Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2171398	09/02/2021
Name of Provider or Supplier	**Street Address, City, State**	
Pdp Of Texas, Pllc Dba Dermatology	610 Uptown Blvd Suite 102, Cedar Hill, 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	Laboratory representatives were present at the entrance conference. The survey process was discussed. An opportunity for questions and comments was given. The exit conference was held with the laboratory representatives. The laboratory was found to be in substantial compliance for the specialties/subspecialties for which it was surveyed. The standard level deficiencies cited were discussed. The process for submitting the corrections was explained. CMS form 2567 will be emailed from the Texas Health and Human Services Commission, Health Facility Compliance Arlington Group. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: I. Based on review of Centers for Medicare and Medicaid Services (CMS)-116 form, laboratory policy, laboratory proficiency testing records and confirmed by staff interview, the laboratory failed to verify the accuracy of non-regulated potassium hydroxide (KOH) procedures at least twice annually for 2 of 2 testing events in 2019 and 2 of 2 testing events in 2020. Findings: 1. Review of the CMS-116 form submitted at survey by the laboratory revealed the laboratory performed KOH procedures. 2. Review of the laboratory's Potassium Hydroxide (KOH) procedure stated: "Frequency and Record of Quality Control Analysis Bi-Annual testing of a

patient specimen by two physicians (split sample) or by sending a split sample specimen to another CLIA lab for verification will be used to confirm consistency in reading results. The results obtained with each reading will be documented on the KOH Quality Control Log. Differences in interpretations must be investigated, resolved, and documented." 3. Review of the laboratory's proficiency testing records for 2019 and 2020 revealed the laboratory failed to verify the accuracy of KOH procedures at least twice annually for 2 of 2 testing events in 2019 and 2 of 2 events in 2020. 4. During an interview on 09/02/2021 at 10:33 am, the Back Office Manager was asked for documentation of twice annual accuracy for KOH procedures for 2019 and 2020. The Back Office Manager stated that there were no twice annual accuracy assessments for 2019 or 2020. This confirmed the above findings. II. Based on review of laboratory policy, the laboratory's twice annual accuracy assessments for histopathology slide interpretations (MOHs), and confirmed in staff interview, the laboratory failed to verify the accuracy of for histopathology slide interpretations (MOHs) for 2 of 2 events in 2019 and 1 of 2 events in 2020 and failed to have documentation of evaluating the results of the peer reviews for histopathology slide interpretations (MOHs) to determine accuracy for 1 of 2 events in 2020 and 2 of 2 events in 2021. Findings: 1. Review of the laboratory's policy "Quality Assessment" stated: "General Laboratory Systems ... Proficiency Testing ... The PT testing process is recorded on the PT Event Report. PT samples are tested exactly like patient specimens to the extent possible, i.e., the same number of times and using the same personnel and methods as for patient testing. PT results are reviewed and retained for a period of at least two years. Any PT results less than 100% are investigated and remedial action is documented on the PT Event Report. Ungraded PT results (due to lack of consensus, nonparticipation, or late return of results) are self-graded by the laboratory, using the PT agency's report and summary sheets. Incorrect answers on ungraded results are investigated and remediated the same as graded results." 