

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  14D0432268	<b>(X3) Date Survey Completed</b>  01/31/2024
<b>Name of Provider or Supplier</b>  Associates In Dermatology, Sc	<b>Street Address, City, State</b>  1404 Eastland Dr, Bloomington, IL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5219</b>	<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 testing personnel (TP) #3; the laboratory failed to perform bi-annual method accuracy evaluations for scabies wet mount testing in 2022 and 2023 as required by 493.1236. Findings Include: 1. Upon review of the laboratory's "Quality Assessment Policy" manual, under "Proficiency Testing", it's stated, "Associate[s] in Dermatology will evaluate all of its testing staff in May and November of each year." In addition, "Each provider will read six KOH and six scabies slides that they collected from a patient and then have the slides read a second time [by] another provider to confirm their results. The second provider will not be given the initial results from the first reviewer, so their results will be unbiased." 2. Review of proficiency testing documentation found no documented bi-annual method accuracy evaluations for scabies wet mount testing. 3. Interview with TP#3 on 01/31/2024, at 12:15 pm, confirmed that the laboratory failed to perform bi-annual method accuracy verifications for scabies wet mount testing in 2022 and 2023.</p>
<b>D5473</b>	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The</p>

laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies, record review, lack of documentation, and interviews with testing personnel (TP) #3 and technical supervisor (TS) #2; the laboratory failed to test staining material for intended reactivity each day of use as required by 493.1256 for five of five testing dates reviewed. Findings include: 1. Review of the document "Histopathology Policy", under "Quality Control", it's stated, "The physicians will evaluate the staining quality of each slide during reading and only slides of a satisfactory quality will be diagnosed." 2. Patient test results were reported for five of five patients reviewed without documentation of Hematoxylin and Eosin (H&E) stain reactivity. Patient Accession #: Sample Accession #: Date of testing: 23115 AD482-22 02/22/2022 12657 AD2079-22 06/10/2022 145295 AD1146-23 03/10/2023 130088 AD4091-23 08/18/2023 149228 AD6049-23 12/15/2023 3. Interviews conducted with both TP #3 and TS #2 (who is also TP #2) on 01/31/2024, at 10:36 am, confirmed the above findings.

**D5801**

TEST REPORT

CFR(s): 493.1291(a)

The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

This STANDARD is not met as evidenced by:

Based on review of laboratory test reports and interviews with the laboratory representative and testing personnel (TP) #2; the laboratory failed to have a reliable system to ensure that manually transcribed test results are accurately transferred to the final report destination for one of two scabies wet mount patient test reports reviewed and one of three potassium hydroxide (KOH) wet mount patient test reports reviewed. Findings include: 1. Upon review of the laboratory's "Quality Assessment Policy" document, under "Record Keeping", it's stated, "All paper records will be used to ensure the results has been recorded into our electronic medical record accurately." 2. Review of scabies wet mount patient reports revealed one of two manually transcribed patient test results reviewed was not transferred to the patient's final report. Patient Accession #: Date of Testing: 145434 03/06/2023 3. Review of KOH wet mount patient reports revealed one of three manually transcribed patient test results reviewed was not transferred to the patient's final report. Patient Accession #: Date of Testing: 130832 02/22/2022 4. Interviews with the laboratory representative at 11:36 am and TP #2 at 12:15 pm, both on 01/31/2024, confirmed the above findings.

**D5805**

TEST REPORT

CFR(s): 493.1291(c)

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.

This STANDARD is not met as evidenced by:

Based on review of laboratory records and interview with the laboratory representative; the laboratory failed to include the address of the laboratory that performed the wet mount testing for two of two scabies test reports and three of three potassium hydroxide (KOH) test reports reviewed as required per 493.1291. Findings Include: 1. Review of two of two scabies patients test reports for wet mount testing found the laboratory failed to indicate the address of the performing laboratory on the final reports. Patient Accession #: Date of Testing: 138938 02/08/2022 145434 03/06 /2023 2. Review of three of three KOH patient test reports for wet mount testing found the laboratory failed to indicate the address of the performing laboratory on the final reports. Patient Accession #: Date of Testing: 130832 02/22/2022 22509 01/16 /2023 117580 12/13/2023 3. On survey date 01/31/2024, at 11:36 am, the laboratory representative confirmed the above findings.