

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  14D2030411	<b>(X3) Date Survey Completed</b>  01/11/2019
<b>Name of Provider or Supplier</b>  Metro Chicago Surgical Oncology	<b>Street Address, City, State</b>  3201 Old Glenview Rd Ste 205, Wilmette, IL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor's review of the Laboratory Personnel Report (CMS 209), policies, procedures, records, and an interview with the laboratory director (LD); the laboratory failed to establish written policies and procedures that meet the personnel requirements in subpart M to assess employees performing testing in the specialty of Pathology, Clinical Cytogenetics, and the subspecialty of Endocrinology, affecting 4 out of 4 testing personnel (TP). Findings: 1. The CMS 209 report lists 4 TP (lines 2 thru 5) performing Histopathology, non-gynecological cytology, and Fluorescence In-Situ hybridization (FISH) testing and processing in the laboratory. 2. The personnel files revealed that 3 TP (lines 2 thru 4) are performing Prostrate Specific Antigen (PSA) testing in the laboratory. 3. The manual's personnel policies and competency procedure for histopathology, non- gynecological cytology, and FISH testing does not include the following required assessment processes when evaluating the competency of their TP: *). Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and *). Assessment of problem solving skills. 4. The competency procedure for PSA testing (under "Clinical Chemistry" in the competency procedure on page 7) does not include the following required assessment processes when evaluating the competency of their TP: *) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing; *). If applicable, review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records; *). Assessment of test performance through testing previously analyzed specimens, internal blind testing</p>

samples or external proficiency testing samples; and \*). Assessment of problem solving skills; 5. On a Simultaneous Validation survey conducted with the accrediting organization, CAP, on January 11, 2019 at 3:15 PM, the LD confirmed the above findings.