Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0663033	03/16/2021
Name of Provider or Supplier	**Street Address, City, State**	
Baylor College Of Medicine	1977 Butler Boulevard, Suite E6 200, 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.
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on surveyor observation and confirmed in interview, the laboratory failed to ensure the safety of the laboratory by incorrect storage of 1 of 6 reagents (Alcohol) used in Mohs testing. Findings included: 1. Surveyor observations on 3/16/21 at 0920 hours in the laboratory revealed the following Alcohol reagent stored under the sink in the laboratory. 95% Reagent Alcohol ACS Grade dehydrant lot 069330, exp 09/1 /2020 2. Review of the label of the of the above alcohol reagent revealed "highly flammable liquid and vapor...keep container tightly closed. Storage: store in a locked dry, cool and well ventilated place." 3. An interview with the histology supervisor on 3 /16/21 at 1120 hours in the laboratory confirmed the above findings. She stated that she kept the alcohol under the sink temporarily since the facility used the lab supply if stored in the flammable cabinet.
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 observations, review of laboratory and patient test records from 11 /4/20 to 3/9/21 and confirmed in interview, the laboratory failed to establish and monitor the proper storage of 2 of 6 (KOH and Alcohol) reagents stored in 2 of 3 rooms used in the laboratory. A. KOH room B. storage room Findings were: A. KOH room 1. Surveyor observations on 3/16/21 at 1020 hours in the KOH room revealed 2 dropper bottle of KOH (lot 0564-01, exp 2/28/22). 2. Review of the label for the KOH solution revealed a storage temperature of 15-30 C. 3. Surveyor observations on 3/16 /21 at 1025 hour in the KOH room revealed no mechanism to monitor the room temperature. 4. Random sampling of KOH testing from 11/4/20 to 03/09/21 revealed the laboratory performed the following 10 KOH tests. Date Patient initials Result 11 /04/20 RM Positive 11/05/20 BB Negative 11/18/20 LD Positive 12/02/20 MC Negative 12/14/20 WS Negative 01/15/21 JR Negative 01/15/21 CS Positive 02/02/21 IG Positive 03/01/21 MN Negative 03/09/21 AH Negative 5. An interview with the histology supervisor on 3/16/21 at 1120 hours in the laboratory confirmed the above findings. key: KOH - Potassium Hydroxide prep to test for fungal elements B. Storage Room 1. Surveyor observations on 3/16/21 at 1040 hours in the storage room revealed 4 unopened bottles of MCC (Medical Chemical Corporation) 100% Alcohol (lot 1684-00, exp 12/31/23). 2. Review of the label for the alcohol solution revealed a storage temperature of 15-35 C. 3. Surveyor observations on 3/16/21 at 1045 hour in the storage room revealed no mechanism to monitor the room temperature. 4. An interview with the histology supervisor on 3/16/21 at 1120 hours in the laboratory confirmed the above findings
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on surveyor observations, patient test records from November 2020 to March 2021, and confirmed in interview, the laboratory failed to document the appropriate lot number and expiration date of the KOH solution that was transferred onto 2 of 2 dropper bottles used for KOH testing. Findings were: 1. Surveyor observations on 3/16 /21 at 1010 hours in the KOH room revealed 2 of 2 KOH dropper bottles with the following information: lot number 8369-00 and the expiration date blacked out making it unreadable. 2. Interview of the histology supervisor on 3/16/21 at 1012 hours in the KOH room revealed the actual KOH solution in the 2 dropper bottles was transferred from a bigger bottle of KOH (lot 0564-01, exp 2/28/22). She confirmed

	that the label on the dropper bottle used for KOH were not the lot that it was labeled with. 3. Random sampling of KOH testing from 11/4/20 to 03/09/21 revealed the laboratory performed the following 10 KOH tests. Date Patient initials Result 11/04 /20 RM Positive 11/05/20 BB Negative 11/18/20 LD Positive 12/02/20 MC Negative 12/14/20 WS Negative 01/15/21 JR Negative 01/15/21 CS Positive 02/02/21 IG Positive 03/01/21 MN Negative 03/09/21 AH Negative 4. An interview with the histology supervisor on 3/16/21 at 1120 hours in the laboratory confirmed the above findings. key: KOH - Potassium Hydroxide prep to test for fungal elements
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 surveyor observations, review of patient test records from June 2020 to December 2020, and confirmed in interview, the laboratory failed to ensure reagents were not in use after its expiration date for 2 of 6 reagents observed for Mohs testing. Findings were: 1. Surveyor observations on 3/16/21 at 0920 hours in the laboratory revealed the following 2 expired reagents in use. Statlab Submount lot 8142, exp 04 /2020 95% Reagent Alcohol ACS Grade dehydrant lot 069330, exp 09/1/2020 2. Interview with the histology supervisor on 3/16/21 at 1020 hours in the laboratory confirmed that the submount and alcohol were used for Mohs testing. 3. Random review of patient test records from June 2020 to December 2020 revealed the laboratory performed the following 16 Mohs testing using the above expired reagents. 7/14/20 MRN 0300869627 MRN 0300386455 8/12/20 MRN 0300877482 MRN 0303456381 11/10/20 MRN 0300788901 MRN 0300344711 6/19/20 MRN 0301158254 MRN 0301417056 6/23/20 MRN 0302971379 MRN 0304085590 6/24 /20 MRN 0301800338 MRN 0300205142 10/01/20 MRN 0301762804 12/11/20 MRN 0304058748 9/17/20 MRN 0303978259 MRN 0303092235 4. An interview with the histology supervisor on 3/16/21 at 1120 hours in the laboratory confirmed the above findings.
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 the laboratory quality assessment records, review of laboratory records, and confirmed in interview, the laboratory's quality assessment policies failed to monitor assess and correct problems in analytic systems. Refer to D5413, D5415, D5417