

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 32D2188497	(X3) Date Survey Completed 02/02/2023
Name of Provider or Supplier Net Medical Xpress Solutions, Inc	Street Address, City, State 8206 Louisiana Blvd Ne Suite A, Albuquerque, NM	
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 February 2, 2023. The laboratory was found to be out of compliance with the CLIA regulations based on the following CONDITION level deficiencies resulting in Immediate Jeopardy: 493.1240 Pre-Analytic Systems 493.1250 Analytic Systems 493.1403 Laboratory Director, (moderate complexity).
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Centers for Medicare and Medicaid (CMS) 116 form, review of manufacturer's emergency use authorization, lack of environmental records, and interview with the Laboratory Director, the laboratory failed to ensure BinaxNow Covid-19 kits were stored according to manufacturer's instructions. Findings included: 1. Review of the CMS-116 form submitted at the time of the survey revealed the laboratory operated mobile units with the following vehicle identification numbers: 3C6MRVJG2ME558419 1FTYE1C84MKA37655 3C6LRVBG7NE121530 3C6LRVBG9NE121531 During the entrance conference on February 02, 2023 at 09:35am, the Laboratory Director stated that the mobile units were used for waived COVID-19 testing using the BinaxNow COVID-19 Ag Card. 2. The Food and Drug Administration (FDA) emergency use authorization for the BinaxNow COVID-19 Ag Card stated, "...STORAGE and STABILITY Store kit at 2-30C. The BinaxNOW COVID-19 Ag Card kit is stable until the expiration date marked on the outer packaging and containers. Ensure all test components are at room temperature before use ..." 3. In an interview on February 02, 2023 at 12:41pm, the Laboratory Director was asked to provide environmental records for temperature monitoring on the four mobile units. No documentation was provided. The Laboratory</p>

Director stated that there was no temperature monitoring in the mobile units. This confirmed the findings. Word Key: Ag=antigen

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 submitted Centers for Medicare and Medicaid (CMS) 116 form, manufacturer's instructions, laboratory policies, daily environmental logs, patient test reports, and confirmed in interview, the laboratory failed to meet the requirements for preanalytic systems, as evidenced by: 1. The laboratory failed to have a mechanism in place to ensure specimens were maintained at an acceptable temperature range for storage and shipment to the laboratory for testing and failed to ensure temperature of specimens were within manufacturer's requirements for 256 out of 414 days from May 2022 through December 2022. Refer to 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 submitted Centers for Medicare and Medicaid (CMS) 116 form, direct observation, manufacturer's instructions, laboratory procedures, daily environmental logs, patient test reports, and confirmed in interview, the laboratory failed to have a mechanism in place to ensure specimens were maintained at an acceptable temperature range for storage and shipment to the laboratory for testing and failed to ensure temperature of specimens were within manufacturer's requirements for 256 out of 414 days from May 2022 through December 2022. Findings included: 1. Review of the CMS-116 form submitted at the time of the survey revealed the laboratory operated mobile units with the following vehicle identification numbers: 3C6MRVJG2ME558419 1FTYE1C84MKA37655 3C6LRVBG7NE121530 3C6LRVBG9NE121531 During the entrance conference on February 02, 2023 at 09:35am, the Laboratory Director stated that the mobile units were used for waived COVID-19 tests and for specimen collection for additional polymerase chain reaction (PCR) testing. He stated that PCR specimens were collected by the mobile unit personnel and stored in coolers until the mobile unit returned to the laboratory's physical location. The specimens were then transferred to a laboratory refrigerator. 2. During a tour of the laboratory area, a Biofire Torch

