Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 19D0988844	**(X3) Date Survey Completed** 02/14/2025
Name of Provider or Supplier Arunavathi Sangisetty, Md, Apmc	**Street Address, City, State** 1281 West Tunnel Boulevard, Houma, LA	
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	A Validation survey was performed on February 14, 2025 at Arunavathi Sangisetty, MD, APMC, CLIA ID #19D0988844. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) (d) 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. (d)(3) At least once each day patient specimens are assayed or examined perform the following for: This STANDARD is not met as evidenced by: I. Based on observation; review of the laboratory's policies, quality control records, and patient test records; as well as interview with personnel, the laboratory failed to perform quality control (QC) every thirty (30) days as required by the laboratory on the BD Max analyzer for bacteriology and parasitology testing for two (2) of thirteen (13) months reviewed. Findings: 1. Observation by surveyor during the laboratory tour on February 14, 2025 at 8:45 a.m. revealed the laboratory utilized the BD Max analyzer for Chlamydia trachomatis, Trichomonas vaginalis, and Neisseria gonorrhea testing. 2. Review of the laboratory's Individualized Quality Control Plan (IQCP) for the testing identified above revealed the laboratory must perform quality control every thirty (30) days. 3. Review of the laboratory's quality control records from January 2024 through January 2025 revealed the laboratory did not perform quality control

	every thirty (30) days as follows: a) QC performed 03/26/2024 and 04/29/2024 (four (4) days overdue) b) QC performed 11/22/2024 and 01/09/2025 (eighteen (18) days overdue) 4. Review of patient test records revealed the following patients were tested and reported without QC performed: a) Patient date of birth 5/1/2007 tested 4/25/2024 b) Patient date of birth 4/16/2010 tested 4/25/2024 c) Patient date of birth 9/4/20025 tested 4/26/2024 d) Patient date of birth 2/17/2007 tested 4/26/2024 e) Patient date of birth 3/27/2006 tested 4/26/2024 f) Patient date of birth 1/16/2006 tested 4/26/2024 g) Patient date of birth 6/6/2005 tested 12/27/2024 h) Patient date of birth 11/3/2011 tested 12/27/2024 i) Patient date of birth 12/16/2004 tested 12/27/2024 j) Patient date of birth 9/24/2007 tested 12/27/2024 k) Patient date of birth 12/20/2005 tested 12/27 /2024 l) Patient date of birth 11/4/2004 tested 12/27/2024 m) Patient date of birth 12/3 /2007 tested 12/27/2024 n) Patient date of birth 11/29/2010 tested 12/27/2024 5. In interview on February 14, 2025 at 11:48 a.m., the Technical Consultant confirmed patient testing was performed without QC as identified above. II. Based on review of the laboratory's Individualized Quality Control Plan (IQCP) records and interview with personnel, the laboratory failed to have a complete IQCP to support the reduction in frequency of quality control (QC) for bacteriology and parasitology testing. Findings: 1. Review of the laboratory's IQCP for Chlamydia trachomatis, Trichomonas vaginalis, and Neisseria gonorrhea testing on the BD Max revealed the IQCP did not include a Quality Assessment Plan (QAP). 2. In interview on February 14, 2025 at 10:33 a.m., the Technical Consultant confirmed the laboratory's IQCP did not include a Quality Assessment Plan as identified above.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory failed to establish complete procedures to monitor, assess, and correct problems identified with the analytic system. Findings: 1. Review of the laboratory's policies and procedures revealed the laboratory had a quality assessment process in place; however, the following deficient practice was not identified: a) The laboratory failed to perform quality control (QC) every thirty (30) days as required by the laboratory's IQCP on the BD Max analyzer for bacteriology and parasitology testing for two (2) of thirteen (13) months reviewed. Refer to D5445 I.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure that a quality control and quality assessment program was maintained to assure the quality of laboratory testing. Findings: 1. The laboratory

	failed to perform quality control (QC) every thirty (30) days as required by the laboratory's policy on the BD Max analyzer for bacteriology and parasitology testing for two (2) of thirteen (13) months reviewed. Refer to D5445 I. 2. The laboratory failed to have a complete IQCP to support the reduction in frequency of quality control (QC) for bacteriology and parasitology testing. Refer to D5445 II. 3. The laboratory failed to establish complete procedures to monitor, assess, and correct problems identified with the analytic system. Refer to D5791.
D6051	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(v) (b)(8)(v) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and This STANDARD is not met as evidenced by: Based on review of the CMS-209 (Laboratory Personnel Report) form and personnel records as well as interview with laboratory personnel, the Technical Consultant failed to ensure all testing personnel were assessed through testing previously analyzed specimens, internal blind samples, or external proficiency samples for one (1) of two (2) testing personnel reviewed. Findings: 1. Review of the laboratory's CMS-209 form revealed the following testing personnel: a) Testing Personnel 1 b) Testing Personnel 2 2. Review of the laboratory's 2023 and 2024 competency records for Testing Personnel 1 revealed annual competency assessments were performed, but the laboratory failed to provide documentation to support the performance of blind sample testing. 3. In interview on February 14, 2025 at 9:48 a.m., the Technical Consultant confirmed Testing Personnel 1 was not assessed for blind sample testing as identified above.