

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0863732	(X3) Date Survey Completed 02/27/2019
Name of Provider or Supplier Essex Hudson Urology Pc	Street Address, City, State 256 Broad St, Bloomfield, NJ	
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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on the lack of a Biannual Assessment (BA) records and interview with the Office Manager (OM), the laboratory failed to verify the accuracy of Histopathology and Cytology testing twice annually in the calendar years 2017 and 2018. The OM confirmed on 2/27/19 at 10:00 am the laboratory did not perform BA twice annually.</p>
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 surveyor review of the Accession Log (AL), Final Reports (FR) and interview with the Laboratory Director (LD) via telephone, the laboratory failed to maintain an accurate record system for Histopahtology tests on the date of survey. The finding includes: 1. The AL listed reference laboratory patient information which did not belong to the facility. 2. The LD confirmed on 2/21/19 at 10:00 am via telephone that the laboratory did not maintain an accurate record system.</p>