Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 45D2287935	**(X3) Date Survey Completed** 01/25/2024
Name of Provider or Supplier Baylor College Of Medicine Dba	**Street Address, City, State** One Baylor Plza Room 214 E Rm 214 B, 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	The laboratory was surveyed and found to be in compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780, and recertification is recommended.
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: Based on surveyor observation, a review of the operations manuals for the Olympus U-DO3 and BX 41 Microscopes, the laboratory's records, and staff interview, the laboratory failed to have documentation of monitoring the temperature and humidity in two offices of testing personnel where laboratory equipment was used for patient testing for six of six months from August 2023 to January 2024. Findings include: 1. Surveyor observation on 1/25/24 at 920 hours found the following laboratory equipment in the offices of 2 testing personnel: a) Office of testing person #1 room 214-B: Olympus BX 41 System Microscope No. 2C18105 b) Office of testing person #2 room 214-E: Olympus U-DO3 System Microscope No. 2M07857 2. A review of the operations manuals for the microscopes found in the testing personnel's offices revealed the manufacturer required the following conditions for operation: a) Olympus BX 41 System Microscope (M 050, 11/2001) "Ambient temperature: 5C to 40C (41 to 104 F) Maximum relative humidity: 80% for temperatures up to 31C

	(88F), decreasing linearly through 70% at 34C (93F), to 60% at 37C (99F), to 50% relative humidity at 40C (104F)." b) Olympus U-DO3 System Microscope (M 002, 03 /2000) "Ambient temperature: 5C to 40C (41 to 104 F) Maximum relative humidity: 80% for temperatures up to 31C (88F), decreasing linearly through 70% at 34C (93F), to 60% at 37C (99F), to 50% relative humidity at 40C (104F)." 3. A review of the laboratory's records from August 2023 to January 2024 revealed the laboratory failed to have documentation of monitoring the temperature and humidity in the two offices where the microscopes were used for patient testing 4. A random review of the laboratory's records revealed the following patients were reported using the Olympus microscopes and the laboratory failed to have documentation of monitoring the temperature and humidity in the offices: Case number: DB-23-04165 reported on 8/22 /23 Case number: DB-23-04303 reported on 8/28/23 Case number: DB-23-04567 reported on 9/11/23 Case number: DB-23-04968 reported on 9/28/23 Case number: DB-23-05693 reported on 11/7/23 5. In an interview on 1/25/24 at 910 hours in the conference room, after review of the records, the laboratory director confirmed the above findings.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on surveyor observation, a review of the operations manuals for the Olympus U-DO3 and BX 41 Microscopes, the laboratory's policies, the laboratory's records, and staff interview, the laboratory failed to have documentation of performing the required maintenance procedures on two Olympus microscopes for six of six months from August 2023 to January 2024. Findings include: 1. Surveyor observation on 1/25 /24 at 920 hours found the following laboratory equipment in the offices of 2 testing personnel: a) Office of testing person #1 room 214-B: Olympus BX 41 System Microscope No. 2C18105 b) Office of testing person #2 room 214-E: Olympus U-DO3 System Microscope No. 2M07857 2. A review of the operations manuals for the microscopes found in the testing personnel's offices revealed the manufacturer required the following maintenance procedures: a) Olympus BX 41 System Microscope (M 050, 11/2001) "Clean all glass components by wiping gently with gauze." b) Olympus U-DO3 System Microscope (M 002, 03/2000) "Clean all glass components by wiping gently with gauze." 3. A review of laboratory's policies revealed the laboratory failed to have protocols in place that addressed microscope maintenance (cleaning) and its frequency. 4. A review of the laboratory's records revealed the laboratory failed to have documentation of performing the required cleaning of two Olympus microscopes for six months from August 2023 to January 2024. 5. A random review of the laboratory's records revealed the following patients were reported using the Olympus microscopes and there was no documentation of the laboratory performing the required cleanings: Case number: DB-23-04165 reported on 8/22/23 Case number: DB-23-04303 reported on 8/28/23 Case number: DB-23-04567 reported on 9/11/23 Case number: DB-23-04769 reported on 9/21/23 Case number:

	SB-23-06929 reported on 9/22/23 Case number: DB-23-04867 reported on 9/26/23 Case number: DB-23-04968 reported on 9/28/23 Case number: DB-23-04971 reported on 9/28/23 Case number: DB-23-05004 reported on 10/2/23 Case number: DB-23-05693 reported on 11/7/23 6. In an interview on 1/25/24 at 915 hours in the conference room, after review of the records, the laboratory director 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 August to November 2023 and staff interview, the laboratory failed to include the address of the testing facility on ten of ten patient's test reports reviewed. Findings include: 1. A random review of patient's test reports from August to November 2023 revealed the laboratory failed to include the address of the testing facility on the following 10 patient's test reports: Case number: DB-23-04165 reported on 8/22/23 Case number: DB-23-04303 reported on 8/28/23 Case number: DB-23-04567 reported on 9/11/23 Case number: DB-23-04769 reported on 9/21/23 Case number: SB-23-06929 reported on 9/22/23 Case number: DB-23-04867 reported on 9/26/23 Case number: DB-23-04968 reported on 9 /28/23 Case number: DB-23-04971 reported on 9/28/23 Case number: DB-23-05004 reported on 10/2/23 Case number: DB-23-05693 reported on 11/7/23 2. In an interview on 1/25/24 at 1020 hours in the conference room, after review of the records, the laboratory director confirmed the above findings.