

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D0666777	(X3) Date Survey Completed 10/17/2019
Name of Provider or Supplier Delphos Family Physicians Inc	Street Address, City, State 1775 E Fifth St, Delphos, 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 Testing Personnel (TP) #1, the laboratory failed to establish and follow a written policy and procedure to assess competency of one out of one Technical Consultant (TC), based on the regulatory responsibility of that role, at a frequency determined by the lab, as specified in the personnel requirements in subpart M. All patients tested at this laboratory have the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's 'Form CMS-209 Personnel Report (CLIA)', approved and signed by the Laboratory Director on 10/7/19, found one individual serving as the TC. 2. Review of the laboratory's policies and procedures failed to find instructions for competency assessment of the TC, based on the regulatory responsibility of that role, at a frequency determined by the lab. 3. Review of the laboratory's competency assessment documentation failed to find evidence that the TC was being assessed for competency based on the regulatory responsibility of that role, at a frequency determined by the lab. However, on 9/19/19, the TC was assessed for competency based on the role of TP. 4. An interview with the TP #1, on 10/17/19 at 11:46 am, confirmed that TC did function in the role of a TP, and that the lab failed to establish and follow 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.</p>
D6107	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15)</p>

The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as 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 result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on record review and an interview with Testing Personnel (TP) #1, the Laboratory Director (LD) failed to specify the duties and responsibilities of one out of one Technical Consultant (TC) listed on the CMS-209, in writing. All patients tested at this lab have the potential to be affected by this deficient practice. Findings include: 1. Review of the laboratory's 'Form CMS-209 Personnel Report (CLIA) found one 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, with regulatory responsibilities delegated to that individual by the LD. 3. An interview with TP #1, on 10/17/19 at 2:53 pm, confirmed that the LD failed to specify the duties and responsibilities of the TC in writing, with regulatory responsibilities delegated to that individual by the LD.