

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D0708455	<b>(X3) Date Survey Completed</b>  01/23/2018
<b>Name of Provider or Supplier</b>  Bill V Way Do,Pa	<b>Street Address, City, State</b>  706 West Center Street, Duncanville, TX	
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 a review of quality assurance data during the period 5/1/16 to 1/23/18 and staff interview, the laboratory failed to define and perform accuracy verification for tests approved by the laboratory director at least twice annually. Findings were: A. A review of any method or system approved by the lab director to perform and verify accuracy revealed that no policy or method was defined. The laboratory performed tests for the presence or absence of dermatophytes, other fungi, yeast, presence /absence of scabies, and the KOH (potassium hydroxide) test. B. Upon request for evidence of accuracy verification testing, the laboratory was unable to provide this data for the tests: Acu-DTM Acu-Sabouraud Acu-Nickersons Medium Presence /absence of scabies KOH (potassium hydroxide) test The laboratory failed to perform this testing twice annually for calendar years 2016 and 2017. C. The above findings were confirmed by interview with the back office manager on 1/23/18 at 1020 hours in the lunch room.</p>
<b>D5403</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step</p>

performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's policy manual, manufacturer's instructions and staff interview, the laboratory failed to include all the applicable sections of the procedure for the growth and detection of pathogenic fungi and yeast. Findings were:

A. The laboratory chose to utilize the manufacturer's instructions as outlined in the following "Directions For Use." 1. Acuderm, Inc. (incorporated) "Acu-Nickerson (Nickerson Medium) - isolation and presumptive identification of Candida species. 2. Acuderm, Inc. (incorporated) "Acu-Sabouraud (Sabouraud Dextrose Agar - growth of most fungi associated with skin infections 3. Acuderm, Inc. (incorporated) "Acu-DTM (Dermatophyte Test Medium) - for growth and detection of dermatophytes from cutaneous sources B. When the manufacturer's instructions fail to provide applicable and necessary information relative the performance of the procedure, the laboratory must incorporate that information into the written procedure. The following applicable instructions were absent from the manufacturer's procedure, and NOT supplemented by the laboratory director: 1. The manufacturer's instructions for the Acu-Sabouraud agar test for fungal infections of the skin stated in step 5.: "Slides should be prepared from yeast-like colonies for microscopic examination. The laboratory director failed to describe the steps of this process, to include, how results would be interpreted, reported from such a microscopic examination and entered into the patient record. 2. For all Acuderm procedures listed above under paragraph A., the lab failed to describe how patient results would be interpreted and reported, including how those results would be entered into the patient's record. 3. For all tests performed by the laboratory, the lab's procedure manual failed to describe the course of action in the event the test system was unable to be performed. C. For the Acuderm procedures, Acu-Sabouraud and Acu-Nickerson Medium, KOH (potassium hydroxide) and Scabies examination, the lab failed to describe in detail how quality control was performed. D. The above findings were confirmed by interview with the back office manager on 1/23/18 at 1340 hours in the lunch room.

