Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D1006481	(X3) Date Survey Completed 12/11/2018
Name of Provider or Supplier North County Dermatology Clinic Pa	**Street Address, City, State** 6500 N Socrum Loop Rd Ste 100, Lakeland, FL	

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
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 observation, record review, and interview with the General Supervisor, the laboratory failed to dispose of Formalin per the material safety data sheets (MSDS) for an undetermined amount of time. Findings Included: 1. Tour of the laboratory on 12/11/2018 at 10:00 AM revealed multiple containers labeled 10% Formalin Fixative and a drum that was labeled xylene waste. (Photographic evidence was obtained). 2. Review of the Material Safety Data Sheet (MSDS) for Forrmalin revealed the waste disposal method was to "check with your local waste authorities" and "Do not dispose of in drains". 3. On 12/11/2018 at 11:00 AM, the General Supervisor confirmed that with the exception of xylene, chemicals were dumped down the drain with copious amounts of water.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on record review and interview with the General Supervisor, the laboratory failed to ensure the accuracy of histology testing twice a year for one (2018) of two years reviewed (2017 - 2018). Findings Included: 1. Review of Histology Peer

	Review revealed this peer review had been performed twice for 2017 and once for 2018, 02/13/2018. The laboratory did send histology specimens to another laboratory for peer review in June of 2018 (06/2018). The other laboratory failed to complete the Peer Review form the laboratory sent with the histology specimens and instead sent the results in the form of a patient report. The laboratory failed to document if the original results agreed with the other laboratory's results. 2. Interview on 12/11/2018 at 12:45 p.m. with the General Supervisor, confirmed that the laboratory failed to document the results of the 06/2018 peer review.
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, record review, and interview with the Head Nurse, the laboratory failed to ensure the potassium hydroxide was removed from use after the expiration date for 2 out of 2 years (2017-2018). Findings Included: 1. Observation on 12/11/2018 at approximately 10:45 AM revealed a bottle of potassium hydroxide with an expiration date of 02/13/2014, with no other bottles available to be used for testing. Photographic evidence was obtained. 2. Review of the KOH test logs (2017-2018) revealed that potassium hydroxide testing had been performed using the expired potassium hydroxide. 3. Interview on 12/11/2018 at 10:45 AM with the Head Nurse, confirmed that the potassium hydroxide had expired on 02/13/2014.
D5475	CONTROL PROCEDURES CFR(s): 493.1256(e)(3)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(3) Check fluorescent and immunohistochemical stains for positive and negative reactivity each time of use. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review, observation, and interview with the General Supervisor, the laboratory failed to test a positive and negative control for immunohistochemical stains and to document the results as positive or negative for 2 out of 2 years reviewed (2017-2018) Findings included: 1. Record review of the quality control log revealed results for special stains was recorded as "good" for 2017 and 2018. 2. Observation on 12/11/2018 at 1:00 PM of immunohistochemical quality control slides that were pulled for the same day as requested patient slides and reports revealed that the laboratory was only preparing a quality control slide and not a positive and negative control slide. 3. Interview on 12/11/2018 at 11:45 AM with the General Supervisor, confirmed the laboratory was not performing positive and negative quality controls for immunohistochemical stains.