

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  36D2183170	<b>(X3) Date Survey Completed</b>  09/09/2020
<b>Name of Provider or Supplier</b>  Procter & Gamble Mason Business	<b>Street Address, City, State</b>  8700 S Mason Montgomery Road, Mason, OH	
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>D6102</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(12)</p> <p>The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.</p> <p>This STANDARD is not met as evidenced by: Based on record review and an interview with the General Supervisor (GS) #1, the Laboratory Director failed to ensure prior to testing patients' specimens, Testing Personnel (TP) #1, TP#2 and TP#3 had received the appropriate training and had demonstrated that they could perform all testing operations reliably to provide and report accurate results for the high complexity procedures performed. All patients had the potential to be affected by this deficient practice. 1. Review of the laboratory's policy and procedure manuals titled "CLIA Required Personnel", provided on the date of the inspection, approved via signature and date by the Laboratory Director on 05/24 /2020, did not find any mention of initial training and competency assessment prior to patient testing. 2. The Surveyor requested the laboratory's TP initial training and competency assessment documentation prior to testing patients' specimens for TP#1, TP#2 and TP#3 from the GS#1. 3. The GS confirmed the laboratory did not document initial training and competency assessment for TP, and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 09 /09/2020 at 10:47 AM.</p>