

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D1012674	(X3) Date Survey Completed 08/25/2026
Name of Provider or Supplier Anthony Martin Mills, Md	Street Address, City, State 9201 Sunset Blvd Ste 812, West Hollywood, CA	
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 onsite validation survey was conducted on 08/25/26. Standard-level deficiencies were cited.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) (a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral. This STANDARD is not met as evidenced by: Based on direct observation, a review of the laboratory's written procedures, a patient requisition, and interview with the clinical consultant, the laboratory failed to document the specimen acceptability for three of three Chlamydia trachomatis (CT) /Neisseria gonorrhoeae (NG) specimens and one of one Rapid Plasma Reagin (RPR) specimen. Findings included: 1. On 08/25/26 at 11:55 am, the clinical consultant confirmed the following: a. The laboratory performed Chlamydia trachomatis (CT) /Neisseria gonorrhoeae (NG) testing on the Hologic Panther. b. The laboratory performed Rapid Plasma Reagin (RPR) testing on the ASI Evolution. c. The laboratory accepted outside specimens from three different clinics. 2. A review of the laboratory's written procedures revealed the following: a. CT/NG testing - "Swab Specimens" stated, "a. After collection, transport and store the swab in the specimen transport tube at 2C to 30C until tested." (C = Celsius) b. RPR testing - "Specimen stability" stated, Temperature "20~25 C" Stability "3 days". 3. Direct observation on 08/25/26 at 12:10 pm of specimens arriving in the laboratory in a soft-sided cooler with ice packs revealed the laboratory did not have a mechanism to ensure specimen integrity during transportation of three CT/NG specimens and one RPR specimen for

	the following patient: a. Patient requisition 000375689 collected on 08/24/26 and received into the laboratory on 08/25/26. 4. In an interview on 08/25/26 at 12:25 pm with the clinical consultant, the clinical consultant confirmed the laboratory failed to document specimen acceptability as indicated above. 5. The laboratory performs approximately 63,398 CT/NG tests annually and approximately 19,680 RPR tests annually.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on a review of the laboratory's written procedure, hematology quality control (QC) records, and interview with the clinical consultant, the laboratory failed to follow its own written procedure for implementing a new lot of hematology QC material for one of one lot. Findings included: 1. On 08/25/26 at 09:30 am, the clinical consultant confirmed the following: a. The laboratory performed complete blood count (CBC) testing on the Sysmex XN-430. b. The laboratory performed QC each day of patient testing using three levels of Sysmex XN-L Check hematology controls. 2. A review of the laboratory's written procedure titled "Sysmex XN-430" section "New QC lot crossover or parallel studies" stated, " ...Parallel test new controls by analyzing the 3 levels of control, a minimum of once a day for 5 days prior to expiration of previous lot." 3. A review of the Sysmex XN-L Check hematology controls for Lot# 62071401 Expiration (Exp) date 11/03/26 (Level 1), Lot# 62071402 (Level 2) Exp date 11/03/26, and Lot# 62071403 (Level 3) Exp date 11/03/26, put into use for patient acceptability on 07/31/26, revealed no evidence of analyzing the 3 levels of control, a minimum of once a day for 5 days. 4. In an interview on 08/25/26 at 11:10 am with the clinical consultant, the clinical consultant confirmed the above findings. 5. The laboratory performs approximately 27,337 hematology tests annually.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) (d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on a review of the laboratory's written procedure and interview with the clinical consultant, the laboratory director failed to approve, sign, and date a procedure before patient testing for one of one procedure. Findings included: 1. On 08/25/26 at 11:25 am, the clinical consultant confirmed the following: a. The laboratory performed Rapid Plasma Reagin (RPR) testing on the ASI Evolution. b. The first day of patient testing was 02/02/26. 2. A review of the laboratory's written procedure titled "Rapid Plasma Reagin (RPR) Test for Syphilis on ASI Evolution" revealed the laboratory director approved, signed, and dated the written procedure on 03/20/26 (after the first day of patient testing). 3. In an interview on 08/25/26 at 11:40 am with the clinical consultant, the clinical consultant confirmed the laboratory director failed to approve,

	sign, and date the RPR testing procedure before the first day of patient testing. 4. The laboratory performs approximately 19,680 RPR tests annually.
D5807	TEST REPORT CFR(s): 493.1291(d) (d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on a review of the laboratory's chemistry performance specification records, a final patient report, and interview with the clinical consultant, the laboratory failed to provide accurate reference intervals for one of one patient report. Findings included: 1. On 08/25/26 at 11:50 am, the clinical consultant confirmed the laboratory performed chemistry testing on the Abbott Alinity and was approved for patient testing on 09/23/25. 2. A review of the laboratory's Abbott Alinity performance specification records revealed the following: a. Alkaline Phosphatase normal reference range (40 -150) U/L b. Calcium, serum normal reference range (8.8 - 10.2) mg/dL c. Carbon Dioxide normal reference range (23 - 31) mEq/L d. Glucose normal reference range (82 -115) mg/dL e. Total Bilirubin normal reference range (0.0 - 0.5) mg/dL 3. A review of one patient's final report (Patient 260824024; Collected 08/24/26; Received into the laboratory on 08/24/26; and Reported on 08/25/26) revealed the following normal reference ranges for the following: a. Alkaline Phosphatase normal reference range (40 -120) U/L b. Calcium, serum normal reference range (8.5 - 10.3) mg/dL c. Carbon Dioxide normal reference range (21 - 30) mEq/L d. Glucose normal reference range (67 - 99) mg/dL e. Total Bilirubin normal reference range (0.2 - 1.2) mg/dL 4. In an interview on 08/25/26 at 02:10 pm with the clinical consultant, the clinical consultant confirmed the laboratory's approved reference ranges did not match the patient's final report as indicated above. 5. The laboratory performs approximately 247,516 chemistry tests annually.