

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2227207	(X3) Date Survey Completed 01/12/2023
Name of Provider or Supplier Laboratory & Pathology Diagnostics	Street Address, City, State 1220 Hobson Rd - Ste 244, Naperville, 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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of documentation, and interview with the clinical consultant (CC 2), the laboratory failed to evaluate biannual method accuracy for histopathology testing at least twice a year in 2022. Findings Include: 1. Review of laboratory records revealed the laboratory failed to have policies and procedures in place to biannually evaluate the accuracy of histopathology testing in 2022. 2. Review of laboratory records found the laboratory failed to document biannual method accuracy for histopathology slide reading in 2022. 3. On 01/12/2023 at 1:15 p.m., CC 2 stated that the laboratory did not have a procedure in place to evaluate histopathology consultations.</p>
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory records, patient case logs (PCL), and interview with the</p>

clinical consultant (CC 2), the laboratory failed to follow written procedures for the return of five of five patients slides to the Lockport laboratory in 2022 and 2023. Findings Include: 1. Surveyor reviewed five patient logs from 06/21/22 to 01/08/2023. a. PCL 1 - 06/21/2022 - Case Tracking Summary #L22-16842 b. PCL 2 - 07/05/2022 - 07/06/2022 - Case Tracking Summary #L22-18143 c. PCL 3 - 09/06/2022 - 09/12/2022 - Case Tracking Summary #L22-24450 d. PCL 4 - 12/30/2022 - 01/01/2023 - Case Tracking Summary #L22-36544 e. PCL 5 - 01/04/2023 - 01/08/2023 - Case Tracking Summary #L23-00012 2. Review of the laboratory's Daily Slide Distribution procedure revealed: a. "Slides that are sent to other locations will be included on a corresponding packing list." 3. Review of laboratory records and the case tracking summaries listed in Finding 1 failed to reveal corresponding packing lists for returning patients slides (Finding 1) to the Lockport laboratory location. 4. On 01/12/2023 at 9:10 a.m., CC 2 stated the laboratory does not document the return of patient slides to the Lockport laboratory location.

D5801

TEST REPORT
CFR(s): 493.1291(a)

The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

This STANDARD is not met as evidenced by:
Based on review of patient case logs (PCL), direct observation, and interview with the clinical consultant (CC 2), the laboratory failed to ensure the correct laboratory location was indicated on the electronic patient case logs reviewed in 2022 and 2023. Findings Include: 1. Review of PCL 3 Case Tracking Summary #L22-24450 (09/06/2022 - 09/12/2022) revealed the laboratory failed to electronically record the correct laboratory location of the practitioner reporting surgical pathology results for two of two patient samples reviewed. (A1-1 and A1-2). a. A1-1: Received at the Hobson laboratory location on 09/06/2022 at 3:47 p.m. Pathology results erroneously entered on 09/09/2022 at 3:54 p.m. as the Lockport laboratory location. b. A1-2: Received at the Hobson laboratory location on 09/12/2022 at 9:33 a.m. Pathology results erroneously entered on 09/12/2022 at 3:29 p.m. as the Lockport laboratory location. 2. Review of PCL 5 Case Tracking Summary #L23-00012 (01/04/2023 - 01/08/2023) revealed the laboratory failed to electronically record the correct laboratory location of the practitioner reporting surgical pathology results for six of six patient samples reviewed. (A1-1, A2-1, A3-1, A4-1, A5-1, and A6-1). a. A1-1, A2-1, A3-1, A4-1, A5-1, and A6-1: Received at the Hobson laboratory location on 01/04/2023 at 3:58 p.m. Pathology results erroneously entered on 01/08/2023 at 9:57 p.m. as the Lockport laboratory location. 3. On 01/12/2023 at 12:40 p.m., clinical consultant CC 2 demonstrated how the practitioner selected the incorrect laboratory location of patient analysis via computer entry error. 4. On 01/12/2023 at 12:40 p.m., clinical consultant CC 2 confirmed the above findings.

D5891

POSTANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1299(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.

This STANDARD is not met as evidenced by:

Based on review of laboratory records, patient case logs (PCL), and interview with the clinical consultant (CC 2), the laboratory failed to establish a post analytic quality assessment procedure to monitor and correct errors for histopathology testing in 2022 and 2023. Findings Include: 1. Review of the laboratory's procedures manual titled, "Laboratory & Pathology Diagnostics: Hobson Laboratory Services", failed to establish a post analytic quality assessment procedure for histopathology. 2. Surveyor review of patient case logs revealed the laboratory failed to electronically record the correct laboratory location of the practitioner reporting surgical pathology results affecting eight of eight patient samples reviewed. (Refer to D5801) 3. On 01/12/2023 at 1:15 p.m., clinical consultant CC 2 confirmed the above findings.