2. Review of the laboratory's twice annual accuracy assessment for 2019 revealed the laboratory did not have twice annual accuracy assessment records for histopathology slide interpretations (MOHs). Review of the laboratory's twice annual accuracy assessment for 2020 revealed the laboratory performed accuracy assessment for histopathology slide interpretations on 06/26/2020 but failed to perform a second accuracy assessment in 2020. Further review of records for 06/26/2020 revealed the following: The laboratory had a letter addressed to the laboratory director from the peer reviewer. The letter stated the following: "Dr. XX, I have reviewed the above noted cases for your quality assurance program. Below is a summary of my findings. The thickness of the sections is appropriate tom maximize the ability of interpret the slides. Processing artifact does not obscure critical findings. The submitted slides accomplish the goal of the Mohs surgery, which is visualization of the complete undersurface of the excised tissue. Slide MO20-0031, A1.1-1.3 No evidence of skin cancer. Slide MO20-0086, A1.1-1.3 No evidence of skin cancer. In summary, these slides are of excellent quality." The letter was signed by the peer reviewer. There was no documentation of the results from the peer reviewer being evaluated by the Mohs surgeon for accuracy. The laboratory failed to have documentation of evaluating the results of the peer reviews to determine accuracy for the first testing event in 2020. Review of the laboratory's twice annual accuracy assessment for histopathology slide interpretations (MOHs) for 2021 revealed the following: 02/23/2021 Case Number: MO20-0305 QA REPORT: REPORT WITHOUT ERROR? No Error QA DIAGNOSIS Agree with diagnosis The form was signed by the peer reviewer. There was no documentation of the results from the peer reviewer being evaluated by the Mohs surgeon for accuracy. 02/23/2021 Case Number: MO21-0026 QA REPORT: REPORT WITHOUT ERROR? No Error QA DIAGNOSIS Agree with diagnosis The form was signed by the peer reviewer. There was no documentation of the results

	from the peer reviewer being evaluated by the Mohs surgeon for accuracy. 02/23/2021 Case Number: MO21-0064 QA REPORT: REPORT WITHOUT ERROR? No Error QA DIAGNOSIS Agree with diagnosis The form was signed by the peer reviewer. There was no documentation of the results from the peer reviewer being evaluated by the Mohs surgeon for accuracy. 08/19/2021 Case Number: MO21-0309 QA REPORT: REPORT WITHOUT ERROR? No Error QA DIAGNOSIS Agree with diagnosis The form was signed by the peer reviewer. There was no documentation of the results from the peer reviewer being evaluated by the Mohs surgeon for accuracy. The laboratory failed to have documentation of evaluating the results of the peer reviews to determine accuracy for the above-mentioned 2021 testing events. 3. During an interview on 09/02/2021 at 10:33 am, the Back Office Manager was asked for documentation of twice annual accuracy for histopathology slide interpretations (MOHs) for 2019 and 2020. The Back Office Manager stated that there were no twice annual accuracy assessments for 2019 and only one event for 2020. This confirmed the above findings.
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on review of Centers for Medicare and Medicaid Services (CMS)-116 form, laboratory policy, laboratory proficiency testing records and confirmed by staff interview, the laboratory failed to ensure an effective QA (Quality Assessment) system was in place to monitor, assess and correct problems in the laboratory. Findings: 1. Review of the laboratory's policy titled: "Quality Assessment" "Policy Number PP-18" stated: "Quality Assessment This laboratory has instituted quality systems for all general laboratory systems and for all phases of the total testing process, including preanlytic, analytic, and post analytic phases. We will ensure continuous improvement of our performance through ongoing monitoring of each phase of each testing system that will assure that accurate and reliable test results are obtained and reported successfully to our providers in a timely manner. Each of the following systems in our laboratory will be evaluated as needed to be sure that it meets our quality goals. If a problem is identified, we will design and implement a solution that is approved by the laboratory director. The Quality Assessment Plan will be reviewed annually and updated or revised as needed. Quarterly Quality Assessment checklist to be signed off by the lab director." 2. The laboratory failed to verify the accuracy of non-regulated potassium hydroxide (KOH) procedures at least twice annually for 2 of 2 testing events in 2019 and 2 of 2 testing events in 2020. Refer to D5217-I. 3. The laboratory failed to verify the accuracy of for histopathology slide interpretations (MOHs) for 2 of 2 events in 2019 and 1 of 2 events in 2020 and failed to have documentation of evaluating the results of the peer reviews for histopathology slide interpretations (MOHs) to determine accuracy for 1 of 2 events in 2020 and 2 of 2 events in 2021. Refer to D5217-II. 4. During an interview on 09/02/2021 at 11:30 am, the laboratory representatives stated that quality assessments were performed by the consulting company that provides their laboratory portal. They stated that the consulting company provides a report to the laboratory for review. The representatives

