

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2125465	(X3) Date Survey Completed 06/04/2019
Name of Provider or Supplier Inform Diagnostics	Street Address, City, State 101 B Villa Drive Suite 108, Daphne, AL	
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 a lack of documentation for the on-site daily slide control quality, and interviews with the Assessment Supervisor and the Laboratory Director, the surveyor determined the Laboratory Director (also the Testing Personnel) failed to document his assessment of the slide stain quality each day of patient testing from December 2017 through May 2019. The findings include: 1. During the entrance interview and tour of the laboratory at approximately 12:15 PM on 6/4/2019, the Assessment Supervisor explained the primary function of the facility was to enter requisition information into the Winsurg computer system, and assign assessment numbers to all Histopathology specimens received at the other corporate locations. However, the Laboratory Director came to this location and performed on-site reading of slides approximately once a quarter beginning in December 2017. No slide processing or other testing was performed at this laboratory. 2. A review of the Histopathology records revealed the Laboratory Director had performed on-site reading of slides on 12/8/17, 3/16/18, 6/25/18, 9/25/18, 12/12/18, 3/13/19 and 5/22 /19, however there was no documentation of daily slide stain quality for these dates. 3. During an interview on 6/4/2019 at 1:55 PM, the surveyor requested the slide quality control (QC) documentation, and the Assessment Supervisor provided the slide QC performed by the off-site processing technicians. The surveyor then explained it was the responsibility of the testing personnel (i.e., the Director performing the reading) to assess and document the slide QC for this laboratory. 4. As the interview continued on</p>

6/4/2019 at 2:00 PM, the Assessment Supervisor telephoned the Laboratory Director who confirmed he had not documented on-site slide QC, and had not realized this was a CLIA requirement. Thus the above noted findings were confirmed. SURVEYOR ID# 32558 Licensure and Certification Surveyor