Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2117782	08/13/2018
Name of Provider or Supplier	**Street Address, City, State**	
Chattanooga Skin & Cancer Clinic Cleveland	3891 Adkisson Dr Nw, Cleveland, TN	

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
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: ========== Based on observation of Xylene, Bluing Reagent and Histoprep chemicals during survey 8/13/18, lack of documentation of receipt dates, lot numbers, open dates and expiration dates and upon interview with the MOH's technician, determined the laboratory failed to document receipt dates, lot numbers, open dates and expiration dates of chemicals used since 2017. The findings include: 1. Observation during survey 8/13/18 at approximately 9: 30 a.m. of Xylene, Bluing Reagent and Histoprep chemicals used in processing MOH's specimens. 2. Lack of documentation of receipt dates, lot numbers, open dates and expiration dates for chemicals used in MOH's processing since 2017. 3. Interview at approximately 9:30 a.m. August 13, 2018 with MOH's technician confirmed the laboratory failed to document receipt dates, lot numbers, open dates and expiration dates for chemicals used in processing MOH's specimens since 2017. ==========
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	This STANDARD is not met as evidenced by: ========== Based on observation of outdated KOH (Potassium Hydroxide) and Tzanck testing solution 8/13/18 during on-site survey, log books and patient charts with documentation of 2018 KOH and Tzanck testing and interview with the MOH's technician and one of three MOH's Dermatologists, the laboratory used KOH and Tzanck Testing Solution when they had exceeded their expiration dates. The findings include: 1. Observation 8/13/18 at approximately 9:15 a.m. of KOH solution with January 2018 expiration date and Tzanck Solution with April 2018 expiration date. 2. Log books and 2 patient charts with documentation of KOH and Tzanck testing results for 2018. 2. Interview at approximately 9:30 a.m. August 13, 2018 with the MOH's technician and 1 of 3 MOH's Dermatologists, confirmed KOH and Tzanck analysis had been performed on patients using outdated testing solution in 2018. ==========
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's maintenance policy for the cryostat, lack of preventive maintenance documentation for cryostat and interview with the MOH's technician, determined the laboratory failed to have preventive maintenance done on cryostat annually since 2016. The findings include: 1. The Laboratory's maintenance policy for the cryostat states that PM (preventative maintenance) is to be performed annually. 3. Lack of Cryostat PM documentation since installation in 2016. 4. Interview with the MOH's technician at approximately 11: 30 a.m. August 13, 2018 confirmed there were no PM's performed on the cryostat since installation in 2016. ==========
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (E) The laboratory director must-- (E)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by:

	========== Based on review of the laboratory procedure manual.which lacked procedure for microscopic examination and reporting of Tzanck smears to include personnel competency and interview with MOH's technician and one of three dermatologists, the laboratory director failed to ensure procedure for performing Tzanck smears and competency performance of testing personnel since 2017. The findings include: 1. Review of the laboratory procedure manual revealed no procedure for the microscopic examination and reporting of Tzanck smears including personnel competency. 2. Interview on August 13, 2018 at approximately 11:30 a.m. with MOH's technician and one of three dermatologists, confirmed the laboratory performed and reported microscopic examination and reporting of Tzanck smears without an approved procedure in place to include personnel competency since 2017. ==========