| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number<br><br>07D0893482 | (X3) Date Survey Completed<br><br>02/28/2019 |
|---|---|---|
| **Name of Provider or Supplier**<br><br>Fpim Of New Haven County Llc | **Street Address, City, State**<br><br>205 Main St, East Haven, CT | |
| 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 |
|---|---|
| **D6107** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(15)<br><br>The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and staff interview, the laboratory failed to specify in writing, the responsibilities and duties of each consultant and each supervisor for high complexity testing in the subspecialty of toxicology. Findings include: 1. Record review of the laboratory's personnel duties/responsibilities binder on 2/28/19 revealed the lab failed to provide evidence or documentation for the clinical consultant, technical and general supervisor duties/responsibilities for 2017 and 2018. 2. Staff interview with the laboratory director on 2/28/19 at 9:15 AM confirmed the above. 3. Approximately 17,200 toxicology tests are performed annually. |