(Serial Number KTB02358) and the Diasorin MDX Simplexa (Serial Number 1D0893) was observed to be use for PCR testing. 3. Review of the manufacturer's instructions for the Biofire and Diasorin revealed the following: a. The manufacturer's instructions for Biofire Respiratory 2.1 (BFR0000-8579-01 March 2021) stated the following: "...Transport and Storage ...Specimens should be tested with the Biofire RP2.1 as soon as possible. If storage is required, specimens can be held ...Refrigerated for up to 3 days (2-8C) ..." b. The manufacturer's instructions for Diasorin Simplexa Covid-19 Direct9 (REF MOL4150, Rev. 9), stated the following: "...Materials Required but not Supplied ...6. Refrigerator at 2-8C (for specimens) ..." 4. Review of the laboratory's procedures for the Biofire and Diasorin revealed the following: a. The laboratory procedure titled, "Biofire Respiratory 2.1 (RP2.1) Panel" (Approved by the Laboratory Director 05/23/2021) stated the following: "...II. Sample Requirements ... Transport and Storage If storage is required, specimens can be held ...Refrigerated for up to 3 days (2-8C) ..." b. The laboratory procedure titled, "Diasorin Simplexa Covid-19 Direct" (Approved by the Laboratory Director 02/27/2022), stated the following: "...Materials Required but not Supplied ...6. Refrigerator at 2-8C (for specimens) ..." 5. Review of the laboratory environmental log titled, "Temperature Control Record", from May 2022 through December 2022, revealed 256 of 414 days when cooler temperatures were out of the acceptable range. The following are the days and the recorded cooler temperature: May 2022 "Dodge Cooler" 05/01/2022, 42C; 05/02/2022, 11C; 05/05/2022, 11C; 05/06/2022, 11C; 05/07/2022, 18C; 05/08/2022, 9C; 05/09/2022, 10C; 05/10/2022, 15C; 05/11/2022, 12C; 05/13/2022, 9C; 05/14/2022, 16C; 05/15/2022, 22C; 05/16/2022, 31C; 05/17/2022, 16C; 05/18/2022, 21C; 05/19/2022, 18C; 05/20/2022, 17C; 05/21/2022, 18C; 05/22/2022, 21C; 05/23/2022, 11C; 05/24/2022, 17C; 05/27/2022, 19.2C; 05/28/2022, 21C; 05/29/2022, 9.6 C; 05/30/2022, 8.2C "Ford Cooler" 05/24/2022, 1.7C; 05/26/2022, 33C; 05/27/2022, 14C; 05/28/2022, 12.7C June 2022 "Dodge Cooler" 06/03/2022, 8.6C; 06/05/2022, 9.8 C; 06/06/2022, 11.1C; 06/07/2022, 12.1C; 06/08/2022, 11.7C; 06/11/2022, 9.6C, 06/12/2022, 15.7C; 06/13/2022, 19.4C; 06/14/2022, 16.1C; 06/15/2022, 15.6C; 06/16/2022, 23.8C; 06/17/2022, 15.4C; 06/19/2022, 16.9C, 06/20/2022, 10.5C; 06/21/2022, 8.9C; 06/23/2022, 9.4C; 06/24/2022, 23C; 06/25/2022, 8.9C; 06/27/2022, 15.9C; 06/28/2022, 18.3C, 06/29/2022, 19.0C; 06/30/2022, 21.6C; 06/31/2022, 19.5C "Ford Cooler" 06/02/2022, 7.2C; 06/04/2022, 13.6C; 06/11/2022, 11.2C; 06/12/2022, 0.6C; 06/16/2022, 10.4C; 06/18/2022, 0.7C, 06/23/2022, 8.6C; 06/26/2022, 14.7C; 06/29/2022, 10.0C July 2022 "Dodge Cooler" 07/01/2022, 19.5C; 07/02/2022, 17.0C; 07/03/2022, 15.8C; 07/05/2022, 18.9C; 07/06/2022, 18.0C; 07/07/2022, 18.0C, 07/09/2022, 21.7C; 07/10/2022, 12.3C; 07/11/2022, 19.6C; 07/12/2022, 21.0C; 07/13/2022, 25.0 C; 07/14/2022, 19.0C; 07/15/2022, 22.0C, 07/16/2022, 16.0C; 07/17/2022, 17.0C; 07/18/2022, 24.5C; 07/19/2022, 9.4C; 07/20/2022, 28.7C; 07/21/2022, 23.0C; 07/22/2022, 21.1C, 07/23/2022, 27.7C; 07/24/2022, 17.4C; 07/25/2022, 22.5C; 07/26/2022, 22.0C, 07/27/2022, 19.1C; 07/28/2022, 19.2C; 07/29/2022, 18.7C; 07/30/2022, 22.2C; 07/31/2022, 28.2C; "Ford Cooler" 07/01/2022, 11.0C; 07/02/2022, 9.5C; 07/03/2022, 10.0C; 07/07/2022, 9.9C; 07/08/2022, 8.6C; 07/09/2022, 9.2C, 07/10/2022, 9.8C; 07/12/2022, 12.3C; 07/13/2022, 12.6C; 07/14/2022, 8.6C; 07/22/2022, 10.2C; 07/25/2022, 12.0C; 07/27/2022, 13.0C; 07/29/2022, 12.1C August 2022 "Dodge Cooler" 08/01/2022, 19.5C; 08/02/2022, 19.7C; 08/03/2022, 23.5C; 08/04/2022, 23.3C; 08/05/2022, 22.1C; 08/06/2022, 17.6C, 08/07/2022, 15.4C; 08/08/2022, 24.2C; 08/09/2022, 24.2C; 08/10/2022, 19.7C; 08/11/2022, 20.1C; 08/12/2022, 21.0C; 08/13/2022, 18.0C, 08/14/2022, 15.0C; 08/15/2022, 19.7C; 08/16/2022, 18.1C; 08/17/2022, 18.0C; 08/18/2022, 19.1C; 08/19/2022, 14.0C; 08/20/2022, 18C, 08/21/2022, 14C; 08/22/2022, 18.7C; 08/23/2022, 11.0C; 08/24/2022, 11.7C, 08/25/2022, 11.3C; 08/26/2022, 13.0C; 08/27/2022, 15.2C; 08/29/2022, 12.0C, 08/30/2022, 11.4C; 08/31/2022, 13.5C "Ford Cooler" 08/13/2022, 13C; 08/15/2022, 15C; 08/18/2022, 15C "Hot Shots 1" 08/02

