

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2260971	(X3) Date Survey Completed 06/11/2024
Name of Provider or Supplier Jds Labs, Llc	Street Address, City, State 1220 Texan Trl Suite 210, Grapevine, 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 NOT to be in compliance with the CLIA regulations found at 42 CFR 493 CLIA requirements. The conditions not met were: D5300 - 42 C.F.R. 493.1240 Condition: Preanalytic systems; D5400 - 42 C.F.R. 493.1250 Condition: Analytic systems; D6076 - 42 C.F.R. 493.1441 Condition: Laboratories performing high complexity testing; laboratory director;
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on review of College of American Pathologists (CAP) instruction for proficiency testing (PT), laboratory's policies/procedures, PT records and staff interview, the laboratory failed to ensure attestations were signed for 3 of 3 PT events reviewed from 2023. Findings included: 1. Review of CAP instruction for PT (document AO 2023, 1222) revealed: "Attestation Statement ... The laboratory director or designee and the testing personnel must sign on the result form. You may use the attestation page provided in the kit instructions or, alternatively, print, sign, and retain a copy of this page for your records and inspection purposes." 2. Review of laboratory's policy "Quality Assessment Plan" (document DCN: QA-030, signed by laboratory director 10/18/2023) revealed: "5.6.1.4 Attestation forms will be signed by the testing personnel performing the test and the Laboratory Director." 3. Review of laboratory's CAP PT records from 2023 revealed there were no testing personnel or laboratory director signatures on the attestation forms for any of the 3 events from that year. 4. In an interview on 06/11/2024 at 1010 hours in the office, the Laboratory Director (as indicted on submitted form CMS 209) confirmed the findings.</p>

D3003

FACILITIES

CFR(s): 493.1101(a)(2)

The laboratory must be constructed, arranged, and maintained to ensure contamination of patient specimens, equipment, instruments, reagents, materials, and supplies is minimized.

This STANDARD is not met as evidenced by:

Based on surveyor's observations, review of laboratory's policies/procedures and staff interview, the laboratory failed to ensure protocols were in place and followed for prevention of sample's cross contamination for one of one test performed by the laboratory, the SARS-CoV-2, Flu & RSV Real Time PCR (polymerase chain reaction). Findings included: 1. Surveyor's observations on 06/11/2024 at 1110 hours in the laboratory, during staff demonstration of the specimen preparation/testing process revealed the laboratory used open array plates that can accommodate multiple patients' samples for both the extraction and amplification processes of the PCR testing, necessitating precautions for handling patients' samples in a way to minimize cross contamination. The same observations revealed Testing Person number 1 (as indicated on submitted form CMS 209) did not change gloves between patient samples to prevent cross contamination. She also did not change lab coats between the separated extraction and PCR amplification areas/rooms during the progression of the testing processes, to minimize said cross contamination. 2. Review of laboratory's policy "General Precautions of Molecular Assays" (document DCN: SOP-008, Revision 1) revealed: "Gloves must be worn and must be changed handling specimens to prevent contamination". And, "Physically separate the workspaces used from PCR setup and post-PCR processing or non-PCR operations." There was no mention of the frequency of glove changing, or the need to change lab coats between the different workspaces of testing (extraction room and PCR room). 3. In an interview on 06/11/2024 at 1120 hours in the office, the Testing Person number 1 confirmed the findings.

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 surveyor observation, review of manufacturer instructions, the laboratory's policies, and staff interview, the laboratory failed to meet pre-analytic system requirements for one of one laboratory test performed from September 2022 to June 2024. Findings include: 1. Laboratory failed to establish a written policy for the collection, storage, and shipping/transport requirements of patient specimens. Refer to D5311 A. 2. Laboratory failed to have a mechanism in place to ensure the temperature of patient's specimens were maintained during transport to the laboratory for testing. Refer to D5311 B. 3. Laboratory failed to provide written instructions to its clients for the patient preparation, collection, labeling, storage, transportation, processing, and acceptability/rejection criteria of specimens. Refer to D5317.

