

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D0675575	(X3) Date Survey Completed 05/07/2019
Name of Provider or Supplier Dermassociates Ltd	Street Address, City, State 3608 W Main St, Belleville, IL	
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
D5213	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1)</p> <p>The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the laboratory director (LD); the laboratory failed to ensure ungraded 2017 event 1 proficiency testing (PT) samples for potassium hydroxide (KOH) preparations were evaluated. Findings Include: 1. Review of American Proficiency Institute (API) PT records for 2017 event 1 found API did not grade samples KOH-01 and KOH-02. 2. Review of API PT performance evaluation records for event 1 of 2017 failed to address the ungraded PT samples and the LD indicated no corrective action was needed. 3. On survey date 05-07-2019, at 1:00 pm, the LD confirmed the laboratory failed to evaluate the 2017 event 1 ungraded KOH preparations and no corrective action was documented.</p>
D5219	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(2)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure listed in subpart I of this part for which compatible proficiency testing samples are not offered by a CMS-approved proficiency testing program.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the laboratory director (LD); the laboratory failed to perform bi-annual method accuracy evaluations for scabies wet mount testing in 2017 through date of survey (05-07-2019) in 2019.</p>

	<p>Findings Include: 1. Review of proficiency testing documentation found no documented wet mount bi-annual method accuracy evaluations. 2. Interview with the LD on 05-07-2019, at 1:00 pm, confirmed that the laboratory failed to perform bi-annual method accuracy verifications for scabies wet mount testing in 2017 through 2019.</p>
<p>D5805</p>	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the laboratory director (LD); the laboratory failed to identify the name of the test performed on 6 of 6 patient test reports reviewed in the specialty of microbiology. Findings Include: 1. Review of 3 of 3 patient test reports for scabies wet preparations failed to indicate the test performed. a. Patient #: P1, Test Log Date: 04 -11-2017 b. Patient #: P2, Test Log Date: 03-27-2018 c. Patient #: P3, Test Log Date: 03-12-2019 2. Review of 3 of 3 patient test reports for potassium hydroxide preparation failed to indicate the test performed. a. Patient #: P4, Testing Log Date: 06-28-2017 b. Patient #: P5, Testing Log Date: 10-30-2018 c. Patient #: P6, Testing Log Date: 04-29-2019 3. On survey date 05-07-2017, at 1:00 PM, the LD confirmed the above findings.</p>
<p>D6054</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the laboratory director (LD); the technical consultant (TC) failed to ensure annual competency assessments were completed for all testing personnel performing parasitology testing. Findings Include: 1. Review of competency assessment records for 2 of 2 testing personnel (TP#1 and TP#2) performing wet preps for scabies found no documented competency assessments in 2018. 2. On survey date 05-07-2019, at 1:00 pm, the laboratory director confirmed no competency assessments were documented for 2 of 2 TP for scabies wet preps.</p>