

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 51D0707433	(X3) Date Survey Completed 02/22/2022
Name of Provider or Supplier Wvu Medicine Thomas Hosp Ob & Gyn Ii	Street Address, City, State 4607 Maccorkle Avenue Sw Suite 301, South Charleston, WV	
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
D0000	An announced, on site, routine recertification survey was conducted at Bassam N Shamma MD PLLC on February 22, 2022, by the West Virginia Office of Laboratory Services. The laboratory was surveyed to assess compliance with the Federal Clinical Laboratory Improvement Amendment (CLIA) regulations under 42 CFR 493. Specific deficiencies are explained below.
D2025	<p>BACTERIOLOGY CFR(s): 493.823(c)</p> <p>Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to submit the results of American Proficiency Institute (API) Microbiology 2020 2nd proficiency testing (PT) event before the deadline. Findings: 1. Review of API records identified an unsatisfactory score of 0% (Failure to Participate) for the analyte #0005 Bacteriology. 2. An interview with testing personnel (TP1), on 2/22/2022 at approximately 10:20 AM, confirmed the results for API 2020 2nd PT event were not submitted before the deadline.</p>
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p>

This STANDARD is not met as evidenced by:
Based on record review, lack of documentation, and interview the laboratory failed to document the evaluation of unsatisfactory and unacceptable scores for one of three American Proficiency Institute (API) proficiency testing (PT) events in 2020 and one of three events in 2021. Findings: 1. Review of API records identified the following scores in Bacteriology: 2nd event 2020= 0% (failure to participate) 3rd event 2021= 80% (unacceptable response for specimen VP-15) 2. No documentation of an investigation or corrective action could be located. 3. An interview with the testing personnel (TP1), on 2/22/2022 at approximately 10:30 AM, confirmed the findings.

D5445

CONTROL PROCEDURES
CFR(s): 493.1256(d)(1)(2)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--
(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on review of written policies and procedures (P&P), record review, lack of documentation, and interview the laboratory failed to perform external quality control (d)(2) at the intervals specified by the Individualized Quality Control Plan (IQCP) for the BD Affirm VP III test system for 12 of 24 months reviewed in 2020 and 2021. Findings: 1. Review of P&P identified an IQCP for the BD Affirm VP III test system that states external QC is to be performed with every new lot or shipment and every 30 days. 2. Review of quality control (QC) records for the BD Affirm VP III test system revealed no external QC documented for all 12 months of 2021. 3. An interview with testing personnel (TP1), on 2/22/2022 at approximately 11:00 AM, confirmed that no external QC was performed from January 2021 until date of survey.