/2022, 1.6C; 08/03/2022, 0.9C; 08/26/2022, 1.6C September 2022 "Dodge Cooler" 09/01/2022, 19.6C; 09/02/2022, 17.4C; 09/03/2022, 17.5C; 09/04/2022, 10.7C; 09/05/2022, 17.6C; 09/06/2022, 19.0C; 09/07/2022, 17.6C; 09/08/2022, 19.6C; 09/09/2022, 19.0C; 09/10/2022, 17.5C; 09/11/2022, 16.0C; 09/12/2022, 21.0C; 09/13/2022, 17.0C; 09/14/2022, 21.1C; 09/15/2022, 19.0C; 09/16/2022, 19.6C; 09/17/2022, 18.8C; 09/18/2022, 22.8C; 09/19/2022, 21.0C; 09/20/2022, 21C; 09/21/2022, 19C; 09/22/2022, 20C; 09/23/2022, 20C; 09/24/2022, 18.2C; 09/25/2022, 19.4C; 09/26/2022, 21.6C; 09/27/2022, 19.2C; 09/28/2022, 19.0C; 09/29/2022, 11.0C "Hot Shots 1" 09/01/2022, 0.6C; 09/15/2022, 1.6C; 09/30/2022, 1.9C October 2022 "Hot Shots 2" 10/10/2022, 1.9C; 10/18/2022, 1.7C; 10/19/2022, 1.7C; 10/28/2022, 1.6C "Wilson Cooler" 10/01/2022, 17.7C; 10/02/2022, 19.4C; 10/03/2022, 18.7C; 10/04/2022, 19.0C; 10/05/2022, 17.2C; 10/06/2022, 18.2C; 10/03/2022, 19.1C; 10/08/2022, 16.3C; 10/09/2022, 18.0C; 10/10/2022, 17.9C; 10/11/2022, 18.1C; 10/12/2022, 16.4C; 10/13/2022, 14.8C; 10/14/2022, 11.3C; 10/15/2022, 15.7C; 10/16/2022, 13.6C; 10/17/2022, 18.6C; 10/21/2022, 21.7C; 10/22/2022, 15.5C; 10/23/2022, 15.7C; 10/24/2022, 15.3C; 10/25/2022, 15C; 10/29/2022, 15.0C "Ram Cooler, Milne" 10/03/2022, 12.2C; 10/04/2022, 11.0C; 10/05/2022, 8.4C; 10/06/2022, 11.6C; 10/07/2022, 14.1C; 10/08/2022, 12.6C; 10/17/2022, 15C; 10/18/2022, 13C; 10/19/2022, 15.7C; 10/20/2022, 11.0C; 10/21/2022, 10.1C; 10/22/2022, 8.3C "Ford Cooler" 10/14/2022, 13.9C; 10/15/2022, 11.4C; 10/19/2022, 12.0C; 10/23/2022, 10.0C November 2022 "Milne Cooler" 11/01/2022, 13.0C; 11/02/2022, 15.7C; 11/03/2022, 11.7C; 11/04/2022, 9.0C; 11/08/2022, 16.4C; 11/13/2022, 8.7C; 11/14/2022, 11C; 11/16/2022, 8.2C "Wilson Cooler" 11/05/2022, 14.4C; 11/07/2022, 15.0C; 11/08/2022, 13.8C; 11/09/2022, 10.3C; 11/10/2022, 9.1C; 11/11/2022, 11.0C; 11/12/2022, 15.1C; 11/15/2022, 9.0C; 11/18/2022, 18.4C; 11/19/2022, 19.6C; 11/20/2022, 11.0C; 11/21/2022, 11.2C; 11/23/2022, 16.2C; 11/28/2022, 12.8C; 11/29/2022, 12.7C December 2022 "Cooler" 12/01/2022, 12.8C; 12/06/2022, 11.8C; 12/09/2022, 10.9C; 12/10/2022, 11.4C; 12/12/2022, 9.7C; 12/15/2022, 9.7C; 12/16/2022, 9.8C; 12/17/2022, 11.5C; 12/18/2022, 11.3C; 12/21/2022, 9.9C; 12/22/2022, 11.8C; 12/23/2022, 12.6C; 12/28/2022, 11.0C; 12/29/2022, 8.8C "Milne Cooler" 12/02/2022, 15.6C; 12/12/2022, 9.4C; 12/15/2022, 10.5C