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:

A. Based on a review of the Viasure Real Time PCR Detection Kits Instructions for Use, the laboratory's policies, the laboratory's records, and staff interview, the laboratory failed to establish a written policy for the collection, storage, and shipping /transport requirements of patient specimens for one of one test performed by the laboratory from September 2022 to June 2024. Findings include: 1. A review of the Viasure Real Time PCR Detection Kits Instructions for Use (IU-CFR 196TRUOenes1120 rev.03) revealed the following: "Patient samples must be collected, transport, and storage according to appropriate laboratory guidelines." 2. A review of the laboratory's policies revealed the laboratory failed to establish a written policy for the collection, storage, and shipping/transport requirements for patient specimens. 3. A review of the laboratory's records revealed the laboratory started patient testing using the Viasure Real Time PCR Detection Kit for SARS-COV-2, Influenza A/B, and Respiratory Syncytial Virus A/B in September 2022. 4. In an interview on 6/11/24 at 1:00 p.m. in the laboratory, after review of the records, testing person #1 (as indicated on the CMS 209 form) confirmed the above findings. Key: PCR = Polymerase Chain Reaction B. Based on a review of the Viasure Real Time PCR Detection Kits Instructions for Use, the laboratory's policies, surveyor observation, the laboratory's records, and staff interview, the laboratory failed to have a mechanism in place to ensure the temperature of patient's specimens were maintained during transport to the laboratory for testing for 21 of 21 months from September 2022 to June 2024. Findings include: 1. A review of the Viasure Real Time PCR Detection Kits Instructions for Use (IU-CFR 196TRUOenes1120 rev.03) revealed the following: "Patient samples must be collected, transport, and storage according to appropriate laboratory guidelines." 2. A review of the laboratory's policies revealed the laboratory failed to define collection, storage, and shipping /transport requirements for patient specimens. 3. Surveyor observation of the laboratory's accessioning area on 6/11/24 at 9:30 a.m. revealed the laboratory failed to have a mechanism in place for ensuring the temperature of the specimens were maintained during transport to the laboratory for testing. 4. A review of the laboratory's records revealed the laboratory started patient testing using the Viasure Real Time PCR Detection Kit in September 2022. 5. In an interview on 6/11/24 at 9:30 a.m. in the laboratory, after review of the records, testing person #1 (as indicated on the CMS 209 form) confirmed the above findings. Key: PCR = Polymerase Chain Reaction

D5317

SPECIMEN SUBMISSION, HANDLING, AND REFERRAL

CFR(s): 493.1242(d)

If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section.

This STANDARD is not met as evidenced by:
 Based on surveyor observation, a review of the laboratory's records, and staff interview, the laboratory failed to provide written instructions to its clients for the patient preparation, collection, labeling, storage, transportation, processing, and acceptability/rejection criteria of specimens for one of one test performed by the laboratory from September 2022 to June 2024. Findings include: 1. Surveyor observation of the laboratory on 6/11/24 at 9:30 a.m. revealed the laboratory received patient specimens from outside clients for Real-Time PCR (polymerase chain reaction) testing for SARS-CoV-2, Influenza A/B, and Respiratory Syncytial Virus A/B. 2. A review of the laboratory's records revealed the laboratory failed to have documentation of providing written instructions to its clients for the patient preparation, collection, labeling, storage, transportation, processing, and acceptability/rejection criteria of specimens. 3. In an interview on 6/11/24 at 9:30 a.m. in the laboratory, after review of the records, testing person #1 (as indicated on the CMS 209 form) confirmed the above findings.

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 surveyor's observations, review of manufacturer instructions, laboratory's policies/procedures, test establishment studies, temperature/humidity records and staff interview, the laboratory failed to meet analytic system requirements for one of one laboratory's test platform reviewed from September 2022 to June 2024, the laboratory developed SARS-CoV-2, Flu & RSV Real Time PCR (polymerase chain reaction). Findings included: 1. Laboratory failed to monitor and document reagent/kit storage room temperature to ensure reagent/kit integrity. Refer to D5413A. 2. Laboratory failed to follow manufacturer instructions for storage of reagents stored in the freezer. Refer to D5413B. 3. Laboratory failed to ensure the STM transport media had not exceeded its expiration date. Refer to D5417. 4. Laboratory failed to laboratory failed to perform complete establishment studies for its LDT (laboratory developed test): SARS-CoV-2, FLU & RSV Viasure Real-Time PCR (polymerase chain reaction) Assay. Refer to D5423. 5. Laboratory failed to utilize two control materials during the extraction phase every day of patient testing. Refer to D5453.

