

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D2299939	<b>(X3) Date Survey Completed</b> 02/12/2025
<b>Name of Provider or Supplier</b> Dharmesh Bhakta Dpm Pa	<b>Street Address, City, State</b> 3050 S Center Street Suite 140, Arlington, 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>D0000</b>	An announced onsite initial survey was performed from 02/11/2025 to 02/12/2025 and the laboratory was found to not be in compliance with the following CLIA conditions for specialties/subspecialties surveyed for 42 CFR: 493.1240 Preanalytic systems
<b>D5300</b>	<p>PREANALYTIC SYSTEMS CFR(s): 493.1240</p> <p>Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as specified in 493.1249 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on review the laboratory's policies, review of laboratory's verification records, surveyor observation, and staff interview, the laboratory failed to monitor and evaluate the overall quality of the pre-analytic systems. Findings include: 1. The laboratory failed to ensure test requisitions included the name and address of the referring laboratory requesting the test. Refer to D5305. 2. The laboratory failed to establish stability studies for specimens stored in the laboratory for future testing. Refer to D5311-I 3. The laboratory failed to ensure specimens were maintained at an appropriate temperature during transport from referring locations to the laboratory. Refer to D5311-II 4. The laboratory failed to establish the preanalytical requirements for the laboratory-developed wound panel using the Copan eSwab. Refer to D5311-III</p>
<b>D5305</b>	<p>TEST REQUEST CFR(s): 493.1241(c)</p>

(c) The laboratory must ensure the test requisition solicits the following information:  
(c)(1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (c)(2) The patient's name or unique patient identifier. (c)(3) The sex and age or date of birth of the patient. (c)(4) The test(s) to be performed. (c)(5) The source of the specimen, when appropriate. (c)(6) The date and, if appropriate, time of specimen collection. (c)(7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (c)(8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable.

This STANDARD is not met as evidenced by:

Based on a random review of patient final reports from December 2024 to February 2025, a random review of patient test requisitions from December 2024 to February 2025, and staff interview, the laboratory failed to ensure the address of the referring laboratory requesting the test was included on the test requisitions for one of three patient test requisitions reviewed from December 2024 to February 2025 (random review). Findings include: 1. Review of patient final reports determined: a) Patient Name: see patient alias list b) Patient DOB: see patient alias list c) Location: Accent Podiatry Associates - Midlothian 2. Random review of patient requisitions from January 2025 to February 2024 determined the laboratory failed to include the name and address of the referring laboratory requesting the test for one of three patient requisitions: a) Patient Name: see patient alias list b) Patient DOB: see patient alias list c) Location: submitting laboratory not listed 3. The General Supervisor (as listed on the CMS-209 form) confirmed the laboratory did not have the requesting location on the patient test requisition at the time of survey during an interview conducted on 02/12/2025 at 1050 hours in the break room. Key: DOB - Date of Birth CMS - Centers for Medicare and Medicaid Services

**D5311**

**SPECIMEN SUBMISSION, HANDLING, AND REFERRAL**  
CFR(s): 493.1242(a)

(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral.

This STANDARD is not met as evidenced by:

I. Based on review of the laboratory's policy, the laboratory's verification records, review of patient final reports from December 2024 to February 2025 (random review), and staff interview, the laboratory failed to ensure stability studies were performed for laboratory-developed real-time polymerase chain reaction (RT-PCR) testing for extended storage in the laboratory. Findings include: 1. Review of the laboratory's policy titled "NA 2 APA APA: SOP Nail Fungal Specimen Collection and Handling", approved by the laboratory director on 01/13/2025 stated: "5.4 Specimen Shipping and Storage Conditions ...Specimen should be stored, if not tested

