Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2218756	05/09/2022
Name of Provider or Supplier	**Street Address, City, State**	
Recon Diagnostics, Inc	3810 Medical Parkway, Ste 253, Austin, 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	An initial survey was performed and the laboratory was found out of compliance with the CLIA regulations. The condition not met was: D5300 - 42 C.F.R. 493.1240 Condition: Preanalytic systems.
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 review of the laboratory's policies and procedures, observation, review of laboratory records, interview, and pre-survey paperwork, the laboratory failed to monitor and evaluate the overall quality of the preanalyitic systems and correct identified problems for its laboratory developed test (LDT) Recon COVID-19 test for SARS-CoV-2 (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 review of the laboratory's policies and procedures, observation, review of laboratory records, interview, and pre-survey paperwork, the laboratory failed to follow their own procedure for specimen transport for its laboratory developed test (LDT) Recon COVID-19 test for SARS-CoV-2 for 411 out of 703 specimens collected between 09/21/2021 - 3/29/2022. Findings follow. A. Review of the laboratory's policy and procedure titled COVID-19 test with dry anterior nares swabs: individual and pooled, approved Sept 18, 2021, under Sample Transport stated, "If the time between sample collection and processing is likely to exceed 24 hours, samples can be stored at 2 to 8 degrees Celsius for up to 72 hours, -20 degrees Celsius for 2 to 4 weeks, or -80 degrees Celsius for long term storage, then later thawed on ice or cold block for testing." B. Surveyor observed specimens received in the laboratory on 05/05 /2022 at 1000 (for surveillance testing to reflex to CLIA for positive pools) received 48 specimens without cold packs. C. Review of the file titled JCMA Timing Data, dated 05/06/2022, showed a compilation of all surveillance testing reflexed to CLIA (positive pools) performed with columns for each specimen ID, date and time of specimen collection, and date and time of accessioning when received in the laboratory. The first 703 specimens were reviewed and those exceeding 24 hours are listed below: (listed times are approximate and the elapsed time listed are the more conservative) specimen IDs collection accessioning elapsed time lines 2-36 01/24 /2022 6:52 PM 01/25/2022 8:56 PM 1 day, 2 hours, 4 minutes lines 77-90 09/21/2021 4:04 PM 09/22/2021 4:49 PM 1 day, 45 minutes lines 91-113 01/25/2022 6:10 PM 01 /26/2022 9:44 PM 1 day, 3 hours, 34 minutes lines 147-154 02/02/2022 2:50 PM 02/07 /2022 8:22 PM 5 days, 5 hours, 32 minutes lines 155-165 03/29/2022 1:36 PM 03/30 /2022 2:41 PM 1 day, 1 hour, 5 minutes lines 248-269 01/27/2022 6:23 PM 01/28 /2022 9:43 PM 1 day, 3 hours, 20 minutes lines 270-289 01/20/2022 6:07 PM 01/22 /2022 1:28 AM 1 day, 7 hours, 21 minutes lines 290-303 12/22/2021 2:33 PM 12/23 /2021 6:19 PM 1 day, 3 hours, 46 minutes lines 340-361 01/24/2022 6:09 PM 01/25 /2022 9:13 PM 1 day, 3 hours, 4 minutes lines 468-496 01/10/2022 8:17 PM 01/12 /2022 7:45 PM 1 day, 23 hours, 28 minutes lines 497-504 04/05/2022 1:39 PM 04/06 /2022 5:00 PM 1 day, 3 hours, 21 minutes lines 505-514 02/08/2022 4:36 PM 02/09 /2022 8:00 PM 1 day, 3 hours, 24 minutes lines 515-524 02/08/2022 4:34 PM 02/09 /2022 6:56 PM 1 day, 2 hours, 22 minutes lines 525-534 02/08/2022 4:21 PM 02/09 /2022 8:08 PM 1 day, 3 hours, 47 minutes lines 535-544 02/08/2022 4:32 PM 02/09 /2022 7:55 PM 1 day, 3 hours, 23 minutes lines 545-554 02/08/2022 3:46 PM 02/09 /2022 8:16 PM 1 day, 4 hours, 30 minutes lines 555-564 02/08/2022 4:22 PM 02/09 /2022 6:56 PM 1 day, 2 hours, 34 minutes lines 565-584 02/08/2022 3:46 PM 02/09 /2022 8:06 PM 1 day, 4 hours, 20 minutes lines 585-594 02/08/2022 3:39 PM 02/09 /2022 5:04 PM 1 day, 1 hour, 25 minutes lines 595-604 02/08/2022 6:09 PM 02/09 /2022 7:36 PM 1 day, 1 hour, 27 minutes lines 