Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2041010	09/10/2020
Name of Provider or Supplier	**Street Address, City, State**	
Baylor College Of Medicine	333 N Texas Avenue, Webster, 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 at the entrance and exit conferences. The facility representative was 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. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
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 a review of the laboratory's procedure manuals and staff interview, it was revealed 2 of 3 current laboratory procedure manuals were not approved, signed and dated by the laboratory director. The findings were: 1. A review of the current laboratory procedure manuals revealed 2 of 3 manuals were not approved, signed and dated by the current laboratory director. The manuals without documentation of laboratory director review and approval were: "Collection Manual" and "Gross Dissection Manual" which included procedures for collection of pathology specimens and gross dissection. 2. An interview with facility personnel on 09/10/2020 at 0940 hours in the laboratory, stated " Oh I guess he didn't sign it".

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: Review of the laboratory policy, review of manufacturer instructions for the Leica Cryostat, review of the instrument environmental records and interview with facility personnel found that the laboratory failed to document the temperature and humidity in laboratory on 1 of 26 days of use. The findings included: 1. Review of the laboratory's "Histology Quality Control Maintenance Leica Cryostat Policy" under " Upon Use", states "Check Relative humidity: less than 60%. Check room temperature: Less than 95 degrees Fahrenheit". 2. Based on review of the manufacturer's instructions for the Leica Cryostat CM1859UV (serial # 1523/11 2008) under "Technical Data" states, " Operating temperature range (ambient temperature): 18 C to 35 C. All specifications related to temperature are valid only up to an ambient temperature of 22 C and air humidity lower than 60%." 3. Review of the Leica Cryostat Instrument Quality Control record, revealed no documentation for temperature or humidity June 11, 2020. 3. In an interview with facility personnel conducted on September 10, 2020 at 1215 hours confirmed that the laboratory did not record the temperature and humidity of the room where instrumentation was used to prepare patient specimens. Key C - Celsius
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 laboratory policies, and laboratory environmental logs and confirmed in interview it was revealed that the laboratory failed to: A) Document maintenance protocols for the Leica Cryostat used at the facility, and; B) Document maintenance for the Olympus Microscope. The findings were: A) No documentation of maintenance protocols for the cryostat: 1. Review of laboratory procedure "Histology Quality Control Maintenance Leica Cryostat" under " After Use", states" Clean and disinfect inside of machine with 100% Alcohol. Clean outside of machine with EPA approved tuberculocidal disinfectant or bleach solution. 2. Review of laboratory Leica Cryostat Instrument Quality Control logsheet from September 2018 through September 2020, revealed no documentation for cleaning the cryostat on 5 of 26

	processing's of patient specimens. 3. An interview with the facility personnel on 09/10 /2020 at 1215 hours in the 2nd floor conference room confirmed the findings. B) No documentation of maintenance for the Olympus microscope 1. A review of laboratory procedure "Histology Quality Control and Maintenance Olympus" under " When Used" states " Dust off stage and lens with lens paper. Turn off when not in use. Cover when finished. Replace bulb as needed. Document on Frozen Section Logsheet." 2. Review of Houston Physician Hospital Frozen Section Log Book from September 2018 through September 2020 revealed no documentation of QC for the Olympus microscope for 1 of 26 days on April 16, 2019. 3. An interview with the facility personnel on 09/10/2020 at 1215 hours in the 2nd floor conference room confirmed the findings. Key QC - Quality Control
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 the laboratory's quality assurance program, review of the Leica cryostat instrument quality control log, an interview with facility personnel the laboratory failed to document corrective action when documenting and H&E stain as unacceptable. The findings were: 1. A review of the laboratory's procedure "Quality Assurance Program" under "Quality Control" states "All H&E and DIFFQUIK stained tissue sections are evaluated by the pathologists and documented on the frozen section summary form. Any suboptima staining or microtomy issues will be immediately addressed and documented on these forms under corrective action. The histotechnician is responsible for documenting this corrective action." 2. A review of the Leica cryostat instument quality control log from September 2018 through September 2020, revealed no corrective action was documented for unacceptable H&E stains for 2 of 26 days, September 25, 2018 and October2, 2019. 4. An interview with facility personnel on 09/10/2020 at 1025 hours confirmed the findings. Key H&E -Hemotoxylin & Eosin
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of Quality Assurance plan, review of laboratory records from

	September 2018 through September 2020, and confirmed in staff interview, the laboratory director failed to ensure an effective QA (Quality Assessment) system was in place to monitor, assess and correct problems in the laboratory. Finding were: 1. A review of the laboratory policy "Quality Assurance Program" revealed the laboratory had a quality assurance program policy placed in the laboratory's manual. The policy revealed under "Principle" states "The laboratory is committed to complete compliance with all State and Federal regulations. Part of these requirements state that a quality control/quality assurance plan be in place to monitor analytic performance, document problems, assignment of responsibilities and implement resolutions". a. "The Medical Director will review and sign the QC charts." b. "All H&E and DIFFQUICK stained tissue sections are evaluated by the pathologists and documented on the frozen section summary form. any sub-optimal staining or microtomy issues will be addressed immediately and documented on these forms under corrective action." c. "Laboratory benches and cryostat are cleaned upon completion of the frozen section case." 2. A review of the monthly temperature and humidity checks revealed no corrective action when temperature and humidity were not recorded Date of no Date signed by Corrective action Laboratory Director 06/11/2020 06/07/2020 3. A review of the monthly Leica Cryostat Instrument Quality Control revealed no corrective action when the cryostat cleaning was not documented. Date of no Date signed by Corrective action Laboratory Director 03/26/2019 3/29/2019 09/02/2019 10 /29/2019 01/28/2020 04/13/2020 02/20/2020 04/13/2020 04/24/2020 06/05/2020 06/11 /2020 07/07/2020 4. A review of the monthly Frozen Section Log Book for Olympus microscope QC, revealed no corrective action when the microscope QC was not documented. Date of no Date signed by Corrective action Laboratory Director 04/16 /209 no date 5. A review of monthly Leica Cryostat Instrument Quality Control for H&E, revealed no corrective action when the H&E quality was documented as unacceptable. Date of no Date signed by Corrective action Laboratory Director 09/25 /2018 10/4/2018 100/2/2019 04/13/2020 6. An interview with the facility personnel on 09/10/2020 at 1215 hours revealed this was the only quality assurance policy in place and after she reviewed the records, she confirmed the laboratory director did not catch the lack for corrective action for unacceptable results or QC. Key QC- Quality Control H&E- Hematoxolyin and Eosin