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:

A. Based on surveyor's observations, review of manufacturer instructions, laboratory's temperature records and staff interview, the laboratory failed to monitor and document reagent/kit storage room temperature to ensure integrity for 2 of 2 reagents/kits stored in the storage room, the Beckman Dickinson Universal Viral Transport and the Genolution NX-48S Viral NA Kit. Findings included: 1. Surveyor's observations on 06/11/2024 at 1220 hours revealed the following reagents/kits were stored in the storage room: a. Beckman Dickinson Universal Viral Transport for Viral Chlamydial, Mycoplasmal, and Ureaplasma Specimens Lot: N40050800 Expiration: 2025-07-25 Quantity: 1 box (50 count) b. Genolution NX-48S Viral NA Kit Lot: CVN153-231026 Expiration: 241025 quantity: 4 boxes 2. Review of manufacturer instructions for storage for the above reagent/kit (information provided on reagent/kit boxes) revealed: a. For the Beckman Dickinson Universal Viral Transport storage temperature was defined as 2-25C (Degrees Celsius). b. For the Genolution NX-48S Viral NA Kit storage temperature was defined as 15-35C. 3. Review of laboratory's temperature records revealed the laboratory did not monitor/document temperature in the storage room to ensure integrity of reagents/kits stored there. 4. In an interview on 06/11/2024 at 1225 hours in the office the laboratory's Testing Person number 1 (as indicated on submitted form CMS 209) confirmed the findings. B. Based on surveyor's observations, review of manufacturer instructions and staff interview, the laboratory failed to follow manufacturer instructions for storage of 3 of 3 reagents stored in the freezer, the Viasure CFR Positive Control, Negative Control and RNase/DNase Free Water. Findings included: 1. Surveyor's observations on 06/11/2024 at 1230 hours in the laboratory revealed the following reagents stored in the freezer in the Extraction Room: a. Viasure CFR Positive Control Lot: CFT1C-008 Expiration: 2026-01 Quantity: 27 vials b. Viasure Negative Control Lot: NC1-111 Expiration: 2027-08 Quantity: 37 vials c. Viasure RNase/DNase Free Water Lot: H2O-094 Expiration: 2026-02 Quantity: 23 vials d. Viasure SARS-CoV-2, Flu & RSV Real Time PCR Detection Reagents RUO Lot: CFR196TRUO-031 Expiration: 2024-10 Quantity: 1 box The temperature of the freezer at the time of surveyor's observations was -24.9C. 2. Review of manufacturer instructions for storage for the above reagents (information provided on reagent vials and box) revealed storage temperature was defined as 2-40C for all the above reagents. 3. In an interview on 06/11/2024 at 1230 hours in the Extraction Room, the laboratory's Testing Person number 1 (as indicated on submitted form CMS 209) confirmed the findings.

D5417

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

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on a review of the Instructions for Use for the MedSchenker Smart Transport Medium (STM), surveyor observation, a review of patient test records, and staff interview, the laboratory failed to ensure the STM had not exceeded its expiration date for 30 of 30 patient specimens tested on June 3, 2024. Findings include: 1. A review

of the Instructions for Use for the MedSchenker Smart Transport Medium (October 20,2020 Ver. 2.0) revealed the following: "Do not use after expiration date, which is clearly printed on the outer box and on each individual sterile pouch unit and the specimen transport tube label." 2. Surveyor observation of the laboratory on 6/11/24 at 10:50 a.m. revealed 30 patient specimens had been collected using the MedSchenker STM Lot number: EAC0SA1 expiration date: 7/2/23. 3. A review of patient test records confirmed the following 30 expired patient specimen tubes were used for Real-Time PCR (polymerase chain reaction) testing for SARS-CoV-2, Influenza A/B, and Respiratory Syncytial Virus A/B testing on 6/3/24: Patient IDs: 117707, 117713, 117714, 117696, 117702, 117701, 117708, 117694, 117704, 117720, 117724, 117716, 117709, 117715, 117698, 117705, 117706, 117717, 117722, 117721, 117710, 117697, 117712, 117695, 117723, 117711, 117718, 117699, 117703, 117700 4. In an interview on 6/11/24 at 10:50 a.m. in the laboratory, after review of the records, testing person #1 (as indicated on the CMS 209 form) confirmed the above findings.