605-614 02/08/2022 5:31 PM 02/09 /2022 7:57 PM 1 day, 2 hours, 26 minutes lines 615-624 02/08/2022 6:04 PM 02/09 /2022 7:23 PM 1 day, 1 hour, 19 minutes lines 625-634 02/08/2022 5:26 PM 02/09 /2022 8:02 PM 1 day, 2 hours, 36 minutes lines 635-644 02/08/2022 6:02 PM 02/09 /2022 7:35 PM 1 day, 1 hour, 33 minutes lines 645-654 02/08/2022 5:13 PM 02/09 /2022 8:10 PM 1 day, 2 hours, 57 minutes lines 655-664 02/08/2022 5:56 PM 02/09 /2022 6:53 PM 1 day, 57 minutes lines 665-674 02/08/2022 5:32 PM 02/09/2022 8:03 PM 1 day, 2 hours, 31 minutes lines 675-684 02/08/2022 5:50 PM 02/09/2022 7:36 PM 1 day, 1 hour, 46 minutes lines 685-694 02/08/2022 5:00 PM 02/09/2022 8:09 PM 1 day, 3 hours, 9 minutes lines 695-704 02/08/2022 6:28 PM 02/09/2022 6:53 PM 1 day, 25 minutes D. Interview with Technical Supervisor #2 on May 5, 2022 at 1020 via phone call confirmed specimens were received in the laboratory without cold

	packs. Interview with Technical Supervisor #2 on May 9, 2022 at 0915 in the office acknowledged specimens were not shipped according to the procedure. Interview with Technical Supervisor #2 on May 9, 2022 at 0930 in the office confirmed they had not established their own shipping studies (see D5423), and were following the stability of another study that showed stability at room temperature for five days, and had not updated their policy and procedure. E. Review of pre-survey worksheets showed testing began on 9/18/2021 and 6108 specimens had been reported out from 09/18 /2021 - 04/30/2022.
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 review of the laboratory's policies and procedures, validation studies, interview, and pre-survey paperwork, the laboratory failed to perform establishment studies for its laboratory developed test (LDT) Recon COVID-19 test for SARS-CoV-2 for Specimen Stability, Shipping studies, and the Analytical Specificity to include interfering substances. Findings follow. A. Review of the laboratory's policy and procedure titled COVID-19 test with dry anterior nares swabs: individual and pooled, Sept 18, 2021, under 7.2 Sample Transport stated, " If the time between sample collection and processing is likely to exceed 24 hours, samples can be stored at 2 to 8 degrees Celsius for up to 72 hours, -20 degrees Celsius for 2 to 4 weeks, or -80 degrees Celsius for long term storage, then later thawed on ice or cold block for testing." And at 7.4 Sample Storage stated, "Upon receipt and if the above acceptance criteria are met and initial processing steps are likely to exceed 24 hours, specimens are stored at 2 to 8 degrees Celsius for up to 72 hours consistent with CDC recommendations, --20 degrees Celsius for 2 to 4 weeks, or -80 degrees Celsius for longer term storage. Viral RNA remains stable at 4 degrees Celsius, room temperature, and 30 degrees Celsius for up to 7 days." B. Review of the COVID test with dry Anterior Nasal Swabs Individual and Pooled Validation Study, 05/17/2021, did not include the specimen stability, shipping studies, or the analytical specificity to include interfering substances. C. Interview with the Technical Supervisor #1, as listed on the CMS form 209, on May 4, 2022 at 1025 hours in the office confirmed validation studies for specimen stability and shipping studies were not performed. Interview with Technical Supervisor #1 on May 4, 2022 at 1250 hours in the office confirmed analytical specificity including interfering substances was not performed. D. Review of pre-survey worksheets showed testing began on 9/18/2021 and 6108 specimens had been reported out from 09/18/2021 - 04/30/2022.
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 review of the laboratory's policies and procedures, validation studies, interview, and pre-survey paperwork, the laboratory director failed to perform establishment studies for its laboratory developed test (LDT) Recon COVID-19 test for SARS-CoV-2 for Specimen Stability, Shipping studies, and the Analytical Specificity to include interfering substances (see D5423).