

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D0722710	(X3) Date Survey Completed 05/11/2022
Name of Provider or Supplier Drs Levine, Reigle, Schneider And Davili, Inc	Street Address, City, State 6803 Mayfield Rd, #418, Mayfield, OH	
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
D6106	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14)</p> <p>The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.</p> <p>This STANDARD is not met as evidenced by: Based on record review and an interview with Testing Personnel (TP) #1, the Laboratory Director (LD) failed to ensure that an approved procedure manual was available to all personnel responsible for the urine microscopic procedures performed in the specialty of Chemistry. All 1544 patient urine microscopic procedures performed from 03/31/2021 to 05/11/2022 had the potential to be affected by this deficient practices. Findings Include: 1. Review of the laboratory's CMS-209 forms found 4 individuals credentialed by the LD, by signature and date, as TP to perform moderate complexity urine microscopic examination. 2. Review of the laboratory's CMS-116 form found the annual volume of urine microscopic examinations under the speciality of chemistry to be 5,115 total tests. 3. The Inspector requested the laboratory's approved urine microscopic policies and procedures on the date of inspection, 05/11/2022. 4. An interview with TP #1, on 05/11/2022 at 2:12 PM confirmed that the urine microscopic policy and procedure manual could not be found. Note: Past CLIA surveys in 2018 and 2020 found an approved urine microscopic policy and procedure manual that complied with the applicable CLIA regulations. 5. An interview with TP #1 via video phone call on 05/18/2022 at 1:36 PM confirmed that the urine microscopic policy and procedure manual was found; however, the manual was unapproved by the current LD, who took over that regulatory role as of 03/31/2021.</p>