Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1107220	05/30/2018
Name of Provider or Supplier	**Street Address, City, State**	
Ut Health San Antonio Cancer Center	7979 Wurzbach, Mc 7878, San Antonio, 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.
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 observation of testing materials in use in the laboratory, and staff interview, it was revealed the laboratory failed to ensure expired reagents were not available for use. The findings were: 1. Surveyor observation of materials available in the laboratory on 05/30/2018 at 1100 hours revealed the following expired materials available for use: a) 1 bottle Black Tissue marking dye Lot: 046209 exp. 03/2018 b) 1 bottle Green Tissue marking dye Lot: 046060 exp. 02/2018 c) 3 bottles Mounting media Richard Allen Scientific Lot: 334080 exp. 05/2017 2. An interview with testing personnel number 6 (as listed on Form CMS 209) on 05/30/2018 at 1100 hours in the laboratory revealed each of the identified materials were currently in use by the

	facility. She stated she was unaware the supplies were expired. This confirmed the findings.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of the technical consultant performing competency assessments twice within the first year of employment for 1 of 1 testing personnel who required it. The findings were: 1. A review of the laboratory's submitted Form CMS 209 (signed by the laboratory director on 05/25/2018) revealed the laboratory identified 5 testing personnel who performed moderate complexity testing. 2. A review of the laboratory's personnel records revealed testing personnel number 5 was employed by the laboratory from February 2017 to February 2018. Additional review revealed the technical consultant had performed a competency assessment on 11/03 /2017. No other competency assessment was in the file. 3. The laboratory was asked to provide documentation of a second competency assessment being performed within the first year of employment for testing personnel number 5. No documentation was provided. 4. An interview with the laboratory director on 05/30/2018 at 1000 hours in the office - after her review of the records- confirmed the findings.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of the technical consultant performing annual competency assessments on 2 of 2 testing personnel requiring one in 2017. The findings were: 1. A review of the laboratory's submitted Form CMS 209 (signed by the laboratory director on 05/25/2018) revealed the laboratory identified 5 testing personnel who performed moderate complexity testing. Two of these testing personnel required annual competency being performed for 2017. 2. A review of the laboratory's personnel records revealed the following testing personnel failed to have documentation of an annual competency assessment being performed in 2017: Testing personnel number 2 Testing personnel number 4 3. The laboratory was asked to provide documentation of annual competency assessments being performed in 2017. No documentation was provided. 4. An interview with the laboratory director on 05/30 /2018 at 1000 hours in the office revealed she was unaware competency assessments for testing personnel were required annually after the first year of employment. This confirmed the findings.

D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel records, and staff interview, it was revealed the laboratory director failed to ensure there was documentation of training for 1 of 1 testing personnel who performed inking of MOHS specimens. The findings were: 1. A review of the laboratory's personnel records revealed testing personnel number 6 (as listed on Form CMS 209) started performing inking of MOHS specimens in December 2017. 2. The laboratory was asked to provide documentation of training for testing personnel number 6. No documentation was provided. 3. An interview with the technical supervisor on 05/30/2018 at 1045 hours in the laboratory revealed training was not documented. This confirmed the findings.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of the technical supervisor performing annual competency assessments on 1 of 1 testing personnel requiring one in 2017. The findings were: 1. A review of the laboratory's submitted Form CMS 209 (signed by the laboratory director on 05/25/2018) revealed the laboratory identified 1 testing personnel who performed high complexity testing. 2. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of a competency assessment being performing in 2017 for high complexity testing performed by testing personnel number 2 (as listed on Form CMS 209). Testing personnel number 4 3. The laboratory was asked to provide documentation of an annual competency assessment being performed in 2017. No documentation was provided. 4. An interview with the laboratory director on 05/30/2018 at 1000 hours in the office revealed she was unaware competency assessments for testing personnel were required annually after the first year of employment. This confirmed the findings.