**D5477**

**CONTROL PROCEDURES**

CFR(s): 493.1256(e)(4)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on a review of quality control data performed for the Acuderm test systems: Acu-DTM (Dermatophyte), Acu-Sabouraud and Acu-Nickerson Medium from the period 5/1/16 to 1/23/18 and staff interview, the laboratory failed to perform quality control (QC), or QC with the frequency required. Findings were: A. A review of quality control (QC) data during defined period revealed that QC was not performed for each batch or lot number of media upon receipt from the manufacturer, concurrent with or prior to initial use, for the following test systems: 1. Acuderm, Inc. (incorporated) "Acu-Nickerson (Nickerson Medium) - isolation and presumptive identification of Candida species. 2. Acuderm, Inc. (incorporated) "Acu-Sabouraud (Sabouraud Dextrose Agar - growth of most fungi associated with skin infections 3. Acuderm, Inc. (incorporated) "Acu-DTM (Dermatophyte Test Medium) - for growth and detection of dermatophytes from cutaneous sources B. Before or concurrent with initial use for the Acu-DTM test system, the laboratory failed to check each batch/lot number of test medium for its ability to support growth, and/or select/inhibit specific organisms. (The lab was accepting the manufacturer's quality certificates as the only method of quality control.) During the period, the lab received the following lot numbers of M101 ACU-DTM test medium: 1. D-1163-0116, received 5-5-16 2. D-1163-0116, received 5-26-16 3. D-1169-0216, received 6-10-16 4. D-1169-0216, received 6-22-16 5. D-1177-0316, received 7-07-16 6. D-1180-0416, received 8-04-16 7. D-1177-0316, received 7-19-16 8. D-1180-0416, received 9-07-16 9. D-1180-0416, received 10-07-16 10. D-1187-0716, received 10-20-16 11. D-1187-0716, received 11-18-16 12. D-1196-0816, received 10-26-16 13. D-1187-0716, received 10-20-16 14. D-1192-0716, received 1-19-17 15. D-1192-0716, received 2-07-17 16. D-1203-1016, received 3-02-17 17. D-1203-1016, received 3-27-17 18. D-1213-1117, received 4-18-17 20. D-1213-1117, received 5-04-17 21. D-1215-0217, received 5-19-17 22. D-1215-0217, received 6-19-17 23. D-1221-0317, received 7-10-17 24. D-1221-0317, received 7-27-17 25. D-1223-0417, received 8-09-17 26. D-1232-0617, received 8-28-17 27. D-1234-0617, received 9-20-17 28. D-1232-0617, received 11-17-17 29. D-1234-0617, date not recorded 30. D-1234-0617, received 11-17-17 31. D-1245-0917, received 12-12-17 32. D-1250-1017, received 1-05-18 33. D-1250-1017, received 1-22-18 Upon receipt of batches or lot numbers of ACU-DTM test medium, the lab failed to perform testing to verify its ability to support growth 29 of 33 times (29/33) or 88 % (percent) of the time quality control was not performed. (Lot numbers were verified on 4-26-16, 8-18-16, 4-10-17, and 8-3-17) Upon receipt of batches or lot numbers of ACU-DTM test medium, the lab verified sterility and visual inspection for 4 of 33 lot number or batches of media. (12% of the time). Lot numbers were verified on 4-26-16, 8-18-16, 4-10-17, and 8-3-17. For 29 of 33 lot number batches received the lab stated only "All in good condition." C. Before or concurrent with initial use for the Acu-Sabouraud test system, the laboratory failed to check each batch/lot number of test medium for its ability to support growth, and/or select/inhibit specific organisms. (The lab was accepting the manufacturer's quality certificates as the only method of quality control.) During the period, the lab received the following lot number of M103 ACU-Sabouraud test medium: 1. S-51-0914, verified on 4-26-16 2. S-58-0716, verified on 4-01-17 3. S-58-0716, verified on 8-03-17 S-53-0215, received 7-1-16 was not verified through acceptable QC for its ability to support growth, and/or select/inhibit specific organisms. D. Before or concurrent with initial use for the Acu-Nickerson test system, the laboratory failed to check each batch/lot number of test medium for its ability to support growth, and/or select/inhibit specific organisms. (The lab was accepting the manufacturer's quality certificates as the only method of quality control.) During the period, the lab received the following lot number of M104 ACU-

