Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0919666	12/22/2020
Name of Provider or Supplier	**Street Address, City, State**	
Respiratory Virus Diagnostic Laboratory	Baylor College Of Medicine, Houston, TX	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) 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. This STANDARD is not met as evidenced by: Based on a review of the College of American Pathologists Attestation form, a review of the laboratory's College of American Pathologists proficiency testing records from 2019 and 2020, a review of personnel files, and staff interview, it was revealed the laboratory failed to have documentation of the laboratory director or designee signing 5 of 5 attestation statements and documentation of the testing personnel signing 2 of 5 attestation statements for 2019 and 2020. Findings include: 1. A review of the College of American Pathologists Attestation form revealed the following: "The laboratory director or designee and the testing personnel must sign on the result form." 2. A review of the laboratory's College of American Pathologists proficiency testing records from 2019 and 2020 revealed the following 5 events that had missing signatures on the attestation forms: a) Laboratory director or designee 2019 Nucleic acid amplification, Respiratory - ID2 First event 2019 Nucleic acid amplification, Respiratory - ID2 Second event 2020 Nucleic acid amplification, Respiratory - ID2 First event 2020 Nucleic acid amplification, Respiratory - ID2 Second event 2020 SARS-CoV-2 - COV2 *The attestation statements were signed by technical

	supervisor #2 (as indicated on the CMS 209 form, signed by the laboratory director on 12/21/20). b) Testing personnel 2020 Nucleic acid amplification, Respiratory - ID2 First event 2020 SARS-CoV-2 - COV2 3. A review of technical supervisor #2 personnel records revealed a Delegation of Duties form. The Delegation of Duties form for technical supervisor #2, signed by the laboratory director on 12/14/20, revealed no delegation for the technical supervisor to sign attestation statements. 4. An interview with laboratory quality director on 12/21/20 at 12:25 p.m. in the office, after review of the records, confirmed the above findings.
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 manufacturer's instructions, laboratory policies and records, surveyor observations, and confirmed in interview, the laboratory failed to establish and follow written policies for conditions for specimen transport and specimen acceptability and rejection for the qualitative detection of nucleic acid from SARS-CoV-2 using the CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel. Findings were: 1. Review of Instructions for Use (IFU) for the CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel (CDC-006-00019, Revision: 06) under Specimen Collection, Handling, and Storage revealed "Inadequate or inappropriate specimen collection, storage, and transport are likely to yield false test results...Specimens can be stored at 2-8C for up to 72 hours after collection. If a delay in extraction is expected, store specimens at -70C or lower. Extracted nucleic acid should be stored at -70C or lower." 2. Review of the laboratory policies available revealed no documentation of the conditions for specimen transport or specimen acceptability and rejection for the qualitative detection of nucleic acid from SARS-CoV-2 using the CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel. Specimen Transport 3. Surveyor observations on 12/21/20 at 1225 hours in the laboratory revealed a laboratory courier delivering viral transport kits in an Igloo cooler for the qualitative detection of Covid-19 nucleic acid testing with no documentation of the transport temperature for 26 of 26 specimen delivered. Sample ID 192023043D 192023044D 192023045D 192023046D 192023047D 192023048D 192023049D 192023050D 192023051D 192023052D 192023053D 192023054D 192023055D 192023056D 192023057D 192023058D 192023059D 192023060D 192023061D 192023062D 192023063D 192023064D 192023065D 192023066D 192023067D 192023068D Specimen Rejection and Acceptability 4. Review of the laboratory quality assessment records from 12/2020 revealed a memo dated 12/8/20 that revealed "These Nu samples were received from McNaire Transport Team for PCR testing. Below is the list of samples that came with no transport media...[laboratory] has added 3 ml of Viral Transport media since they had a swab in the tubes. 192010495D 192010590D 192010905D 192015831D 192017902D 192018187D 192018225D 192020636D 5. Review of the laboratory records revealed the laboratory analyzed and reported the above specimens. 6. Review of the laboratory records revealed the laboratory started Covid-19 testing in 03/25

