

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2212719	(X3) Date Survey Completed 03/22/2022
Name of Provider or Supplier Primescope Diagnostics, Llc	Street Address, City, State 4427 Highway 6 Suite C, Sugar Land, 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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. 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.
D5445	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the Luminex Aries SARS-CoV-2 Assay Package Insert, the laboratory's records, and staff interview, it was revealed that the laboratory failed to have documentation of establishing an IQCP (Individualized Quality Control Plan) for the two Luminex Aries Systems to support the modification in quality control testing</p>

for one of one analyte tested. Findings include: 1. A review of the Luminex Aries SARS-CoV-2 Assay Package Insert (89-30000-00-865 Rev D, 10/2020) revealed the following: "External negative and positive controls should be used in accordance with local, state, and federal accrediting organizations, as applicable." 2. A review of the laboratory's records revealed the facility started using the two Luminex Aries Systems (Serial numbers: M12V121062001 and M12V121060001) in March 2021 for testing SARS-CoV-2. 3. A review of the laboratory's Luminex Aries System External Control Log Sheets revealed the laboratory ran 2 levels of control material (AccuPlex SARS-CoV-2, positive and negative controls), on each analyzer, with every new kit of testing reagents. A random review of the External Control Log Sheets from June 2021 to October 2021 revealed the following 9 days when quality control was run: 6/10/21 6/23/21 (elapsed time between QC runs = 13 days) 7/8/21 (elapsed time between QC runs = 15 days) 8/17/21 (elapsed time between QC runs = 40 days) 8/26/21 (elapsed time between QC runs = 9 days) 9/4/21 (elapsed time between QC runs = 9 days) 9/22/21 (elapsed time between QC runs = 18 days) 9/29/21 (elapsed time between QC runs = 7 days) 10/6/21 (elapsed time between QC runs = 7 days) 4. Further review of the laboratory's records revealed the laboratory failed to have documentation of an IQCP for the Luminex Aries Systems to support the modification in quality control testing. 5. A random review of the laboratory's patient test records from June 2021 to October 2021 revealed the following 6 patient's test samples were run on days when 2 levels of quality control material were not tested on the Luminex Aries System analyzers: Patient: CV21-3178 Reported: 7/22/21 Patient: CV21-3180 Reported: 7/22/21 Patient: CV21-5602 Reported: 9/8/21 Patient: CV21-5629 Reported: 9/8/21 Patient: CV21-8844 Reported: 10/15/21 Patient: CV21-8966 Reported: 10/15/21 6. An interview with the laboratory director on 3/22/22 at 1:40 p.m. in the office, after review of the records, confirmed the above findings.