Nickerson test medium: 1. N-60-0815, received 5-02-16 2. N-60-0815, received 7-08-16 (separate batch; same lot #) 3. N-62-0116, received 7-28-16 4. N-62-0116, received 9-07-16 (separate batch; same lot #) 5. N-63-0416, received "unknown" - no date entered 5. N-64-0516, received 1-12-17 6. N-64-0516, received 6-15-17 (separate batch; same lot #) 7. N-67-0117, received 10-19-17 8. N-67-0117, received 11-01-17 (separate batch; same lot #) a. N-64-0516, received 1-12-17 was not verified through acceptable QC for its ability to support growth, and/or select/inhibit specific organisms. And this lot number did not have verifiable documentation for sterility and visual inspection. b. N-64-0516, received 6-15-17 was not verified through acceptable QC for its ability to support growth, and/or select/inhibit specific organisms. And this lot number did not have verifiable documentation for sterility and visual inspection. c. N-60-0815, received 7-08-16 was not verified through acceptable QC for its ability to support growth, and/or select/inhibit specific organisms. And this lot number did not have verifiable documentation for sterility and visual inspection. d. N-62-0116, received 9-07-16 was not verified through acceptable QC for its ability to support growth, and/or select/inhibit specific organisms. And this lot number did not have verifiable documentation for sterility and visual inspection. e. N-67-0117, received 10-19-17 was not verified through acceptable QC for its ability to support growth, and/or select/inhibit specific organisms. And this lot number did not have verifiable documentation for sterility and visual inspection. E. The above findings were confirmed by interview with the back office manager on 1/23/18 at 1245 hours in the lunch room.

**D6032**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
 CFR(s): 493.1407(e)(14)

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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:  
 Based on a review of the laboratory's policy/procedure manual in effect during the time of the survey, and staff interview, the laboratory director failed to define in writing the duties and responsibilities of each person engaged in each phase of testing; and, whether supervision was required prior to reporting patient test results. Findings were: A. The laboratory director failed to define in writing the duties and responsibilities for himself as lab director, for himself as technical consultant, and for all testing (test-reporting) persons, including himself. B. The lab director did not define in writing which test or tests testing persons number 2 and 3 (as listed on Form CMS-209) could perform and report with or without supervision prior to release of the results. C. The above findings were confirmed by interview with the lab director on 1/23/18 at 11:10 hours in the lunch room.

**D6045**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
 CFR(s): 493.1413(b)(7)

(b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed;

This STANDARD is not met as evidenced by:

Based on a review of policies and procedures in effect during the time of the survey, the laboratory director/technical consultant failed to identify or define training requirements for each person performing tests, to include regular in-service training, as appropriate. Findings were: A. A review of the lab's policy manual revealed no evidence that the lab director/technical consultant identified the laboratory's training requirements for the tests: KOH (potassium hydroxide), microscopic examination for Scabies, Acuderm ACU-DTM, Acuderm ACU-Sabouraud and Acuderm ACU-Nickerson media. B. Testing persons two and three, as listed on CMS-Form 209, were eligible to receive the appropriately defined training. Upon request, this training could not be provided. C. The above finding was confirmed by interview with the back office manager on 1/23/18 at 0920 hours in the lunch room.

**D6046**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on a review of personnel policies in the laboratory's policy/procedure manual, request for evidence of competency assessment for testing persons during the period 5/1/16 to 1/23/18 and staff interview, the laboratory director/technical consultant failed to perform and document competency assessment for qualified testing persons, to include, the 6 competency assessment criteria. Findings were: A. A review of the laboratory's policies on personnel training and competency revealed that the lab director did not define competency assessment policy and criteria. The laboratory employed testing persons one and two, as identified on Form CMS-209. The lab director could not provide any evidence of competency for himself as a testing person. B. Upon request for evidence of competency assessment performance for testing persons one and two, none was provided for calendar years 2016 and 2017. C. Upon review of the lab's competency assessment criteria, the lab director/technical consultant was unable to provide this criteria in accordance with regulatory requirements found at 493.1413(b)(8)(i) through 493.1413(b)(8)(vi). (D6047 to D6052). These six elements or criteria for competency assessment were not developed or presented at the time of the survey. D. The above findings were confirmed by interview with the lab director and back office manager on 1/23/18 at 0930 hours in the lunch room.