	/2020. Review of the CMS116 revealed the laboratory performed 100,000 Virology testing annually 7. An interview with the laboratory director on 12/22/20 at 1020 hours in the laboratory office confirmed the above findings. He explained that the laboratory practice is to use Rnase contamination detection criteria to determine the specimen quality. He acknowledged that the laboratory should establish and follow their acceptance and rejection criteria along with the transport conditions.
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 review of the laboratory policies and confirmed in interview, the laboratory failed to document a client service manual to include conditions of specimen transport and the specimen acceptability and rejection criteria for the qualitative detection of nucleic acid from SARS-CoV-2 using the CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel. Findings were: 1. Review of the YOCON Biology Technology Company Viral Sampling Kit (March 25, 2020) revealed "the collected nasopharyngeal swab samples should be transported at 2C-8C and submitted for inspection immediately. Sample transport and storage time should be no later than 48h." 2. Review of the laboratory collection manual Covid-19 H-4723 Transportation of Study Samples revealed no documentation of the conditions of specimen transport and specimen acceptability and rejection criteria (stability) for the qualitative detection of nucleic acid from SARS-CoV-2 using the CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel. 3. An interview with the laboratory director on 12/22/20 at 1010 hours in the laboratory office confirmed the above findings. He stated that the specimen collection is typically handled by the testing site. He was unaware he was required to provide specific instructions to the collection site for their testing.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the laboratory policies and records and confirmed in interview the laboratory failed to document an approved laboratory procedure for laboratory processing for the qualitative detection of nucleic acid from SARS-CoV-2 using the CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel prior to start of patient testing. Findings were: 1. Review of the laboratory policies and records revealed the laboratory used the Instructions for Use (IFU) for the CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel (CDC-006-00019, Revision: 06). Review of the IFU revealed no documentation of the laboratory directors approval or signature. 2. Review of the laboratory records revealed the laboratory started Covid-19 testing in 03/25/2020. Review of the CMS116 revealed the laboratory performed 100,000 Virology testing annually. 3. An

	interview with the laboratory director on 12/22/20 at 1000 hours in the laboratory office confirmed the above findings.
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 manufacturer's instructions, CMS guidance Ref: QSO 18-19-CLIA, laboratory records, and confirmed in interview, the laboratory failed to document complete verification studies prior to patient testing for 1 of 2 tests: the qualitative detection of nucleic acid from SARS-CoV-2 using the CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel. Findings were: 1. Review of the Instructions for Use (IFU) (CDC-006-00005, Revision 6) revealed "please consult the following guidance from the Centers for Medicare & Medicaid Services (CMS) regarding diagnostic tests under Emergency Use Authorization (EUA): https://www.cms.gov/Medicare/Provider-Enrollment-andCertification /SurveyCertificationGenInfo/Policy-and-Memos-to-States-and-RegionsItems/QSO18-19-CLIA." 2. Review of the CMS guidance Ref: QSO 18-19-CLIA revealed "When the number of positive samples that a laboratory would normally run for verification of performance specifications is not available, it is the responsibility of the laboratory director (LD) (see 493.1445(e)(3)(ii)) to ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method...Laboratories are required to verify performance specifications for CDC developed EUA assays per 42 CFR 493.1253(b)(1). In general, CDC developed test kits provide an initial set of samples for verifying performance specifications and instructions for their use. Laboratories using a CDC developed assay authorized for emergency use should follow any and all instructions provided for verifying performance specifications." 3. Review of the laboratory policies available revealed no documentation of a policy for verifying 1 of 2 tests: the qualitative detection of nucleic acid from SARS-CoV-2 using the CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel. 4. Review of the laboratory verification records for the qualitative detection of nucleic acid from SARS-CoV-2 using the CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel revealed no documentation of the acceptance or acceptance criteria determined for the studies performed. 5. An interview with the laboratory director on 12/22/20 at 0930 hours in the laboratory office confirmed the above findings. He acknowledged that the laboratory should establish and follow policies when performing verification studies.
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 a review of the Janus G3 Automated Workstation User Manual, a review of the laboratory's installation records, and staff interview, it was revealed the laboratory failed to have documentation of performing the required daily, weekly, and quarterly maintenance procedures on the two Janus G3 workstations for 4 of 4 months in 2020. Findings include: 1. A review of the Janus G3 Automated Workstation User Manual (CLS146040 Rev. F, 4/2019) states the following preventative maintenance is required: a) Daily - Flush the Varispan Pipetting Arm with Degassed Distilled Water - Clean the Work Surface, Tiles, and Racks - Check the Syringe Pump Outlet Tubing - Clean and Fill the System Liquid Container - Empty the Waste Container - Clean the Sampling Tips b) Weekly - Clean the Z-Racks - Flush System if Unused For Any Extended Period - Visually Check Tubing - Visually Check Syringes - Calibrate the Deck c) Quarterly - Disinfect the Fluid Path - Clean the Waste Tubing - Test the Syringes - Test Tip Pickup - Test Liquid Level Sense 2. A review of the laboratory's installation records revealed the two Janus G3 Automated Workstations (Serial numbers JA2012N3119 and JA2044N3671) were installed in July 2020. 3. The laboratory was asked for documentation of performing the required maintenance procedures for the two Janus G3 workstations for the 4 months (August, September, October, November) since installation. No documentation was provided. 4. An interview with technical supervisor #2 (as indicated on the CMS 209 form, signed by the laboratory director on 12/21/20) on 12/21/20 at 3:30 p.m. in the laboratory, after review of the records, confirmed that they are performing some maintenance procedures, but they have not created a form to document which maintenance procedures are being performed and when they are performed.