6. A random review of patient test reports revealed the following patients were stored and tested when cooler temperatures were out of the acceptable range: Patients tested using the Biofire RP2.1 (Respiratory Panel 2.1): 12/02/2022 Patient 10043443 12/06/2022 Patients 10016582; 10020240 12/09/2022 Patient 10043725 12/10/2022 Patients 10043741; 10016390; 10043741; 10016390 12/16/2022 Patients 10030193 12/17/2022 Patients 10043930; 10032191 12/22/2022 Patients 10032191 12/23/2022 Patients 10044091 Patients tested using the Diasorin Simplexa COVID-19 Direct Kit: 12/06/2022 Patients 10043297; 10043298; 10043611; 10034471; 10028227 12/12/2022 Patients 10025915; 10022573; 10020458; 10010558; 10010566; 10043782; 10037620; 10043789; 12/18/2022 Patient 10034093 12/21/2022 Patient 10028627 12/22/2022 Patient 10044027; 10024832; 10044014; 10044069 12/23/2022 Patient 10044044; 10043853; 10043503; 10043852; 10044093; 10044095; 10044094; 12/28/2022 Patient 10041938; 10021792; 10021793

7. Review of the laboratory record titled, "Patient Report Reviews Year-2022" revealed the following patient volumes: May 2022, 277 patients tested; June 2022, 428 patients tested; July 2022, 409 patients tested; August 2022, 247 patients tested; September 2022, 132 patients tested; October 2022, 313 patients tested; November 2022, 308 patients tested; December 2022, 112 patients tested.

8. In an interview on February 01, 2023 at 12:12pm in the conference room, the Laboratory Director stated the coolers failed to maintain the expected 2-8C temperature range . This confirmed the above findings. Word Key: C= degrees Celsius

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 direct observation, review of manufacturer's instructions, laboratory policies, laboratory records, and staff interview, it was revealed the laboratory failed to meet analytic system requirements, as evidenced by: 1. The laboratory failed to provide documentation of performing precision studies for the DiaSorin MDX Simplexa instrument. Refer to D5421. 2. The laboratory failed to perform quality control at the frequency established by the for the BioFire Respiratory Panel 2.1 and for the DiaSorin MDX Simplexa instruments. Refer to D5445. 3. The laboratory failed to ensure laboratory freezer temperatures were maintained according to manufacturer's specifications for the DiaSorin Simplexa COVID-19 Direct reagents. Refer to D5413 I. 4. The laboratory failed to ensure laboratory room temperatures were maintained according to manufacturer's specifications for the BioFire Respiratory Panel 2.1 reagent. Refer to D5413 II. 5. The laboratory failed to ensure laboratory humidity conditions were maintained according to the laboratory's acceptability limits. Refer to D5413 III.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

I. Based on direct observation, review of manufacturer's instructions, laboratory policy, daily environmental logs, and confirmed in staff interview, the laboratory failed to ensure laboratory freezer temperatures were maintained according to manufacturer's specifications for 100 of 153 days (09/2022 - 01/2023) for the DiaSorin Simplexa COVID-19 Direct reagents. Findings included: 1. During a tour of the laboratory on 02/02/2022 at 1:30 pm, the following reagents were observed stored in the laboratory freezer: 4 boxes of Simplexa COVID-19 Direct, Lot number 13998N Expiration date 09/30/2023 1 box of Simplexa COVID-19 Direct, Lot number 16426N Expiration date 11/30/2023 2. Review of the DiaSorin Simplexa COVID-19 Direct manufacturer's instructions (MOL4150I Rev.09) stated: "Materials Provided ... Upon receipt, store at -10 to -30C (do not use a frost-free freezer)." 3. Review of laboratory policy titled "DiaSorin Simplexa COVID-19 Direct" (signed by the laboratory director on 02/27/2022) stated: "REAGENT HANDLING AND STORAGE. 1. Store reagents at -10 to - 30C" 4. Review of the laboratory freezer log

