Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2130142	08/14/2018
Name of Provider or Supplier	**Street Address, City, State**	
Cutis Wellness Dermatology And Dermatopathology	1601 Jacaman Road, Suite 101, Laredo, 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	An entrance conference was held 08/14/2018 with the laboratory director. The survey process was discussed. An opportunity for questions and comments was given. Based upon the onsite survey conducted 08/14/2018, this facility was found to be in substantial compliance for the specialties/subspecialties in which it was surveyed. An exit conference was held 08/14/2018 with the laboratory director. The standard level deficiencies cited were discussed. The process for submitting the corrections was explained. An opportunity for questions and comments was provided.
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: A. Based on surveyor observation of urinalysis reagent in use, review of manufacturer's instructions, review of laboratory Quality Control (QC) records and staff interview, it was revealed that the laboratory failed to provide documentation that urinalysis controls were run monthly. Findings included: 1. Observed on 08/14 /2018 at 09:30 AM in the upper cabinet of the specimen processing room was one box of Consult Diagnostics 60B Urine Reagent Strips 6 Parameter (Lot number URS8020063; expiration date 2020-04-03) with an open date of 06/21/2018. 2. Consult Diagnostics 60B Urine Reagent Strips 6 Parameter package insert (Number 1150835503; Effective date 2016-05-12) stated "Test the strips monthly that are stored for more than 30 days." 3. Review of laboratory log titled "UA dipstick Quality Control" revealed one entry for urinalysis QC on 06/21/2018. The laboratory failed to provide documentation that urinalysis controls were performed in July 2018 for the reagent strips in use. 4. During an interview on 08/14/2018 at 1045 AM in the specimen processing room, the medical assistant (MA) was asked how often

urinalysis QC was performed. The MA stated "When a box is opened." This confirmed the above findings. B. Based on surveyor observation of urinalysis control material in use, review of manufacturer's instructions, review of laboratory Quality Control (QC) records and staff interview, it was revealed that the laboratory failed to document specific positive QC and negative QC reactions for each analyte tested on the Consult Diagnostics 60B Urine Reagent Strips. Findings included: 1. Observed on 08/14/2018 at 1000 AM in the refrigerator in the Laboratory Director's office was 1 box Germaine UA Liquid Controls containing 3 bottles of Level 1 negative control material and 3 bottles of Level 2 positive control material. (Lot number 73391; expiration 2019-09-04) 2. Review of the package insert for the Germaine UA Liquid Controls (#60-51115-EV, 05-11) listed the intended reactions for the control material. Those intended reactions were: Analyte Level 1 Level 2 Leukocytes Negative 15 (+/-) to 500 (3+) Nitrite Negative Positive Urobilinogen 0.2 (-) to 1(+/-) 2(1+) to 12(3+) Protein Negative 30(1+) to 2000(4+) pH 5.0 to 7.0 6.5 to 9.0 Blood Negative 1+ to 3+ Specific Gravity 1.015 to 1.030 1.005 to 1.025 Ketone Negative 5 (+/-) to 1000 (3+) Bilirubin Negative 1 (1+) to 4 (3+) Glucose Negative 100 (+/-) to 1000 (3+) Ascorbic Acid Negative Negative 3. Review of the Consult Diagnostics 60B Urine Reagent Strips 6 Parameter package insert (Number 1150835503; Effective date 2016-05-12) revealed that only glucose, protein, pH, Blood, Nitrite and Leukocytes parameters are tested on the urinalysis strip. 4. Review of laboratory log titled "UA dipstick Quality Control" revealed one entry for urinalysis QC on 06/21/2018. The entries were as follows: Lot#(Box) Positive Passed? Negative Passed? Control Lot # Control Lot # URS8020063 733902 Yes 733901 Yes The laboratory failed to provide documentation for specific positive QC and negative QC reactions for each analyte tested on the Consult Diagnostics 60B Urine Reagent Strips. 5. During an interview on 08/14/2018 at 1045 AM in the specimen processing room, the medical assistant (MA) was asked what ranges were used to assess the urinalysis quality control material. The stated "The ranges for the QC material. But we just put in they passed." This confirmed the above findings. C. Based on surveyor observation of urinalysis control material in use and review of manufacturer's instructions, it was revealed that laboratory utilized urinalysis control material that was not specified for Consult Diagnostics 60B Urine Reagent Strips. Findings included: 1. Observed on 08/14/2018 at 1000 AM in the refrigerator in the Laboratory Director's office was 1 box Germaine UA Liquid Controls containing 3 bottles of Level 1 negative control material and 3 bottles of Level 2 positive control material. (Lot number 73391; expiration 2019-09-04) 2. Review of the package insert for the Germaine UA Liquid Controls (#60-51115-EV, 05-11) listed expected values for "Visual Reading with AimStrip, FisherBrand, & CTMI Urine Reagent Strips." The quality control material was not specified for use with Consult Diagnostics 60B Urine Reagent Strips. 3. Germaine Laboratories was called on 08/14/2018 at 1055 to verify that the Germaine UA Liquid Controls were not specified for use with Consult Diagnostics 60B Urine strips. These findings were verified on this phone call and in a written e-mail. This confirmed the findings. (See attached email.) D. Based on surveyor observation of urine Human Chorionic Gonadotropin (HCG) control material in use, review of manufacturer's instructions and staff interview, it was revealed that the laboratory failed to label the HCG with the new expiration date after the material had been opened. Findings included: 1. Observed 08/14/2018 at 1000 AM in the refrigerator in the Laboratory Director's office was 1 box of Consult Diagnostics HCG urine controls containing 1 bottle of negative control material and 1 bottle of positive control material with an open date of 07/02/2018 written on the box. (Lot number KN00054; expiration 2020-11-30) 2. The package insert for Consult Diagnostics HCG urine controls (Rev.00 12/15) stated "Once opened, the controls are stable at refrigerated storage temperatures for 90 days from the date of opening." The laboratory failed to relabel the control material with