immediately refrigerated (2-8C) and tested within 7 days." Further review of the laboratory's policy titled "APA: SOP Wound Specimen Collection Handling" stated: "5.4. Specimen Shipping and Storage Conditions The specimen is stored refrigerated and shipped on ice. The sample is stable for 7 days at 2-8 C." 2. Review of the laboratory's verification records titled "APA: Nail Validation Summary", approved by the laboratory director on 01/14/2025 determined: "This plan covers the stability testing for: 1) Testing Upon Receipt a) 0 hours 2) Pre-Processing/Shipping Stability a) 7 Days Refrigerated (2-8C) ...Acceptance criteria: Maximum of 20% difference between samples under tested conditions at the time 0 sample." Review of the verification study titled "Table 23. Stability data" determined the study consisted of testing the same samples at Day 0, Day 5, and Day 7. Further review of the verification study determined a 7-day stability study using known positive specimens to validate organism stability was not completed for the following targets for the nail panel developed by the laboratory: a) *Alternaria* species b) *Aspergillus* species c) *Candida* species d) *Candida glabrata* e) *Candida krusei* f) *Candida lusitanae* g) *Scopulariopsis brevicaulis* h) *Acremonium strictum* i) *Neoscytalidium dimidiatum* j) *Curvularia lunata* k) *Epidermophyton floccosum* l) *Fusarium* species m) *Microsporum* species n) *Microsporum gypseum* o) *Microsporum nanum* p) *Pichia onychis* q) *Trichophyton* species r) *Trichosporon* s) *Staphylococcus aureus* t) *Sarcoptes scabiei* Review of the laboratory's verification records titled "WND VAL 1 APA APA: Accent (CLIA ID 45D2294662) Wound Validation Summary", approved by the laboratory director on 01/14/2025 determined: "This plan covers the stability testing for: 1) Testing Upon Receipt a) 0 hours 2) Pre-Processing/Shipping Stability a) 6 Days Refrigerated (2-8C) b) 7 Days Refrigerated (2-8C) ...Acceptance criteria: Maximum of 20% difference between samples under tested conditions at the time 0 sample." Review of the verification study titled "Table 23. Stability data" determined the study consisted of testing the same samples at Day 0, Day 6, and Day 7. Further review of the verification study determined a 7-day stability study using known positive specimens to validate organism stability was not completed for the following targets for the wound panel developed by the laboratory: a) *Acinetobacter baumannii* b) *Bacteroides fragilis* c) *Citrobacter* species d) *Enterobacter* species e) *Enterococcus* species f) *Escherichia coli* g) *Serratia marcescens* h) *Morganella morganii* i) *Proteus* species j) *Pseudomonas aeruginosa* k) *Staphylococcus* species l) *Staphylococcus aureus* m) *blaKPC* n) *blaVIM*, *blaNDM* o) *blaCTX-M* p) *mecA* q) *ermA*, *ermB*, *ermC* r) *qnrA* s) *tetM* t) *vanA*, *vanB* 3. Review of patient final reports from December 2024 to February 2025 (random review) determined the following patients were tested within 7 days of collection without a stability study for in-house laboratory developed tests: Accession #: a) WND-24-0128 Collected: 12/27/2024 - 12:00 AM Received: 12/29/2024 - 08:33 AM Tested: 12/29/2025 - 11:01 AM b) WND25-0012 Collected: 02/05/2025 - 12:00 AM Received: 02/10/2025 - 01:42 PM c) NAIL25-0077 Collected: 02/07/2025 - 12:00 AM Received: 02/10/2025 - 04:09 PM Tested: 02/10/2025 - 05:28 PM d) NAIL25-0078 Collected: 02/07/2025 - 12:00 AM Received: 02/10/2025 - 04:38 PM Tested: 02/10/2025 - 05:28 PM e) NAIL25-0079 Collected: 02/07/2025 - 12:00 AM Received: 02/10/2025 - 04:39 PM Tested: 02/10/2025 - 05:28 PM f) NAIL25-0080 Collected: 02/07/2025 - 12:00 AM Received: 02/10/2025 - no received time Tested: 02/10/2025 - 05:28 PM g) NAIL25-0081 Collected: 02/07/2025 - 12:00 AM Received: 02/10/2025 - 04:42 PM Tested: 02/10/2025 - 05:28 PM 4. The General Supervisor (as listed on the CMS-209 form) confirmed the findings during an interview conducted on 02/11/2025 at 1355 hours in the break room. Key: CMS - Centers for Medicare and Medicaid Services II. Based on review of the laboratory's policy, surveyor observation, review of patient final reports and staff interview, the laboratory failed to ensure specimens were maintained at an appropriate temperature during transport from referring locations to the laboratory for three of seven

specimens from December 2024 to February 2025 (random review). Findings include:

1. A review of patient final reports determined patient specimens were received from referring locations: Accession #: a) WND25-0012 Collected: 02/05/2025 - 12:00 AM Received: 02/10/2025 - 01:42 PM Location: Accent Podiatry Associates-Mansfield Office b) NAIL25-0080 Collected: 02/07/2025 - 12:00 AM Received: 02/10/2025 - no received time Location: Accent Podiatry Associates - Midlothian c) NAIL25-0081 Collected: 02/07/2025 - 12:00 AM Received: 02/10/2025 - 04:42 PM Location: Accent Podiatry Associates-Mansfield Office
2. Review of the laboratory's policy titled "NA 2 APA APA: SOP Nail Fungal Specimen Collection and Handling", approved by the laboratory director on 01/13/2025 stated: "5.4 Specimen Shipping and Storage Conditions Specimen can be stored and shipped at room temperature (18-25C) immediately upon collection." Further review of the laboratory's policy titled "APA: SOP Wound Specimen Collection Handling" stated: "5.4. Specimen Shipping and Storage Conditions The specimen is stored refrigerated and shipped on ice ..."
3. The surveyors observed the General Supervisor (as listed on the CMS-209 form) ask staff if specimens were received from the referring laboratories for patient testing on 02/12/2024 at 1015 hours at the nurse's station. The General Supervisor (GS) told the surveyors the specimens were not yet received from referring laboratories for testing. On 02/12/2025 at 1024 hours in the laboratory, the surveyors asked the GS how specimens are received from referring laboratories. The GS stated the specimens are received in a soft-shell cooler with two refrigerated ice packs. The surveyors asked the GS if the specimens received in the soft-shelled cooler are documented for acceptable temperature upon receipt. The GS denied documenting the temperature of the patient specimens upon arrival from referring laboratories. The laboratory was asked to provide documentation of verification that specimens maintained the required temperature during transport from the referring location to the laboratory. No documentation was provided.
4. The General Supervisor confirmed the laboratory failed to ensure patient specimens were maintained at an appropriate temperature from collection to receipt for specimens collected from referring locations to receipt to the laboratory during an interview conducted on 02/12/2025 at 1024 hours in the laboratory.

