| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number

46D2086447 | (X3) Date Survey Completed

09/26/2018 |
|---|---|---|
| **Name of Provider or Supplier**

Physician Laboratory Services | **Street Address, City, State**

2051 E Red Hills Parkway, Suite 7, St George, UT | |

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
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236.

This STANDARD is not met as evidenced by:
Based on semi annual Toxicology test accuracy verification record review, lack of documentation, and interview with staff, the laboratory failed to establish a policy to assess and document corrective action taken for 5 of 5 drugs that failed twice annual accuracy checks. The laboratory performs approximately 6,000 urine drug screen annually. Findings include: 1. Toxicology test accuracy verification records include results from samples sent from a PT provider and the results for 8 drugs not included in the PT providers panel which are sent twice a year for comparison with a peer laboratory. 2. Toxicology results from peer laboratories on 06/11/2018 contained discrepant results for Zaleplon from peer laboratory #1 and for Methylone from peer laboratory #2. Toxicology results on 12/11/2017 from peer laboratory #2 contained discrepant results for Pregabalin and N-Desmethylzopiclone. Toxicology results in 06/2017 from peer laboratory #2 showed discrepant results for Gabapentin and concordant results for Gabapentin from laboratory #1. 3. The laboratory failed to document how discrepant results were resolved to ensure test accuracy. 4. In an interview on 09/24/2018 at approximately 5:00 p.m. staff stated they did not have a formal policy on how to resolve and document steps taken to resolve discrepant peer results. |