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 surveyor observations, review of laboratory's test menu, manufacturer's instructions, laboratory's policy, laboratory-developed test (LDT) validation records and staff interview, the laboratory failed to perform complete establishment studies for one of one LDT: SARS-CoV-2, FLU & RSV Viasure Real-Time PCR (polymerase chain reaction) Assay. Findings included: A review of the laboratory's test menu found the laboratory performed one LDT: SARS-CoV-2, FLU & RSV Viasure Real-Time PCR Assay. A. Specimen Transport Systems: 1. Surveyor observations on 06/11/2024 at 1015 hours in the laboratory found the laboratory accepted two types of transport medium: Becton Dickinson Universal Viral Transport Medium (UTM) and MedSchenker Smart Transport Medium (STM). 2. Review of the laboratory's policy "Summary of Validation Studies Qualifying SARS-CoV-2, Flu & RSV Viasure Real-Time PCR Assay" approved by the laboratory director on September 29, 2023, revealed the policy did not include a specimen transport systems summary for the two of two types of transport media it accepted for testing: Becton Dickinson Universal Viral Transport Medium (UTM) and MedSchenker Smart Transport Medium (STM). 3. The laboratory failed to provide documentation of performing an establishment study for two of two specimen transport systems. 4. In an interview on 6/11/2024 at 1030 hours in the laboratory, testing person number 1 (as listed on Form CMS 209) confirmed the findings. B. Specimen Type: 1. In an interview on 06/11/2024 at 1015 hours in the laboratory, testing person number 1 (as listed on Form CMS 209) stated the laboratory accepted one specimen type, nasal. 2.

Review of random patient reports for samples 112639 (received 1/22/2024), 128003 (received 03/28/2024), and 117662 (received 05/23/2024) revealed the samples' type was documented as nasal. 3. Review of manufacturer instructions for the VIASURE SARS-CoV-2, Flu & RSV Real Time PCR Detection Kits (document IU-CFR196TRUOenes1120 rev.03) revealed: "Specimen Collection, Transport and Storage The VIASURE SARS-CoV-2, Flu & RSV Real Time PCR Detection Kit has been validated on nasopharyngeal and oropharyngeal specimens collected with synthetic fiber swabs with plastic and placed immediately into a sterile transport tube containing Universal transport medium (UTM) or Viral Transport Media (VTM)." 4. Review of the laboratory's policy "Summary of Validation Studies Qualifying SARS-CoV-2, Flu & RSV Viasure Real-Time PCR Assay" approved by the laboratory director on September 29, 2023, revealed the policy did not include a patient specimen summary for the type of patient specimen it accepted for testing, nasal. 5. The laboratory failed to provide documentation of performing an establishment study for patient specimen types. 6. In an interview on 6/11/2024 at 1030 hours in the laboratory, testing person number 1 (as listed on Form CMS 209) confirmed the findings. C. Specimen Stability: 1. In an interview on 06/11/2024 at 1015 hours in the laboratory, testing person number 1 (as listed on Form CMS 209) stated specimens arrived at the laboratory in FedEx envelopes/pouches at room temperature. 2. Review of the manufacturer's instructions for the Becton Dickinson UTM (document HPC173 Rev. 00 2020.07) revealed: "SPECIMEN COLLECTION AND PREPARATION ... Best recovery is obtained when specimens are refrigerated at 2-8C (Degrees Celsius) or kept on wet ice following collection and while in transit." 3. Review of the manufacturer's instructions for the MedSchenker Smart Transport Medium (document STM VECTOR NATE) revealed: "SPECIMEN COLLECTION, STORAGE AND TRANSPORTATION ...Best recovery is obtained when specimens are refrigerated at 2-8C or kept on wet ice following collection and while in transit." 4. Review of the laboratory's policy "Summary of Validation Studies Qualifying SARS-CoV-2, Flu & RSV Viasure Real-Time PCR Assay" approved by the laboratory director on September 29, 2023, revealed the policy did not include a specimen stability summary for specimen stability at room temperature or any other temperature range. 5. The laboratory failed to provide documentation of performing a specimen stability study for temperature for storage and transport of specimens. 6. In an interview on 6/11/2024 at 1030 hours in the laboratory, testing person number 1 (as listed on Form CMS 209) confirmed the findings. D. Interfering Substances: 1. Review of the manufacturer's instructions for the SARS-CoV-2, FLU & RSV Viasure Real-Time PCR Assay (document IU-CFR196TRUOenes1120 rev.03), under "10. Limitations of the test" revealed: "...False Negative results may arise from several factors and their combinations, including: ... the presence of RT-qPCR inhibitors or other types of interfering substances." 2. Review of the laboratory's policy titled "Summary of Validation Studies Qualifying SARS-CoV-2, Flu & RSV Viasure Real-Time PCR Assay" approved by the laboratory director on September 29, 2023, revealed the policy did not include an interfering substances summary. 3. The laboratory failed to provide documentation of performing establishments studies for potential interfering substances. 4. The laboratory reported performing an estimated 19,977 tests annually. 5. In an interview on 6/11/2024 at 1030 hours in the laboratory, testing person number 1 (as listed on Form CMS 209) confirmed the findings.