Key: CMS - Centers for Medicare and Medicaid Services III. Based on review of the laboratory policy, surveyor direct observation and staff interview, the laboratory failed to establish the preanalytical requirements for the laboratory-developed wound panel using one of one Copan eSwab. Findings include:

1. Review of the laboratory's policy titled "Wound Sample Collection & Handling" determined: "5.2. Specimen Collection BD eSwab in liquid amies"
2. On 02/12/2025 at 1025 hours, the surveyors observed a specimen collection device labeled "Copan eSwab". The General Supervisor (as listed on the CMS-209 form) stated the "Copan eSwab" specimen collection devices were stored in the examination rooms and were used for the collection of patient specimens for wound panel testing in the laboratory.
3. The General Supervisor confirmed the "Copan eSwab" specimen collection devices were used for patient specimen collection and testing in the laboratory and are used as collection devices at referring laboratories during an interview on 02/12/2025 at 1028 hours in the laboratory. The Quality Technical Supervisor for Lighthouse Lab Services confirmed the laboratory used the BD eSwab as part of the laboratory-developed verification study in an email on 02/12/2025 at 1045 hours.

Key: CMS - Centers for Medicare and Medicaid Services

**D5400**

**ANALYTIC SYSTEMS**  
CFR(s): 493.1250

Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a

procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:

Based on review of the laboratory's verification records, review of patient final reports, and staff interview, the laboratory failed to monitor and evaluate the overall quality of the analytic system. Findings include: 1. The laboratory failed to document complete establishment studies for one of two laboratory-developed real-time polymerase chain reaction (RT-PCR) tests. Refer to D5423.

**D5423**

**ESTABLISHMENT AND VERIFICATION OF PERFORMANCE**

CFR(s): 493.1253(b)(2)

(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (b)(2)(i) Accuracy. (b)(2)(ii) Precision. (b)(2)(iii) Analytical sensitivity. (b)(2)(iv) Analytical specificity to include interfering substances. (b)(2)(v) Reportable range of test results for the test system. (b)(2)(vi) Reference intervals (normal values). (b)(2)(vii) Any other performance characteristic required for test performance.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's verification records, review of patient final reports from February 2025 (random review), and staff interview, the laboratory failed to document complete establishment studies for one of two laboratory-developed real-time polymerase chain reaction (RT-PCR) tests. Findings include: 1. Review of the laboratory's verification records titled "APA: Nail Validation Summary", approved by the laboratory director on 01/14/2025 under section "Table 13. Contrived Clinical /Accuracy Results/Extraction Efficiency" determined the following organisms were not documented as tested in the establishment study: *Acremonium strictum* *Curvularia lunata* *Pichia onychis* *Sarcoptes scabiei* Further review of the verification records under section "Table 13. Contrived Clinical/Accuracy Results/Extraction Efficiency" stated: "Non-plasmid commercially available controls for *Acremonium strictum*, *Curvularia lunata*, *Pichia onychis*, *Acromonium strictum* and *Sarcoptes scabiei* are not available ..." The laboratory was asked to provide documentation of verifying the organisms not included in the laboratory-developed establishment study for the nail panel test. No documentation was provided. 2. Review of patient final reports from February 2025 (random review) determined the following patients were tested without a documented complete establishment study for the laboratory-developed nail panel test: Accession #: h) NAIL25-0077 Collected: 02/07/2025 - 12:00 AM Received: 02/10/2025 - 04:09 PM Tested: 02/10/2025 - 05:28 PM i) NAIL25-0078 Collected: 02/07/2025 - 12:00 AM Received: 02/10/2025 - 04:38 PM Tested: 02/10/2025 - 05:28 PM j) NAIL25-0079 Collected: 02/07/2025 - 12:00 AM Received: 02/10/2025 - 04:39 PM Tested: 02/10/2025 - 05:28 PM k) NAIL25-0080 Collected: 02/07/2025 - 12:00 AM Received: 02/10/2025 - no received time Tested: 02/10/2025 - 05:28 PM l) NAIL25-0081 Collected: 02/07/2025 - 12:00 AM Received: 02/10/2025 - 04:42 PM Tested: 02