	the new expiration date of 90 days after the 07/02/2018 open date recorded on the box. 3. During an interview on 08/14/2018 at 1034 AM in the specimen processing room, the medical assistant (MA) was asked how long are the urine HCG controls good for after opened. The MA stated "30 days, maybe 90 days. I would have to look." We write the open date on the box. We do not write the new expired date." This confirmed the above findings. E. Based on surveyor observation, review of manufacturer's instructions, review of laboratory Quality Control (QC) records and staff interview, it was revealed that the laboratory failed to document room temperature reading in the area where reagents were stored. Findings included: 1. Observed on 08/14/2018 at 09:30 AM in the upper cabinet of the specimen processing room was one box of Consult Diagnostics 60B Urine Reagent Strips 6 Parameter (Lot number URS8020063; expiration date 2020-04-03) and one box of Consult Diagnostics HCG Urine Tests Dipstick (Lot number HCG7120117; expiration date 2019-11-30). 2. The package insert for the Consult Diagnostics 60B Urine Reagent Strips 6 Parameter (Number 1150835503; Effective date 2016-05-12) stated "store as packaged in the closed canister or the sealed pouch either at room temperature or refrigerated (2-30 or 36-86F)." 3. The package insert for Consult Diagnostics HCG Urine Tests Dipstick stated "store as packaged in the sealed pouch at 36-86F/2-30C." 4. The laboratory was asked to provide documentation of room temperature records for the specimen processing room. No documentation was provided.
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 review of the laboratory's records and staff interview, it was revealed that the laboratory failed to have documentation of performing twice annual accuracy assessment for histology microscopic tests in 2017. Findings included: 1. A review of the form CMS-116 revealed a Certificate of Registration effective date of 05/02/2017. 2. A review of laboratory log titled "Cutis Wellness Dermatology and Dermatopathology" revealed no histopathology slides were submitted for twice annual accuracy verification for 2017. 3. During an interview with the laboratory director on 08/14/2018 at 1132 AM in the specimen processing room, the laboratory director stated, "I submitted slides from 2017 but they were evaluated 07/09/2018." 4. The laboratory was asked to provide documentation of twice annual accuracy assessment for histopathology slides submitted for evaluation in 2017. No documentation was provided. This confirmed the findings.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of laboratory records and staff interview, the laboratory failed to

	have written procedures for Potassium Hydroxide (KOH) testing, Scabies testing and Tzanck testing. Findings included: 1. A review of laboratory records revealed there were no written procedures for KOH, Scabies and Tzanck testing. 2. The laboratory began KOH, Scabies and Tzanck testing in March 2018. The estimated annual volume is 20 tests. 3. During an interview with the MA on 08/14/2018 at 09:30 AM in the specimen processing room, the MA stated "We do not have procedures for the tests." This confirmed the above findings.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based of review of laboratory records and staff interview it was revealed that the laboratory director failed to ensure that a Quality Assessment plan was established for the moderate complexity testing performed at the facility. 1. A review of the form CMS-116 revealed the laboratory performed Potassium Hydroxide Prep, Scabies smear and Tzanck smear testing. 2. Based on review of laboratory records it was revealed that the laboratory failed to have documentation of a quality assessment program to monitor, access and detect issues in laboratory general, pre-analytic, analytic, and post-analytic systems for moderate complexity testing. 3. The laboratory was asked to provide documentation of the laboratory director establishing a quality assurance program. No documentation was provided. 4. An interview with the laboratory director on 08/14/2018 at 1115 AM in the specimen processing room revealed the laboratory did not have a quality assessment program. This confirmed the findings.
D6095	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6) The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system. This STANDARD is not met as evidenced by: Based of review of laboratory records and staff interview it was revealed that the laboratory director failed to ensure that a Quality Assessment plan was established for the high complexity testing performed at the facility. 1. A review of the form CMS-116 revealed the laboratory performed approximately 2000 histopathlogy tests per year. 2. Based on review of laboratory records it was revealed that the laboratory failed to have documentation of a quality assessment program to monitor, access and detect issues for analytical performance for high complexity testing. 3. The laboratory was asked to provide documentation of the laboratory director establishing a quality assurance program. No documentation was provided. 4. An interview with the

	laboratory director on 08/14/2018 at 1115 AM in the specimen processing room revealed the laboratory did not have a quality assessment program. This confirmed the findings.