Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2280103	02/07/2024
Name of Provider or Supplier	**Street Address, City, State**	
Pure Dermatology	8701 W Highway 71 Ste 101, Austin, 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	The laboratory was surveyed and found to be in compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780, and recertification is recommended.
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: Based on review of the manufacturer's instructions, patient testing log, and interview, the laboratory failed to document the internal controls for the Henry Schein One Step + hCG Urine Cassette Test for 6 of 6 months reviewed. Findings follow. A. Review of the Henry Schein One Step + hCG Urine Cassette Test Instructional Insert package insert, Rev 04/2014, under Quality Control stated, "Internal procedural controls are included in the test. A red line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. A clear background is an internal negative background control. If the test is working properly, the background in the result area should be white to light pink and not interfere with the ability to read the test results." B. Review of the HCG Test Log from 07/18/2023 to 02/07/2024 showed no results for the internal procedural controls. Review of the log showed 25 patient tests were performed. C. Interview with Technical Consultant #2/testing personnel #2 on February 7, 2024 at 1550 hours confirmed there was not a column on the pregnancy log to document the internal procedural controls.
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 policy and procedure, pre-survey paperwork, competency evaluations, and interview, the technical consultant failed to evaluate the competency at least semiannually during the first year the individual tested patient specimens for one of one semi-annual competency evaluations for KOH (Potassium Hydroxide) for fungal elements and Mineral Oil for mites testing. Findings follow. A. Review of the laboratory's policy and procedure titled Proficiency testing Competency and CLIA competency assessment, approved 07/01/2023, stated, "Evaluation and documenting competency of personnel responsible for testing is required at least semiannually during the first year the individual sees patient specimens." B. Review of the pre-survey paperwork titled Laboratory Personnel showed testing personnel #2 (as listed on the CMS form 209) was hired 06/19/2023. C. One semi-annual competency evaluation for testing personnel #2 was requested on February 7, 2024 at 1220 hours but not provided. D. Interview with Technical Consultant #2/testing personnel #2 on February 7, 2024 at 1220 hours confirmed a competency evaluation was not performed.
D6127	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 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 policy and procedure, pre-survey paperwork, competency evaluations, and interview, the technical supervisor failed to evaluate the competency at least semiannually during the first year the individual tested patient specimens for one of one semi-annual competency evaluations in Mohs testing. Findings follow. A. Review of the laboratory's policy and procedure titled Proficiency testing Competency and CLIA competency assessment, approved 07/01/2023, stated, "Evaluation and documenting competency of personnel responsible for testing is required at least semiannually during the first year the individual sees patient specimens." B. Review of the pre-survey paperwork titled Laboratory Personnel showed testing personnel #2 (as listed on the CMS form 209) was hired 06/19/2023. C. One semi-annual competency evaluation for testing personnel #2 was requested on February 7, 2024 at 1220 hours but not provided. D. Interview with Technical Supervisor #2/testing personnel #2 on February 7, 2024 at 1220 hours confirmed a competency evaluation was not performed.