D5453

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(iv)(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--

At least once a day patient specimens are assayed or examined perform the following for-- Each test system that has an extraction phase, include two control materials, including one that is capable of detecting errors in the extraction process; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policies, a random review of the laboratory's extraction plate maps, and staff interview, the laboratory failed to utilize two control materials during the extraction phase every day of patient testing on the Nextractor NX-48S system for five of five days reviewed from December 2023 to June 2024. Findings include: 1. A review of laboratory's policy titled 'Extraction Plating of Viasure Real Time PCR Detection Kits Using NX-48S Viral Kit' revealed the procedure failed to include the use of two extraction control materials, including one that was capable of detecting errors in the extraction process. 2. A random review of the laboratory's extraction plate maps from December 2023 to June 2024 revealed the laboratory failed to utilize 2 control materials during the extraction phase on the following 5 dates when patients were tested: Date: 12/5/23 Patients tested: 108169, 108171, 108167, 108173, 108150, 108155, 108154, 108183, 108172, 108156, 108151, 108174, 108175, 108149, 108159, 108160, 108152, 108176, 108182, 108181, 108157, 108180, 108179, 108161, 108168, 108153, 108158, 108165, 108162, 108178, 108170, 108163, 108164, 108166, 108177, 332079 Date: 1/22/24 Patients tested: 112559, 122572, 112542, 112557, 112554, 112569, 112641, 112558, 112547, 112561, 112568, 112565, 112552, 112566, 112564, 112548, 112553, 112543, 112546, 112644, 112550, 112570, 112545, 112556, 112555, 112560, 112544, 112562, 112563, 112551, 112567, 112571, 112622, 112623, 112643, 112612, 112628, 112624, 112636, 112613, 112627, 112620, 112615, 112635, 112639 Date: 3/28/24 Patients tested: 128003, 128005, 128004, 128007, 128008, 128002, 128009, 128010, 128001, 128006, 128011 Date: 5/23/24 Patients tested: 117662, 117652, 117637, 117653, 117635, 117648, 117642, 117643, 117649, 117645, 117638, 117639, 117651, 117640, 117658, 117660, 117654, 117659, 117671, 117670, 117669, 117668, 117685, 117672, 117686, 117693, 117684, 117675, 117678, 117682, 117655, 117646, 117634, 117647, 117656, 117650, 117657, 117641, 117644, 117664, 117676, 117683, 117681, 117679, 117689, 117688, 117667, 117680, 117666, 117687, 117691, 117692, 117674, 117665, 117677, 117690 Date: 6/3/24 Patients tested: 117707, 117713, 117714, 117696, 117702, 117701, 117708, 117694, 117704, 117720, 117724, 117716, 117709, 117715, 117698, 117705, 117706, 117717, 117722, 117721, 117710, 117697, 117712, 117695, 117723, 117711, 117718, 117699, 117703, 117700, 117734, 117729, 117738, 117735, 117737, 117732, 117752, 117754, 117749, 117744, 117727, 117725, 117739, 117741, 117750, 117748, 117746, 117726, 117743, 117731, 117736, 117747, 117740, 117730, 117751, 117753, 117745, 117728, 117742, 124006, 124019, 124009, 124002, 124014, 124003, 124031, 124029, 124008, 124032, 124022, 124011, 124030, 124013, 124005, 124004, 124021, 124010, 124024, 124017, 124007, 124018, 124025, 124012, 124016, 124015, 124023, 124026, 124027 3. In an interview on 6/11/24 at 1:20 p.m. in the laboratory, after review of the records, testing person #1 (as indicated on the CMS 209 form, confirmed the above findings.

