

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D2075892	(X3) Date Survey Completed 05/09/2018
Name of Provider or Supplier Benchmark Diagnostics, Llc	Street Address, City, State 6777 Engle Road, Suite M, Middleburg Heights, 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
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on record review and an interview with Laboratory Director, the laboratory failed to document each step in the testing and reporting of results and maintain all records for 2016 and 2017 Proficiency Testing (PT) samples. All patients tested at this lab have the potential to be affected. Findings Include: 1. Review of the laboratory's proficiency testing records found documents titled "2016 Fall Laboratory Proficiency Testing" and "2017 Spring Laboratory Proficiency Testing, " from The American Society of Dermatopathology. 2. The surveyor requested proficiency testing documentation including handling, preparation, processing, examination, attestation and review. The Laboratory Director confirmed, on 5/9/18 at 10:45 am, that no other proficiency testing documentation was available.</p>