

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0721755	(X3) Date Survey Completed 12/04/2018
Name of Provider or Supplier Skippack Medical Lab, Llc	Street Address, City, State 200 Rittenhouse Circle East, Suite 9, Bristol, PA	
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
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the laboratory director (LD), the laboratory failed to retain patient test records from 2016 to 2018. Findings include: 1. On the day of survey, 12/04/2018, review of the patient test records revealed, the laboratory did not retain patient records from 11/17/2016 to 04/30/2018. 2. The current LD confirmed he could not provide patient test records from the last inspection (11/17/2016) to the date testing was concluded (04/30/2018) on 12/04/2018 around 11:30 am.</p>
D6091	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii)</p> <p>The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.</p> <p>This STANDARD is not met as evidenced by: Based on the review of American Association of Bioanalysts (AAB) proficiency testing records and interview with the laboratory director (LD), the laboratory director failed to identify problems that required a corrective action for Bacteriology results in 2018. Findings Include: 1. On the day of survey, 12/04/2018, review of Urine Culture AAB 2018 proficiency testing records for Event # 1, revealed that the laboratory</p>

scored 50% for bacteriology and did not perform a corrective action assessment for the failure. 2. The LD confirmed the finding above on 12/04/2018 around 9:30 am.