titled "Temperature Control Record" revealed the following temperature results that were outside of the acceptable range of -10 to -30C: September 2022 Acceptable limits "-20 - -30C" (The acceptable limits on the Temperature Control Record log failed to correspond with the acceptable limits of -10 to -30C stated in the policy titled "DiaSorin Simplexa COVID-19 Direct"). 09/01/2022, 32.88C; 09/02/2022, 30C; 09/03/2022, 30C; 09/04/2022, 30C; 09/05/2022, 30C; 09/06/2022, -32.7C; 09/09/2022, -31C; 09/10/2022, -32.5C; 09/11/2022, -32.3C; 09/12/2022, -31C; 09/13/2022, 31.52C; 09/17/2022, 31.63C; 09/18/2022, 32.1C; 09/20/2022, -31C; 09/21/2022, -31C; 09/22/2022, -31C; 09/23/2022-09/25/2022, ND; 09/26/2022, -33.01C; 09/27/2022, 31.64C; 09/28/2022, 31.37C; 09/29/2022, 31.48C; 09/30/2022, 31.48C; 09/31/2022, 32.3C

October 2022 Acceptable limits "2-8C" (The acceptable limits on the Temperature Control Record log failed to correspond with the acceptable limits of -10 to -30C listed in the policy titled "DiaSorin Simplexa COVID-19 Direct"). 10/01/2022, ND; 10/02/2022, ND; 10/03/2022, -32.5C; 10/04/2022, 32.8C; 10/06/2022, -31C; 10/10/2022, -31.8C; 10/12/2022, -31C; 10/13/2022, -31C; 10/14/2022, -31C; 10/15/2022, -31C; 10/16/2022, -31C; 10/18/2022, -31C; 10/19/2022, -31.4C; 10/20/2022, -31C; 10/21/2022, -31.8C; 10/22/2022, 31C; 10/23/2022, -31.1C; 10/24/2022, -32.2C; 10/26/2022, -31.1C; 10/28/2022, -31.1C; 10/29/2022, -31C; 10/30/2022, -37C; 10/31/2022, -37C

November 2022 Acceptable limits "-20 - -40C" (The acceptable limits on the Temperature Control Record log failed to correspond with the acceptable limits of -10 to -30C stated in the laboratory policy titled "DiaSorin Simplexa COVID-19 Direct"). 11/01/2022, -31C; 11/02/2022, -31C; 11/04/2022, -30.5C; 11/05/2022, -30.5C; 11/06/2022, -30.5C; 11/07/2022, 30.5C; 11/08/2022, 30.5C; 11/11/2022, 34.3C; 11/12/2022, -34.3C; 11/13/2022, 31.35C; 11/14/2022, 31.35C; 11/15/2022, -32.2C; 11/16/2022, -31.4C; 11/18/2022, -31.1C; 11/19/2022, -31C; 11/20/2022, -31C; 11/21/2022, -31C; 11/23/2022, -31.7C; 11/24/2022, -31.7C; 11/25/2022, -31.7C; 11/26/2022, 31.70C; 11/27/2022, ND; 11/28/2022, -30.5C; 11/29/2022, -30.6C; 11/30/2022, -31C

December 2022 Acceptable limits "-20 - -40C" (The acceptable limits on the Temperature Control Record log failed to correspond with the acceptable limits of -10 to -30C stated in the laboratory policy titled "DiaSorin Simplexa COVID-19 Direct"). 12/01/2022, 31.22C; 12/02/2022, 31.50C; 12/03/2022, 31.30C; 12/04/2022, 31.30C; 12/07/2022, -30.8C; 12/08/2022, -30.8C; 12/09/2022, -30.8C; 12/10/2022, -30.8C; 12/11/2022, Not Done (ND); 12/12/2022, -30.6C; 12/19/2022, -31C; 12/21/2022, -31; 12/24/2022 - 12/26/2022, ND; 12/27/2022, -31; 12/30/2022, -31C; 12/31/2022, ND

January 2023 Acceptable limits "-20 - -30C" (The acceptable limits on the Temperature Control Record log failed to correspond with the acceptable limits of -10 to -30C stated in the laboratory policy titled "DiaSorin Simplexa COVID-19 Direct"). 01/03/2023, -31C; 01/10/2023, "N/A"; 01/17/2023, -31.2C; 01/18/2023, 31.9C; 01/19/2023, 31.2C; 01/20/2023, 31.2C; 01/22/2023, 31.3C; 01/27/2023, -31C; 01/28/2023, -31C; 01/29/2023, -32C; 01/30/2023, -31C; 01/31/2023, -31C

