

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0190992	(X3) Date Survey Completed 09/13/2018
Name of Provider or Supplier Lvpg-Family Medicine-Southside	Street Address, City, State 1648 S 4th Street, Allentown, 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
D5791	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p> <p>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Quality Assurance Quarterly Checklist, Physicians Office Laboratory Quality Assurance Procedure, interview with the Laboratory Coordinator (LC) and Testing Personnel (TP) # 3, the laboratory failed to have follow their procedure for Quality Assurance, that assesses its Preanalytical, Analytical and Postanalytical system activities from 2017 (2 of 4 quarters) and 2018 (1 of 2 quarters). Findings include: 1. The Physicians Office Laboratory Quality Assurance Procedure: V. Guidelines: c. Assess the effectiveness of the labs policies and procedures: i. states "the lab Quality Assurance Quarterly Checklist is completed quarterly." 2. On the day of survey, 09/13/2018, review of Quality Assurance Quarterly Checklists revealed that the laboratory is not reviewing the Quality Assurance Quarterly Checklist on a quarterly bases. a. 2017 2nd quarter (April-June) has a review date of 5/15/2017 (1.5 months), which is less than a quarter (3 months) to be reviewed. b. 2017 4th quarter (Oct-Dec) has a review date of 10/16/2017 (0.5 months), which is less than a quarter (3 months) to be reviewed. c. 2018 2nd quarter (April-June) has a review date of 4/23 /2018 (1 month), which is less than a quarter (3 months) to be reviewed. 3. The LC and TP #3 confirmed the findings above on 09/13/2018 around 11:00 am.</p>