D5781

CORRECTIVE ACTIONS
CFR(s): 493.1282(b)(1)

(b) The laboratory must document all corrective actions taken, including actions taken

when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on review of manufacturer instructions, laboratory's humidity records and staff interview the laboratory failed to document corrective action for 54 of 54 days from January to March 2023 when the maximum humidity of the PCR room exceeded manufacturer required humidity range for the Endress Houser AnalytikJena qTower polymerase chain reaction (PCR) instrument's operation. Findings included: 1. Review of manufacturer instructions for the operation of the Endress Houser AnalytikJena qTower instrument (document IQ_qTower3_family_en_C, Version C) revealed: "The customer has to ensure, that the installation location meets the following environmental conditions: ... max. 70% (percent) relative humidity" 2. Review of the laboratory's humidity records from January to March 2024 revealed the following 54 days documented maximum humidity in the PCR room exceeded manufacturer instrument operation requirements without any documentation of corrective action: Operation Max. humidity Date: documented (%): 01/02/2022 71 01/03/2022 71 01/04/2022 71 01/05/2022 71 01/08/2022 71 01/09/2022 71 01/10/2022 71 01/11/2022 71 01/12/2022 71 01/15/2022 71 01/16/2022 71 01/17/2022 71 01/18/2022 71 01/19/2022 71 01/22/2022 71 01/23/2022 71 01/24/2022 71 01/25/2022 71 01/26/2022 71 01/29/2022 71 01/30/2022 71 01/31/2022 71 02/01/2022 71 02/02/2022 71 02/05/2022 71 02/06/2022 71 02/07/2022 71 02/08/2022 71 02/09/2022 71 02/12/2022 71 02/13/2022 71 02/14/2022 71 02/15/2022 71 02/16/2022 71 02/19/2022 71 02/20/2022 71 02/21/2022 71 02/22/2022 71 02/23/2022 71 02/26/2022 71 02/27/2022 71 02/28/2022 71 02/29/2022 71 03/01/2022 71 03/04/2022 71 03/05/2022 71 03/21/2022 71 03/22/2022 71 03/23/2022 71 03/24/2022 71 03/26/2022 71 03/27/2022 71 03/28/2022 71 03/29/2022 71 3. In an interview on 06/11/2024 at 1245 hours in the office the laboratory's Testing Person number 1 (as indicated on submitted form CMS 209) confirmed the findings.

D5785

CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(3)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.

This STANDARD is not met as evidenced by:

Based on review of laboratory's temperature records, corrective action records and staff interview, the laboratory failed to document corrective action for 25 of 25 minimum/maximum temperatures from February 2024, documented out of laboratory-defined acceptable range. Findings included: 1. Review of laboratory's temperature records revealed the laboratory defined the following acceptable temperature ranges: a. Extraction Room Acceptable Temperature Range: 20-25C (Degrees Celsius) b. Laboratory Acceptable Temperature Range: 20-25C c. PCR (polymerase chain