Note: Several temperatures listed on the Temperature Control Record log failed to indicate a negative temperature reading. 5. In an interview on 02/02/2023 at 12:15pm in the conference room, after review of the above results, the Laboratory Director confirmed the findings. II. Based on direct observation, review of manufacturer's instructions, laboratory policy, daily environmental logs, and confirmed in staff interview, the laboratory failed to ensure laboratory room temperatures were maintained according to manufacturer's specifications for 8 of 8 months (09/2021-12/2021 and 10/2022-12/2022) for the BioFire Respiratory Panel 2.1 reagent. Findings included: 1. During a tour of the laboratory room on 02/02/2021 at 1:30pm, the following reagents were observed stored: 2 boxes Biofire Respiratory Panel 2.1 kits Lot number 198923 Expiration date 10-16-2023 5 boxes Biofire Respiratory Panel 2.1 kits Lot number 2230422 Expiration date 12-07-2023 1 box Biofire Respiratory Panel 2.1 kits Lot number 1989822 Expiration date 10-16-2023 2. Review of the manufacturer's

instructions titled "BioFire Respiratory Panel 2.1 (RP2.1), version BFR0000-2579-01 March 2021, stated the following: "Reagent storage, Handling, and Stability, 1. Store the test kit, including reagent pouches and buffers, at room temperature (15-25C)." 3. Review of the laboratory policy titled: BioFire Respiratory 2.1 (RP2.1), approved by the Laboratory Director on 05/23/2021, stated: "Reagent storage, Handling, and Stability, 1. Store the test kit, including reagent pouches and buffers, at room temperature (15-25C)." 4. Review of the laboratory form titled "Temperature Control Record; Room" revealed the following temperatures that were outside of the acceptable range of 15 -25C: September 2021 Acceptable limits "20-30C" (The acceptable limits listed on the Temperature Control Record log failed to correspond with the acceptable limits of 15-25C stated in the policy titled "BioFire Respiratory Panel 2.1 (RP2.1)"). 09/01/2021-09/07/2021, Not Done (ND); 09/10/2021-09/18/2021, ND; 09/19/2021, 25.9C; 09/20/2021-09/23/2021, ND; 09/28/2021-09/30/2021 ND October 2021 Acceptable limits "20-30C" (The acceptable limits listed on the Temperature Control Record log failed to correspond with the acceptable limits of 15-25C stated in the policy titled "BioFire Respiratory Panel 2.1 (RP2.1)"). 10/02/2021-10/03/2021, ND; 10/10/2021, ND; 10/16/2021, ND; 10/24/2021, 26.2C; 10/30/2021, 28.2C; 10/31/2021, ND November 2021 Acceptable limits "20-30C" (The acceptable limits listed on the Temperature Control Record log failed to correspond with the acceptable limits of 15-25C stated in the policy titled "BioFire Respiratory Panel 2.1 (RP2.1)"). 11/01/2021, 26.2C; 11/06/2021, 27.6C; 11/07/2021, 26.4C; 11/13/2021, ND; 11/20/2021, 25.7C; 11/24/2021, 25.9C; 11/25/2021, ND; 11/27/2021, ND; 11/28/2021, 26.8C; 11/29/2023, 25.5C December 2021 Acceptable limits "15-30C" (The acceptable limits listed on the Temperature Control Record log failed to correspond with the acceptable limits of 15-25C stated in the policy titled "BioFire Respiratory Panel 2.1 (RP2.1)"). 12/04/2021, 25.7C; 12/05/2021, ND; 12/11/2021, 26.2C; 12/13/2021, 25.2C; 12/16/2021, 25.1C; 12/17/2021, 25.2C; 12/18/2021, 26.2C; 12/25/2021, ND; 12/27/2021, 25.2C October 2022 Acceptable limits "15-30C" (The acceptable limits listed on the Temperature Control Record log failed to correspond with the acceptable limits of 15-25C stated in the policy titled "BioFire Respiratory Panel 2.1 (RP2.1)"). 10/01/2022, 27.9C; 10/02/2022, 28.2C; 10/03/2022, 27.1C; 10/04/2022, 26.2C; 10/05/2022, 26.8C; 10/06/2022, 25.5C; 10/07/2022, 25.5C; 10/08/2022, 26.8 C; 10/09/2022, 25.5C; 10/10/2022, 25.5C; 10/11/2022, 25.5C; 10/15/2022, 25.9C; 10/16/2022, 28.2C; 10/18/2022, ND; 10/19/2022, 25.5C; 10/21/2022, 26.8C; 10/22/2022, 26.8C; 10/23/2022, ND; 10/24/2022, 26.8C; 10/25/2022, 26.8C; 10/26/2022, 27.9C; 10/27/2022, 26.4C; 10/28/2022, 27.6C 10/28/2022, 27.6C; 10/29/2022, 27.6C November 2022 Acceptable limits "15 - 30C" (The acceptable limits listed on the Temperature Control Record log failed to correspond with the acceptable limits of 15-25C stated in the policy titled "BioFire Respiratory Panel 2.1 (RP2.1)"). 11/02/2022, 27.1C; 11/03/2022, 25.5C; 11/04/2022, 25.2C; 11/05/2022, 25.2C; 11/06/2022, 25.2 C; 11/07/2022, 25.9C; 11/08/2022, 25.9C; 11/09/2022, 25.7C; 11/10/2022, 26.4C; 11/11/2022, 26.4C; 11/12/2022, 26.4C; 11/13/2022, 26.4C; 11/14/2022, 26.4C; 11/15/2022, 26.4C; 11/16/2022, 26.4C; 11/17/2022, 26.8C; 11/18/2022, 27.4C; 11/19/2022, 27.1C; 11/21/2022, 25.2C; 11/22/2022, 26.9C; 11/23/2022, 27.2C; 11/24/2022, 27.2 C; 11/27/2022, ND; 11/28/2022, 26.9C; 11/29/2022, 29.0C; 11/30/2022, 29C December 2022 Acceptable limits "15-30C. (The acceptable limits listed on the Temperature Control Record log failed to correspond with the acceptable limits of 15-25C stated in the policy titled "BioFire Respiratory Panel 2.1 (RP2.1)"). 12/01/2022, 29.8C; 12/03/2022, 29.8C; 12/05/2022, 30.0C; 12/06/2022, 30C; 12/07/2022, 28.4C; 12/08/2022, 28.4C; 12/09/2022, 28.4C; 12/10/2022, 26.7C; 12/11/2022, ND; 12/12/2022, 26.3C; 12/13/2022, 26.7C; 12/14/2022, 26.7C; 12/15/2022, 28.2C; 12/16/2022, 28.2C; 12/17/2022, 28.2C; 12/19/2022, 25.7C; 12/20/2022, 26.7C; 12/21/2022, 26C; 12/22/2022, 26.9C; 12/23/2022, 26.4C; 12/24/2022, 26.9C; 12/25/2022 - 12/26/2022,

