Slides," testing personnel are instructed to ensure the integrity of the slides and paper work. 2. Review of paper work sent with patients' slides revealed that there is a log sheet that identifies the patient with their first and last names and a Case #. 3. Review of the log sheets revealed that the patients' slides were not identified with the CPC master case number for 5 of 5 patients' data reviewed. 4. Review of patients' slides revealed that along with the patients' first and last name, there were also 2 separated alpha numeric #s on 5 of 5 patients' slides reviewed. There was no procedure that described why the laboratory used 2 separate numbering systems. 5. Review of 5 patients' test reports revealed that patient's specimens were identified on the test report with the CPC case number for 5 of 5 patients' test reports reviewed. 6. At 1:00 PM on 02/21/2019, the laboratory director confirmed the surveyor's findings.</p> |
| D5219 | EVALUATION OF PROFICIENCY TESTING PERFORMANCE |

CFR(s): 493.1236(c)(2)

At least twice annually, the laboratory must verify the accuracy of any test or procedure listed in subpart I of this part for which compatible proficiency testing samples are not offered by a CMS-approved proficiency testing program.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies and procedures, laboratory records and interview with the laboratory director; the laboratory did not verify the accuracy of its histopathology procedures, at least twice annually. Findings include: 1. The laboratory's policy for how it performs proficiency testing states that the laboratory will perform split sample analysis to satisfy this regulation. 2. There were no records to reflect that the laboratory performs split sample analysis at least twice a year from October 2018 through February 21, 2019. 3. Review of laboratory records revealed that the laboratory director who is also testing personnel at another laboratory submitted records for the performance of Proficiency Testing (PT) from the Collagen of American Pathologists PT program. 4. At 1:00 PM on 02/21/2019, the laboratory director confirmed the surveyor's findings.

D5315

SPECIMEN SUBMISSION, HANDLING, AND REFERRAL
CFR(s): 493.1242(c)

The laboratory must refer a specimen for testing only to a CLIA-certified laboratory or a laboratory meeting equivalent requirements as determined by CMS.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies, procedures and interview with the laboratory director; the laboratory failed to ensure that it refers its specimens for testing only to CLIA-certified laboratories or laboratories meeting equivalent requirements as determined by CMS. Findings include: 1. Review of the laboratory's policies and procedures manual revealed that the laboratory failed to list all of the laboratories that it referred patients' specimens, including those where 2nd opinions or consultations are requested. 2. Review of CLIA certificates from laboratories used as reference laboratories revealed that the laboratory did not have valid copies of CLIA certificate from all laboratories it refers patient specimens, including Mayo Clinic. 3. At 1:00 PM on 02/21/2019, the laboratory director confirmed the surveyor's findings.