Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0907678	05/28/2021
Name of Provider or Supplier	**Street Address, City, State**	
Medical Specialists Of The Palm Beaches Inc	5401 S Congress Ave Ste 105d, Atlantis, FL	

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 recertification survey was conducted on 05/26/21 to 05/28/21 at Medical Specialists of the Palm Beaches. The laboratory was not in compliance with 42 CFR 493, Requirements for Clinical Laboratories. Based on the survey findings, an Immediate Jeopardy situation was identified, and the laboratory was notified at 2:00 PM on 05/28/2021. The laboratory failed to follow manufacturers' instructions for specimen storage (See D5300) and failed to validate a non-FDA approved COVID-19 test kit prior to patient testing (See D5400). The following Condition was not met: D5300- Preanalytic Systems-493.1240 D5400-Analytic Systems-493.1250
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on lack of records and interview the laboratory failed to maintain temperature records and microbiology quality control documentation for 1 (2020) out of 2 years (2020-2021) reviewed. Findings Included: Review of temperature logs for the lab revealed that there were no records from 2020. Review of Microbiology quality control logs revealed that there were no records from 2020. Interview on 05/26/21 at 4: 00 PM the Laboratory Director confirmed that the temperatures and Microbiology quality control were documented, however the logs could not be located.
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 record review and interview with the Laboratory Director the laboratory failed to have competency evaluations for the Clinical Consultant for 2 (2019-2021) out of 2 years reviewed. Findings Included: Review of employee competencies revealed no competencies performed on the Clinical Consultant. Interview on 05/27 /21 at 1:11 PM the Laboratory Director confirmed that there were no competency evaluations performed on the Clinical Consultant.
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, 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 preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on record review and interview with the Laboratory Director the laboratory failed to follow manufacturer's instructions (MI) for specimen storage on the Lugene COVID-19 IgG/IgM Rapid test cassette kit (unvalidated) since testing began June 2, 2020 (See D5311).
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 on record review and interview with the Laboratory Director the laboratory failed to follow manufacturer's instructions (MI) for specimen storage on the Lugene COVID-19 IgG/IgM Rapid test cassette kit (unvalidated) since testing began June 2, 2020. The findings included: Review of Lugene COVID-19 IgG/IgM Rapid test cassette kit MI the specimen should be tested immediately or stored at 2-8 degrees Celsius for 3 days maximum and if longer than 3 days the stored at -20 degrees Celsius. Review of 10 random Patient test reports revealed the following: Patient #1--tested 03/25/21 was drawn at 12:50 PM and ran at 4:48 PM (3 hours and 58 minutes) Patient #2--tested 03/25/21 was drawn at 2:26 PM and ran at 5:23 PM (2 hours 57 minutes) Patient #3--tested 04/23/21 was drawn at 12:27 PM and ran at 1:28 PM (1 hour and 1 minutes) Patient #4--tested 04/26/21 was drawn at 1:15 PM and ran at 4:05 PM (2 hours and 50 minutes) Patient #5--tested 05/19/21 was drawn at 12:32 PM and ran at 1:07 PM (35 minutes) Patient #6--tested 03/25/21 was drawn at 2:45 PM and

	ran at 5:02 PM (2 hours and 17 minutes) Patient #7--tested 03/25/21 was drawn at 2: 53 PM and ran at 5:01 PM (2 hours and 8 minutes) Patient #8--tested 05/10/21 was drawn at 10:43 AM and ran 3:10 PM (4 hours and 27 minutes) Patient #9--tested 05/11 /21 was drawn at 1:03 PM and ran 3:10 PM (2 hours and 7 minutes) Patient #10-- tested 05/11/21 was drawn at 1:03 PM and ran at 3:11 PM (2 hours and 8 minutes) Interview on 05/27/21 at 12:55 PM the Laboratory Director revealed that after the specimens are placed in a rack on the counter after drawn and ran when the tech or the phlebotomists have time to run them, confirming that the tests are not ran immediately.
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 record review and interview with the Laboratory Director the laboratory failed to validate the Lugene COVID-19 IgG/IgM Rapid test cassette kit since starting testing on 06/02/2020. There were 2,238 patients tested. (See 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 record review and interview with the Laboratory Director the laboratory failed to validate the Lugene COVID-19 IgG/IgM Rapid test cassette kit since starting testing on 06/02/2020. There were 2,238 patients tested. The findings included: Review of the Manufacturer's Instructions for the Lugene COVID-19 IgG/IgM Rapid test cassette kit revealed that the test is not FDA approved. Review of the FDA website revealed that there is no EUA for this antibody test kit. This would make the Lugene COVID-19 IgG/IgM Rapid test cassette kit a Laboratory Developed Test and would need a validation. There was no validation of this test kit. Interview on 05/26 /21 at 5:00 PM the Laboratory Director confirmed that the test kit had not been validated and that all testing would stop on 05/26/21.

D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on observation, record review, and interview the laboratory failed to calibrate 1 out of 1 timer and failed to have incubator temperatures that were within the acceptable range on 47 out of 100 days in 2021. Findings Included: Observations taken during the tour of the laboratory on 05/26/21 at 11:22 PM revealed a timer with a sticker on the back that said the next calibration was due 07/27/07. Review of preventative maintenance revealed no calibrations for the timer. Interview on 05/26 /21 at 1:39 PM the Laboratory Director confirmed that no calibrations had been performed on the timer. Review of the manufacturer's instructions for the TSA 5% Sheep Blood/ MacConkey Agar Biplate (used for urine cultures) revealed that the incubation temperature soul be 33-37 degrees Celsius. Review of the temperature logs revealed that the temperature was not acceptable on 01/07/21 (38), 02/17/21 (38), 02 /24/21 (38), 03/04/21 (38), 03/05/21 (38), 03/08/21 (38), 03/09/21 (38), 03/10/21 (38), 03/11/21 (38), 03/12/21 (38), 03/22/21 (38), 03/23/21 (38), 03/24/21 (38), 03/26/21 (38), 03/29/21 (38), 03/30/21 (38), 03/31/21 (38), 04/01/21 (38), 04/02/21 (38), 04/05 /21 (39), 04/06/21 (38), 04/09/21 (38), 04/12/21 (38), 04/13/21 (38), 04/14/21 (38), 04 /19/21 (38), 04/20/21 (38), 04/21/21 (38), 04/26/21 (38), 04/27/21 (38), 04/28/21 (38), 04/29/21 (38), 05/03/21 (39), 05/04/21 (38), 05/05/21 (38), 05/06/21 (39), 05/07/21 (38), 05/10/21 (39), 05/12/21 (38), 05/13/21 (38), 05/14/21 (38), 05/19/21 (38), 05/20 /21 (38), 05/21/21 (38), 05/24/21 (38), 05/25/21 (38), and 05/26/21 (38). Interview on 05/27/21 at 2:30 PM the Laboratory Director confirmed that the temperature range on the incubator was not acceptable and that there was no corrective action on the days.