ND; 12/27/2022, 26.9C; 12/28/2022, 27.2C; 12/29/2022, 27.2C; 12/30/2022, 26.9C; 12/31/2022, ND 5. In an interview on 02/02/2023 at 12:23pm, after review of the above results, the Laboratory Director confirmed the findings. III. Based on daily environmental logs and confirmed in staff interview, the laboratory failed to ensure laboratory humidity conditions were maintained according to the laboratory's acceptability limits for 37 of days 123 (12/2021 and 10/2022-12/2022). Findings included: 1. Review of the laboratory form titled "Temperature Control Record; Room" revealed the following dates that humidity results were outside the laboratory's acceptable limits of 20-80%: December 2021 Acceptable limits "20-80%". 12/01/2021 - 12/17/2021, Not Done (ND); 12/19/2021, ND; 12/20/2021, ND; 12/25/2021, ND October 2022 Acceptable limits "20-80%". 10/18/2022, ND; 10/23/2022, ND November 2022 Acceptable limits "20-80%". 11/15/2022, 10%; 11/22/2022, Low%; 11/23/2022, Low%; 11/24/2022, Low%; 11/27/2022, ND December 2022 Acceptable limits "20-80%." 12/01/2022, Low%; 12/02/2022, Low%; 12/03/2022, Low%; 12/04/2022, Low%; 12/11/2022, Not Done (ND); 12/17/2022, Low%; 12/23/2022, Low%; 12/25/2022 - 12/26/2022, ND; 12/31/2022, ND 2. In an interview on 02/02/2023 at 12:23pm, after review of the above results, the Laboratory Director confirmed the findings. Word Key: C = degrees Celsius

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
 CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:
 Based on review of the laboratory policy, laboratory record, and confirmed in staff interview, the laboratory failed to have documentation of performing precision studies for 1 of 1 assay used on the DiaSorin MDX Simplexa instrument (Serial Number 1D0893) prior to performing patient testing. Findings included: 1. The laboratory policy titled "Test Method Validation" (Version 1.0) stated the following: "Precision is established by repeat measurement of samples at varying concentrations within-run and between-run over a period of time." 2. Review of laboratory record titled "Test Method Validation; Name of Method(s) validated DiaSorin MDX Simplexa COVID-19", signed by the Laboratory Director on May 08, 2022, revealed the laboratory failed to provide documentation of verification studies to include precision. 3. During an interview on 02/02/2023 at 11:15 am, after review of the DiaSorin verification studies, the Laboratory Director and Testing Person 1 (as listed on the Centers for Medicare & Medicaid Services (CMS)-209 FORM, signed by the Laboratory Director on 01/28/2023) confirmed the findings.

