

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 15D0897069	(X3) Date Survey Completed 04/17/2018
Name of Provider or Supplier Dplm At Iu Health - Cicc North Lab	Street Address, City, State 10212 Lantern Rd, Fishers, IN	
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
D5787	<p>TEST RECORDS CFR(s): 493.1283(a)</p> <p>The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, four of six patient test records reviewed had no documentation of the identity of the personnel who performed the tests. Findings include: 1. Review of patient testing records indicated P#1, P#2, P#5, and P#6, had no documentation of the identity of the personnel who performed the tests. 2. In interview on 4/17/18 at 2:00p.m., SP#1 confirmed there was no documentation identifying the testing personnel for P#1, P#2, P#5, and P#6 on the test records.</p>
D6021	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on record review and interview the laboratory director failed to ensure quality assessment programs were established and maintained to assure the quality of laboratory services provided for 2016 through 2018. Findings include: 1. Review of three of three available years of CAP (College of American Pathology) proficiency testing records indicated there was a zero score obtained for Event 3 of 2017. 2. Upon request for documentation of inclusion of this failure in the quality assessment program for staff review, SP#1 and SP#2 confirmed in interview, this was not available on 04/17/18 at 2:00 p.m. 3. Upon request on for a quality assessment policy /procedure on 4/17/18 at 2:00 p.m., SP#1 and SP#2 were unable to provide an established policy/procedure for quality assessment in the DPLM at IU Health-CICC-North Lab. 4. Upon request for documentation of quality assessment reviews or meetings on 4/17/18 at 2:00 p.m., SP#1 and SP#2 could not provide any documentation of quality assessment reviews or meetings for 2016 through 2018.