

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D1002099	(X3) Date Survey Completed 01/18/2018
Name of Provider or Supplier Susan G Woods Md	Street Address, City, State 20 Ohltown Road, Youngstown, 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
D5473	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on record review and an interview with the Laboratory Administrative Consultant (LAC), the laboratory failed to document hematoxylin and eosin (H & E) QC procedures for the intended stain reactivity to ensure predictable staining characteristics each day of use. Findings Include: 1. Review of the laboratory's policies and procedures, provided on the date of the inspection, did not find any mention of the criteria of acceptability of the intended H & E stain reactivity. 2. Review of the laboratory's 2016, 2017 and 2018 quality control (QC) records, provided on the date of the inspection, found a column titled "Staining" with check marks indicated for each day of documented QC. The laboratory did not include any legend defining what the check mark indicated and did not include the intended staining characteristics of the H & E stains in any of their documentation. 3. The LAC confirmed the laboratory did not include established criteria for the intended stain reactivity of the H & E stain in their policies and procedures and did not document the actual observed H & E staining characteristics each day of patient testing. The interview occurred on 01/18/2018 at 1:24 PM.</p>