

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0707975	(X3) Date Survey Completed 09/16/2019
Name of Provider or Supplier Um Oral Pathology Biopsy Service	Street Address, City, State 1011 N University Avenue Room G018, Ann Arbor, MI	
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
D6103	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13)</p> <p>The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.</p> <p>This STANDARD is not met as evidenced by: . Based on lack of documentation of competency assessments and interview with the Laboratory Director (LD), the director failed to ensure that competency assessments were completed for Testing Personnel #2 (TP2) for 2 (September 2017 to September 2019) of 2 years as the grossing fill-in position during vacations. Findings include: 1. Review of the CMS-209 signed by the director on 09/16/2019 listed 2 TP performing the highly complex oral pathology grossing. 2. On 09/16/2019 at approximately 11:45 pm when requested, the laboratory was unable to provide the surveyor with competency assessments for TP2 for 2 years. 3. During the interview on 09/16/2019 at 12:00 pm, the LD confirmed no competency assessments were performed and documented for TP2. ***Repeat Deficiency from June 10, 2015 survey***</p>