reaction) Room Acceptable Temperature Range: 20-25C d. PCR Room Refrigerator Acceptable Temperature Range: 2-8C e. Laboratory Freezer 2 Acceptable Temperature Range: -25C to -15C 2. Review of random laboratory's temperature records from February 2024 revealed the following documented minimum/maximum temperatures were out of laboratory-defined acceptable range: a. Extraction Room Operation Minimum Maximum Date Temperature Temperature 02/05/2022 12.2C 28.2C 02/06/2022 12.2C 28.2C 02/07/2022 12.2C 28.2C 02/08/2022 12.2C 28.2C 02/09/2022 12.2C 28.2C b. Laboratory Operation Minimum Maximum Date Temperature Temperature 02/05/2022 10.8C 28.4C 02/06/2022 10.8C 28.4C 02/07/2022 10.8C 28.4C 02/08/2022 10.8C 28.4C 02/09/2022 10.8C 28.4C c. PCR (polymerase chain reaction) Room Operation Minimum Maximum Date Temperature Temperature 02/05/2022 9.9C 28.2C 02/06/2022 9.9C 28.2C 02/07/2022 9.9C 28.2C 02/08/2022 9.9C 28.2C 02/09/2022 9.9C 28.2C d. PCR Room Refrigerator Operation Minimum Maximum Date Temperature Temperature 02/05/2022 -7.0C 26.9C 02/06/2022 -7.0C 26.9C 02/07/2022 -7.0C 26.9C 02/08/2022 -7.0C 26.9C 02/09/2022 -7.0C 26.9C e. Laboratory Freezer 2 Operation Minimum Maximum Date Temperature Temperature 02/05/2022 -26.2C -9.0C 02/06/2022 -26.2C -9.0C 02/07/2022 -26.2C -9.0C 02/08/2022 -26.2C -9.0C 02/09/2022 -26.2C -9.0C 3. Review of laboratory's corrective action records revealed there was no documentation of corrective action taken for the above minimum/maximum temperatures documented out of laboratory-defined acceptable range. 4. In an interview on 06/11/2024 at 1245 hours in the office the laboratory's Testing Person number 1 (as indicated on submitted form CMS 209) confirmed the findings.

D5801

TEST REPORT
CFR(s): 493.1291(a)

The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

This STANDARD is not met as evidenced by:
Based on a review of the laboratory's policies, the laboratory's extraction plate maps, the laboratory's patient reports, and staff interview, the laboratory failed to have a system in place to ensure patient results were accurate and complete from entry point to final report for 88 of 88 patients tested on 6/3/24. Findings include: 1. A review of the laboratory's policy titled 'Patient Intake with ELIS System' revealed the following: "ELIS has rule generated reports with internal and/or external instrument interfaces Infinitely customizable combination(s) of tests and panels Customizable reports, headers, footers, logos for each lab, each clinic or each provider No reporting middleware required Unlimited number of patient, clinic, provider and/or customer accounts. Customizable, precise rule creation for resulting, cutoffs and alerts Automated test resulting & uploading Secure Reporting, HIPAA Compliant. The ELIS software is fast & efficient instrument integration Interfaces directly with all lab instruments requiring no 3rd party software." 2. A review of the laboratory's extraction plate maps from 6/3/24 revealed 88 patients were run using the Viasure Real Time PCR Detection Kit and tested negative for SARS-COV-2, Influenza A/B,

and Respiratory Syncytial Virus A/B. 3. A review of the laboratory's patient reports for the following 88 patients revealed the results for SARS-COV-2, Influenza A/B, and Respiratory Syncytial Virus A/B were available in the ELIS system but the final reports, available to the healthcare provider, were blank: 117707, 117713, 117714, 117696, 117702, 117701, 117708, 117694, 117704, 117720, 117724, 117716, 117709, 117715, 117698, 117705, 117706, 117717, 117722, 117721, 117710, 117697, 117712, 117695, 117723, 117711, 117718, 117699, 117703, 117700, 117734, 117729, 117738, 117735, 117737, 117732, 117752, 117754, 117749, 117744, 117727, 117725, 117739, 117741, 117750, 117748, 117746, 117726, 117743, 117731, 117736, 117747, 117740, 117730, 117751, 117753, 117745, 117728, 117742, 124006, 124019, 124009, 124002, 124014, 124003, 124031, 124029, 124008, 124032, 124022, 124011, 124030, 124013, 124005, 124004, 124021, 124010, 124024, 124017, 124007, 124018, 124025, 124012, 124016, 124015, 124023, 124026, 124027 4. In an interview on 6/11/24 at 10:00 a.m. in the laboratory, after review of the records, testing person #1 (as indicated on the CMS 209 form) confirmed the above findings.