D5445

CONTROL PROCEDURES
 CFR(s): 493.1256(d)(1)(2)(g)

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.

This STANDARD is not met as evidenced by:

Based on review of the laboratories Individual Quality Control Plans (IQCP), laboratory records (08/2022 - 12/2022), patient laboratory results, and confirmed in staff interview, the laboratory failed to perform quality control at the frequency established by the laboratory for 2 of 5 months (10/2022 and 11/2022) for the BioFire RP 2.1 and 2 of 5 months (11/2022 and 12/2022) for the DiaSorin MDX Simplexa instruments. Findings included: 1. Review of the laboratory IQCP specified for the Biofire RP2.1 stated, "External Quality Control (QC) is performed with each new lot#, shipment and each month." 2. Review of the laboratory IQCP specified for the Simplexa COVID-19 stated, "External controls shall be performed, as follows: a) Each month b) Each new lot number c) Each new shipment." 3. Review of the quality control records revealed the following: a. No documentation of monthly quality control testing for the Biofire RP2.1 for 10/2022 and 11/2022. b. No documentation of monthly quality control testing for the DiaSorin MDX Simplexa for 11/2022 and 12/2022. 4. A random review of patient test reports revealed the following patients were tested when quality control was not performed: a. Patients tested using the Biofire Respiratory Panel 2.1: 10/26/2022 Patients 10040190;10040266; 10040173; 10040251; 10040250 10/30/2022 Patient 1005327 11/03/2022 Patient 10022596 11/07/2022 Patients 10031395; 10033380 11/09/2022 Patient10005439 b. Patients tested using the DiaSorin Simplexa COVID-19 Direct Kit: 11/25/2022 Patients 10042994; 10043035; 10043075; 10042212; 10043034; 10043032; 10042213 11/28/2022 Patients 10043143; 10043126; 10043112; 10043129; 10043140; 10043135; 10043132; 10028442; 10043193; 10043190; 10042761; 10043192 12/04/2022 Patients 10043386; 10043503; 10043466; 10032640; 10043504; 10034093; 10043492; 10043505 12/06/2022 Patients 10043544; 10043298; 10043297; 10043563; 10043514; 10021745; 10021745; 10043611; 10043611;10028227; 10034471 12/11/2022 Patients 10017010; 10017019; 10017022; 10017024 12/15/2022 Patient 10043843 12/21/2022 Patients 10044012; 10044003; 10028627 12/28/2022 Patients 10021793; 10041938; 10021792 5. During an interview on 02/02/2023 at 11:20 am, after review of the above records, the laboratory director confirmed the findings.

D5793

ANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1289(b)(c)

(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on direct observation, review of manufacturer's instructions, laboratory policies, laboratory records, and confirmed in staff interview, the laboratory failed to have an effective quality assessment program in place to identify and correct problems

in the analytic phase of testing, as evidenced by: 1. The laboratory failed to ensure laboratory freezer temperatures were maintained according to manufacturer's specifications for the DiaSorin Simplexa COVID-19 Direct reagents. Refer to D5413 I. 2. The laboratory failed to ensure laboratory room temperatures were maintained according to manufacturer's specifications for the BioFire Respiratory Panel 2.1 reagent. Refer to D5413 II. 3. The laboratory failed to ensure laboratory humidity conditions were maintained according to the laboratory's acceptability limits. Refer to D5413 III. 4. The laboratory failed to ensure quality control was performed at the frequency established by the laboratory. Refer to D5445.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR
CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:
Based on direct observation, review of manufacturer's instructions, laboratory policies, laboratory records, laboratory patient records, and confirmed in staff interview, the Laboratory Director failed to provide overall management and direction as evidenced by: 1. The Laboratory Director failed to ensure verification procedures were complete prior to performing patient testing. Refer to D6013 2. The Laboratory Director failed to ensure an effective quality assurance plan was established and maintained. Refer to D6021. 3. The Laboratory Director failed to ensure the quality assessment plan identified and resolved failures in quality control systems. Refer to D6022.

D6013

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(3)(ii)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) 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 policy, laboratory record, and confirmed in staff interview, the laboratory director failed to verify precision for the DiaSorin MDX Simplexa analyzer prior to performing patient testing. Refer to D5421.

D6021

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(5)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory

director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on direct observation, review of manufacturer's instructions, laboratory policies, laboratory records, and confirmed in staff interview, the laboratory director failed to have an effective quality assessment program in place to identify and correct problems in the analytic phase of testing. Refer to D5793.

D6022

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(5)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on review of laboratory records, patient laboratory records, and confirmed in staff interview, the Laboratory Director failed to ensure quality control was performed at the frequency established by the laboratory. Refer to D5445.