Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0919666	05/22/2024
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	An onsite survey conducted 05/22/2024 found the laboratory in compliance with 42 CFR Part 493, Requirements for Laboratories. Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility was found to be in compliance with applicable Conditions in the CLIA program, and recertification is recommended.
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on a review of the CMS 209 form, personnel records, the laboratory's CAP proficiency testing attestation sheets in 2023, and confirmed in an interview, the laboratory failed to ensure that proficiency testing samples were analyzed by personnel who routinely performed patient testing in the laboratory for 3 of 3 proficiency testing events. The findings were: 1. A review of the laboratory's CMS 209 form, signed by the laboratory director on 05/21/2024, revealed 2 testing personnel performing high complexity testing. 2. Review of the CAP proficiency testing attestation sheets in 2023 revealed all 3 events were tested by Testing person #1. IDR-A 2023 IDR-B 2023 IDR-C 2023 3. In an interview on 05/22/2024 at 11:37 am in the conference room, the technical supervisor confirmed the above findings. Key: CMS=Center of Medicare and Medicaid Services CAP=College of American Pathologists IDR=Infectious Disease, Respiratory
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c)

	(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on the surveyor's direct observation, the laboratory's test menu, the laboratory's records in 2003, the laboratory's CMS 116 application form, and confirmed in an interview, the laboratory failed to have documentation for 2 of 2 comparison evaluations twice a year in 2023 for 4 instruments performing the same 17 viral targets and 2 bacterial targets. The findings were: 1. The surveyor's direct observation on 05/22/2024 at 11:45 am in the lab revealed the laboratory had 4 instruments performing the tests. ABI 7500 DX SN: 215031503 1st patient date: in 2020 ABI Steponeplus SN: 2720013521 1st patient date: in 2022 ABI Steponeplus SN: 2720013578 1st patient date: in 2022 ABI Steponeplus SN: 2720013012 1st patient date: in 2021 2. In an interview with the technical supervisor on 05/22/2024 at 11:55 am in the lab and review of the laboratory's test menu confirmed the above 4 instruments performing all of the following 17 viral targets and 2 bacterial targets. Viral Targets RSV A rt RT-PCR RSV B rtRT- PCR Flu A rtRT-PCR Flu B rtRT-PCR hCov 229E rtRT-PCR hCov OC43 rtRT-PCR hCov HKU1 rtRT-PCR hCov NL63 rtRT-PCR ParaFlu I rtRT-PCR ParaFlu II rtRT-PCR ParaFlu III rtRT-PCR ParaFlu IV rtRT-PCR hMPV (human metapneumovirus) rtRT-PCR Adenovirus rtRT-PCR HRhino V rtRT-PCR Enterovirus rtRT-PCR Bocavirus rtRT-PCR Bacterial Targets Mycoplasma Pneumoniae Bordetella Pertusis 3. Review of the laboratory's records in 2023 revealed the laboratory failed to have documentation for 2 of 2 comparison evaluations twice a year among 4 ABI instruments. 4. Review of the laboratory's CMS 116 application, signed by the laboratory director on 05/21/2024, revealed the annual volume was 150. 5. In an interview on 05/22/2024 at 1:52 pm in the conference room, the testing personnel #1 confirmed the above findings. Key: CMS=Center of Medicare and Medicaid Services ABI=Applied Biosystems Instruments