

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D0674771	(X3) Date Survey Completed 07/20/2021
Name of Provider or Supplier Lucas County Regional Health District	Street Address, City, State 635 North Erie St, Toledo, 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
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interviews with the Technical Consultant (TC) and the Testing Personnel (TP), the laboratory failed to establish and verify performance specifications of the Chembio DDP HIV-Syphilis test system before reporting patient test results. This deficient practice had the potential to affect 10 patients, tested from 05/27/2021 through 06/29/21, in the sub-specialties of General Immunology and Syphilis Serology. Findings Include: 1. A virtual review of the laboratory's policies and procedures, on 07/14/2021, found the following statement: "Chembio DPP HIV - Syphilis Rapid Test Pilot Project. The Toledo Lucas County Health Department has been given an HIV-Syphilis Rapid Test Pilot Project. They are the first organization to do this testing in Ohio. We were given 20 free tests at no charge to the patient. We will decide later if we will coninue and buy the tests. This is non-waived testing." 2. A virtual review of the laboratory's policies and procedures, on 07/14/2021, found manufacturer's instructions for the Chembio DDP HIV-Syphilis test. 3. A virtual review of laboratory records, on 07/14/2021, found Quality Control (QC) performed for the Chembio DDP HIV-Syphilis test: "Chembio DDP HIV-Syphilis External Quality Control... Date HIV Syphilis 05/17/21 (-) (-) 05/17/21 (+) (+) 05/21/21 (+) (+)" 3. A virtual review of the laboratory's patient reports, on 07/14/2021, found the following 10 patients tested for HIV and Syphilis using the Chembio DDP HIV-</p>

Syphilis test: "Patient Date HIV Results Syphilis Results 1 5/27/21 NR NR 2 6/7/21 NR NR 3 6/9/21 NR NR 4 6/9/21 NR NR 5 6/11/21 NR R 6 6/18/21 NR NR 7 6/21/21 R R 8 6/22/21 NR NR 9 6/28/21 NR NR 10 6/29/21 NR R" (NOTE: Per manufacturer's instructions: "NR" is non-reactive; "R" is reactive.) 4. A virtual review of the laboratory's records, on 07/14/2021, failed to find evidence that the laboratory established and verified the performance specifications for the Chembio DDP HIV-Syphilis test prior to reporting patient results. 5. An video phone call interview with the TC and TP, on 07/20/2021 at 10:47 AM, confirmed that the laboratory failed to establish and verify performance specifications for the Chembio DDP HIV-Syphilis test prior to reporting patient results.