Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0660409	01/17/2020
Name of Provider or Supplier	**Street Address, City, State**	
San Antonio Metropolitan Hlth Dist Lab	2303 Se Military Drive, Bldg 533, San Antonio, TX	

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	The laboratory was found out of compliance with the CLIA regulations. The condition not met was: 493.1250 D5400 Condition: Analytic systems Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility representatives were given an opportunity to provide evidence of compliance with noted deficiencies and no such evidence was provided prior to survey exit. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on a review of the laboratory's submitted CMS 209 form, a review of the laboratory's policies, a review of personnel records, and staff interview, it was revealed the laboratory failed to have documentation of a policy to assess competency, based on the position responsibilities, of the technical supervisor. Findings include: 1. A review of the laboratory's submitted CMS 209 form (signed by the laboratory director on 12/9/19) revealed the laboratory identified 1 technical supervisor. 2. A review of the laboratory's policy titled "QA Plan" revealed the laboratory's policy did not contain instructions for performing competency assessments on the technical supervisor. 3. A review of the laboratory's personnel

	records revealed there were 2 competency assessments performed on the technical supervisor for the following dates: 12/4/18 12/6/19 Further review of the competency assessments revealed the assessor was the general supervisor for both dates. The general supervisor does not qualify to perform competency assessments on the technical supervisor. 3. An interview with the general supervisor (as indicated on the CMS 209 form) on 1/13/20 at 10:30 a.m. in the conference room, after review of the records, confirmed the above findings.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based a on review of the manufacturer's instructions for the Quidel AmpliVue HSV 1+2 Assay, a review of patient test records, and staff interview, it was revealed the laboratory failed to follow the manufacturer's instructions for testing patient samples within 5 days of collection. Findings include: 1. A review of the manufacturer's instructions for the Quidel AmpliVue HSV 1+2 Assay (PIM210002EN00 10/16) revealed the following: "Storage, Handling and Stability HSV Specimens: Swabs collected from lesions can be stored in the viral transport medium at 2C - 8C for up to 5 days before being tested." 2. A random review of patient test records from October 2019 identified the following patients whose samples were documented as being received in the laboratory and tested more than 5 days after collection: Patient #2059233 Collection date: 10/03/2019 Received in Lab: 10/24/2019 Date Reported: 10 /28/2019 Patient #2024064 Collection date: 10/09/2019 Received in Lab: 10/24/2019 Date Reported: 10/28/2019 Patient #2766760 Collection date: 10/10/2019 Received in Lab: 10/24/2019 Date Reported: 10/28/2019 3. An interview with the technical supervisor (as indicated on the CMS 209 form, signed by the laboratory director on 12 /9/19) on 1/16/20 at 11:50 a.m. in the office, after review of the records, confirmed the above findings. Key: HSV = Herpes Simplex Virus
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on a review of manufacturer's instructions, review of laboratory records, and staff interview, it was revealed the laboratory failed to identify issues with analytic systems. Findings include: 1. The laboratory failed to have documentation of

	performing complete studies for the modification of a FDA-approved test (refer to D5423).
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on a review of the laboratory's test menu, a review of a letter from Bio-Rad, a review of the laboratory's establishment studies performed on the Bio-Rad Evolis analyzer and staff interview, it was revealed the laboratory failed to have documentation of performing complete studies for the modification of a FDA-approved test. Findings include: 1. A review of the laboratory's test menu revealed the following assays were run on the Bio-Rad Evolis analyzer: Antibody to Hepatitis C Virus Assay (Ortho HCV 3.0 ELISA Test) Antibody to Hepatitis B Surface Antigen Assay (GS HBsAG EIA 3.0) Antibody to Hepatitis B Surface Antigen Confirmatory Assay (GS HBsAG Confirmatory Assay 3.0) 2. A review of a letter from Bio-Rad dated 1/15/20, stated the following: "Reference: GS HBsAg 3.0 EIA Kit (catalog number: 32591) GS HBsAg 3.0 Confirmatory Kit (Catalog number: 32594) Ortho HCV v3.0 EIA Kit (Catalog number: 930740) This letter is to provide you with requested documentation on FDA licensing of the above-referenced EIA test kits with catalog numbers 32591, 32594, and 930740. These EIA test kits are FDA licensed for blood donor testing, and the intended use specifies that they may be used with the Ortho Summit System or tested manually for the screening of blood donors. However, should a laboratory choose to perform testing on the EVOLIS System, they may choose to validate an assay with the EVOLIS System following and instituting their specific laboratory and regulating agency protocols." 3. A review of the laboratory's establishment studies performed on the Bio-Rad Evolis analyzer in October 2018 revealed the laboratory failed to have documentation of the following studies for each of the modified FDA-approved tests listed above: a) analytical sensitivity b) analytical specificity to include interfering substances c) any other performance characteristic required for test performance, including pre-analytic studies for sample stability, sample storage, and sample transport. d) accuracy and precision for the Antibody to Hepatitis B Surface Antigen Confirmatory Assay 4. An interview with the general supervisor (as indicated on the CMS 209 form, signed by the laboratory director on 12 /9/19) on 1/16/20 at 10:05 a.m. in the office, after review of the records, confirmed the above findings.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to

	determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: Based on a review of the laboratory's verification studies for the Bio-Rad Evolis analyzer performed in October 2018, and staff interview, it was revealed the laboratory director failed to approve the verification studies prior to performing patient testing. Findings include: 1. A review of the verification studies for the Bio-Rad Evolis analyzer revealed the laboratory director failed to approve the studies prior to the laboratory performing patient testing. 2. The following assays are run on the Bio-Rad Evolis analyzer: Antibody to Hepatitis C Virus Assay (Ortho HCV 3.0 ELISA Test) Antibody to Hepatitis B Surface Antigen Assay (GS HBsAG EIA 3.0) Antibody to Hepatitis B Surface Antigen Confirmatory Assay (GS HBsAG Confirmatory Assay 3.0) The laboratory started testing patients on the Bio-Rad Evolis analyzer in 01/2019. 3. The laboratory was asked to provide documentation of the laboratory director approving the verification studies. No documentation was provided. 4. An interview with the general supervisor (as indicated on the CMS 209 form, signed by the laboratory director on 12/9/19) on 1/16/20 at 10:05 a.m. in the office, after review of the records, confirmed the above findings.