/10/2025 - 05:28 PM 3.The General Supervisor (as listed on the CMS-209 form) confirmed the findings during an interview conducted on 02/11/2025 at 1345 hours in the break room. Key: CMS - Centers for Medicare and Medicaid Services

**D6076**

**LABORATORY DIRECTOR**  
CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:  
Based on review of the laboratory's policies, review of patient test requisitions, review of patient final reports, review of the laboratory's verification records, review of quality control results, and confirmed in interview, the laboratory director failed to provide overall management and direction of the preanalytical and analytical test systems as evidenced by: 1. The laboratory director failed to meet the requirements for the preanalytical and analytical systems. Refer to D6082 2. The laboratory director failed to ensure a quality control program was developed and followed to provide quality laboratory services. Refer to D6093

**D6082**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(1)

(e) The laboratory director must-- (e)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's policies, review of patient test requisitions, review of the laboratory's verification records, review of quality control (QC) results, review of patient final reports and confirmed in interview, the laboratory director failed to meet the requirements for the preanalytical and analytical systems as evidenced by: 1. The laboratory failed to ensure test requisitions included the name and address of the referring laboratory requesting the test. Refer to D5305 2. The laboratory failed to establish stability studies for specimens stored in the laboratory for future testing. Refer to D5311-I 3. The laboratory failed to ensure specimens were maintained at an appropriate temperature during transport from referring locations to the laboratory. Refer to D5311-II 4. The laboratory failed to establish the preanalytical requirements for the laboratory-developed wound panel using the Copan eSwab. Refer to D5311-III 5. The laboratory failed to document complete establishment studies for one of two laboratory-developed real-time polymerase chain reaction (RT-PCR) tests. Refer to D5423

**D6093**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(5)

(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;

	<p>This STANDARD is not met as evidenced by:  The laboratory director failed to ensure a quality control program was developed and followed. Refer to: D5423</p>
<p><b>D6108</b></p>	<p><b>LABORATORY TECHNICAL SUPERVISOR</b>  CFR(s): 493.1447</p> <p>The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart.</p> <p>This CONDITION is not met as evidenced by:  Based on review of review of the laboratory's policies, review of the laboratory's establishment studies, review of quality control records, patient final reports, and confirmed in interview, the technical supervisor failed to provide technical and scientific oversight as evidenced by: 1. The technical supervisor failed to provide technical and scientific oversight. Refer to D6112 2. The technical supervisor failed to ensure establishment studies were complete prior to performing patient testing. Refer to D6115 3. The technical supervisor failed to ensure a quality control program was developed and followed prior to performing patient testing. Refer to D6117</p>
<p><b>D6112</b></p>	<p><b>TECHNICAL SUPERVISOR RESPONSIBILITIES</b>  CFR(s): 493.1451</p> <p>The technical supervisor is responsible for the technical and scientific oversight of the laboratory. The technical supervisor is not required to be on site at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide supervision as specified in (a) of this section.</p> <p>This STANDARD is not met as evidenced by:  Based on review of the laboratory's policy, review of the laboratory's establishment studies, review of quality control records, patient final reports, and confirmed in interview, the technical supervisor failed to provide technical and scientific oversight as evidenced by: 1. The laboratory failed to establish stability studies for specimens stored in the laboratory for future testing. Refer to D5311-I 2. The laboratory failed to ensure specimens were maintained at an appropriate temperature during transport from referring locations to the laboratory. Refer to D5311-II 3. The laboratory failed to establish the preanalytical requirements for the laboratory-developed wound panel using the Copan eSwab. Refer to D5311-III 4. the laboratory failed to document complete establishment studies for one of two laboratory-developed real-time polymerase chain reaction (RT-PCR) tests. Refer to D5423</p>
<p><b>D6115</b></p>	<p><b>TECHNICAL SUPERVISOR RESPONSIBILITIES</b>  CFR(s): 493.1451(b)(2)</p> <p>(b)(2) Verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system;</p>

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's policy, review of the laboratory's establishment studies, review of quality control records, patient final reports, and confirmed in interview, the technical supervisor failed to ensure establishment studies were complete prior to performing patient testing as evidenced by: 1. The laboratory failed to establish stability studies for specimens stored in the laboratory for future testing. Refer to D5311-I 2. The laboratory failed to ensure specimens were maintained at an appropriate temperature during transport from referring locations to the laboratory. Refer to D5311-II 3. The laboratory failed to establish the preanalytical requirements for the laboratory-developed wound panel using the Copan eSwab. Refer to D5311-III