

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2162518	(X3) Date Survey Completed 05/21/2021
Name of Provider or Supplier Endoscopy Center Of The North Shore, Llc	Street Address, City, State 1732 Central St, Evanston, 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
D6076	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on review of the Allegation of Compliance submitted on 05/17/2021 and lack of communication, the laboratory director (LD) failed to provide overall management and direction in accordance with 493.1445 of this subpart in the specialty of Histopathology. Findings Include: 1. The LD failed to be accessible to provide onsite, telephone, or electronic consultation when needed (See D6080).</p>
D6080	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(c)</p> <p>The laboratory director must be accessible to the laboratory to provide onsite, telephone or electronic consultation as needed.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation, review of the Allegation of Compliance (AOC) submitted on 05/17/2021 and lack of communication, the laboratory director (LD) failed to be accessible to provide onsite, telephone, or electronic consultation as needed affecting the laboratory's recertification survey on 04/16/2021. Findings: 1. The AOC submitted on 05/17/2021 and the laboratory personnel report (CMS 209) were reviewed. 2. The CMS 209 listed the pathologist, Dr Jim Lu as the sole laboratory personnel. Dr Lu functioned as the LD, technical supervisor (TS), clinical consultant (CC), general supervisor (GS) and testing personnel (TP) for</p>

Histopathology slide interpretations. 3. The AOC received on 05/17/2021 stated the following: *GoPath (a different laboratory) was responsible for quality control documentation of slides read at Endoscopy Center of the North Shore. *GoPath was responsible for access to Endoscopy Center of the North Shore patient records when a Center of Medicare & Medicaid Services (CMS) representative conducted surveys. *GoPath was responsible for slide storage and retrieval during surveys. 4. Further review showed the GoPath representative submitted the 05/17/2021 AOC. 5. During the laboratory's recertification survey on 04/16/2021 at 12:30 PM, the surveyor communicated with a representative from GoPath laboratory. The LD was not present or consulted electronically or via telephone during the survey process and all email correspondences dated 04/15/2021; 04/16/2021; 04/21/2021; 05/18/2021; and 05/19/2021 were not copied (cc:) to Dr Lu (the LD). 6. The LD failed to be available to perform the responsibilities of the LD, TS, GS, and/or TP during the laboratory's recertification process. 7. On a Desk Follow-Up survey conducted on 05/21/2021 at 11:30 AM, the LD was notified of the above findings via certified mail.