

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D0674771	(X3) Date Survey Completed 05/20/2019
Name of Provider or Supplier Lucas County Regional Health District	Street Address, City, State 635 North Erie St, Toledo, OH	
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES 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 record review, and an interview with the Technical Consultant (TC), the laboratory failed to establish and follow a written policy and procedure to assess competency of the TC, as specified in the personnel requirements in subpart M. All patients tested at this laboratory have the potential to be affected. Findings Include: 1. Review of the laboratory's CMS-209 Personnel Report form, approved and signed by the Lab Director on 5/15/19, found 1 person serving as TC. 2. Review of the laboratory's Competency Assessment policy and procedure failed to find a policy and procedure for assessing the competency of the TC based on the regulatory responsibility of that role, at a frequency determined by the laboratory. 3. Review of the laboratory's Competency Assessment documentation, failed to find evidence that the TC was assessed for competency, based on the regulatory responsibility of that role, at a frequency determined by the laboratory. 4. An interview with the TC, on 5/20/19 at 1:20 pm, confirmed that the lab did not have a policy, procedure, or documentation for assessing the competency based on the regulatory responsibility of those roles, at a frequency determined by the laboratory.</p>
D6032	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently</p>

and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based upon a record review and an interview with the Technical Consultant (TC), the Laboratory Director (LD) failed to specify the duties and responsibilities of the TC listed on the CMS-209. All patients tested at this laboratory have the potential to be affected. Findings include: 1. Review of the CMS-209 form found 1 individual listed as performing duties of a TC. 2. Review of policies and procedures failed to find evidence that the duties and responsibilities of the TC were specified in writing by the laboratory director. 3. An interview with the TC, on 5/20/19 at 1:20 pm, confirmed that the LD failed to specify the duties and responsibilities of the TC in writing.