D5805

TEST REPORT
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:
Based on a random review of patient's test reports from December 2023 to June 2024 and staff interview, the laboratory failed to include the correct suite number of the testing facility on six of six patient's test reports reviewed. Findings include: 1. A random review of patient's test reports from December 2023 to June 2024 revealed the laboratory failed to include the correct suite number of the testing facility on the following 6 patient's test reports: Patient ID: E2063 Reported: 12/6/23 Patient ID: E4707 Reported: 1/22/24 Patient ID: E4790 Reported: 4/5/24 Patient ID: E47 Reported: 6/4/24 Patient ID: E4704 Reported: 6/4/24 Patient ID: E2131 Reported: 6/4/24 *The above listed patient reports indicated the testing was performed in suite number 205, the correct suite number is 210. 2. In an interview on 6/11/24 at 11:08 a.m. in the laboratory, after review of the records, the testing person #1 (as indicated on the CMS 209 form) confirmed the above findings.

D6076

LABORATORY DIRECTOR
CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:

Based on surveyor observation, review of the laboratory's policies, the laboratory's records, and staff interview, the laboratory director failed to provide overall management and direction for one of one test performed by the laboratory from September 2022 to June 2024. Findings include: 1. Laboratory director failed to ensure pre-analytic, analytic, and post-analytic systems provided quality results. Refer to D6082. 2. Laboratory director failed to ensure establishment/verification procedures were complete. Refer to D6086. 3. Laboratory director failed to ensure a quality control program was established and maintained. Refer to D6093.

D6082

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(1)

The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing.

This STANDARD is not met as evidenced by:
Based on surveyor observation, review of the laboratory's policies, the laboratory's records, and staff interview, the laboratory director failed to ensure pre-analytic, analytic, and post-analytic systems provided quality results for one of one test performed by the laboratory from September 2022 to June 2024. Findings include: 1. Laboratory failed to establish a written policy for the collection, storage, and shipping /transport requirements of patient specimens. Refer to D5311 A. 2. Laboratory failed to have a mechanism in place to ensure the temperature of patient's specimens were maintained during transport to the laboratory for testing. Refer to D5311 B. 3. Laboratory failed to provide written instructions to its clients for the patient preparation, collection, labeling, storage, transportation, processing, and acceptability /rejection criteria of specimens. Refer to D5317. 4. Laboratory failed to monitor and document reagent/kit storage room temperature to ensure reagent/kit integrity. Refer to D5413A. 5. Laboratory failed to follow manufacturer instructions for storage of reagents stored in the freezer. Refer to D5413B. 6. Laboratory failed to ensure the STM transport media had not exceeded its expiration date. Refer to D5417. 7. Laboratory failed to document corrective action when the maximum humidity of the PCR room exceeded manufacturer required humidity range. Refer to D5781. 8. Laboratory failed to document corrective action for minimum/maximum temperatures when documented out of laboratory-defined acceptable range. Refer to D5785. 9. Laboratory failed to have a system in place to ensure patient results were accurate and complete from entry point to final report. Refer to D5801. 10. Laboratory failed to include the correct suite number of the testing facility on patient's test reports reviewed. Refer to D5805.

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 surveyor observation, a review of laboratory's policies, the laboratory's

records, and staff interview, the laboratory director failed to ensure establishment /verification procedures were complete for one of one test performed by the laboratory from September 2022 to June 2024. Findings include: 1. Laboratory failed to document establishment/verification of 5 test performance characteristics to ensure quality testing. Refer to D5423.

D6093

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:
Based on review of laboratory's policies, the laboratory's records, and staff interview, the laboratory director failed to ensure a quality control program was established and maintained for one of one test performed by the laboratory from September 2022 to June 2024. Findings include: 1. Laboratory failed to utilize two control materials during the extraction phase every day of patient testing. Refer to D5453.