	were asked to provide documentation of the laboratory director's review none was provided. The representatives stated that the laboratory director did not review the report, confirming the above findings.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (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 laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: I. Based on review of laboratory procedures, laboratory quality control records, patient records, and confirmed in staff interview, the laboratory failed to define for each day of use, test staining materials for intended reactivity to ensure the predictable staining characteristics for the Hematoxylin and Eosin (H&E) QC for 10 of 10 days in 2020 (November, December random sampling), 27 of 27 days in 2021 (June through September random sampling). Findings: 1. Review of the laboratory policy titled "Staining of Frozen Sections Manual and Automated" revealed: "IV. Quality Control Each day that staining procedures are performed, a quality control slide need to reviewed [sic] and recorded [sic] with each batch of slides. The first slide of the batch will need to be reviewed. The stain quality will be either be deemed acceptable or unacceptable for reviewing the slides. This is to be documented either on paper or in the portal by the histotech. The Doctor [sic] will also need to record the quality of the slide and deem it acceptable or unacceptable. The case slide and medical record number will be recorded on the QC sheet." Further review of the laboratory policy titled "Quality Assessment" revealed: "Pre-analytic Systems ... Quality Control Instrument maintenance is performed as needed and documented on the Maintenance Log. All 3 levels of QC are within acceptable limits before patient samples are reported. Any corrective actions taken are documented. New lot numbers of controls are verified before being used for patient test runs. Identify QC problems and when noted, corrective action is taken. All testing personnel perform QC on a rotating basis. Calibration is performed and documented at least every 6 months and whenever indicated (major parts replacement)." The above-mentioned laboratory policies failed to define the intended reactivity for Hematoxylin and Eosin (H & E) staining to ensure predictable staining characteristics. 2. A random review in 2020 and 2021 of the laboratory's "Pathologist H&E Control Slide Check" log revealed the following: The log listed the following categories as part of the quality control criteria: Air Bubbles Thickness Nuclear Stain Detail Staining Artifacts Fixation Compression/Folds Cytoplasmic Stain Detail Overall Stain Quality Under each category there were boxes where each day stain quality was documented with "checkmarks" to indicate if the categories were "Adequate/Acceptable" or "Poor/Unacceptable". Air bubbles had an additional criterion of "Acceptable with a few air bubbles". The bottom of the log was signed by the pathologist. The log did not specify if "Adequate/Acceptable", "Poor /Unacceptable", or "Acceptable with a few air bubbles" was indicated for H&E intended reactivity to ensure predictable staining characteristics. The following patients were reported on dates (random sampling) where "Air Bubbles, Thickness, Nuclear Stain Detail, Staining Artifacts, Fixation, Compression/Folds, Cytoplasmic Stain Detail, and Overall Stain Quality" were documented with "Adequate /Acceptable": 11/02/2020 Patient ID: MO20-0247 11/06/2020 Patient IDs: MO20-

0249, MO20-0250, MO20-0251, MO20-0252, MO20-0253, MO20-0254, MO20-0255, MO20-0256 11/09/2020 Patient ID: MO20-0257 11/16/2020 Patient IDs: MO20-0267, MO20-0268, MO20-0269, MO20-0270, MO20-0271, MO20-0272, MO20-0273 11/30/2020 Patient IDs: MO20-0284, MO20-0285 12/04/2020 Patient IDs: MO20-0286, MO20-0287, MO20-0288, MO20-0289, MO20-0290, MO20-0291, MO20-0292 12/14/2020 Patient IDs: MO20-0301, MO20-0302, MO20-0303 12/21 /2020 Patient IDs: MO20-0312, MO20-0313, MO20-0314, MO20-0315, MO20-0316 12/28/2020 Patient IDs: MO20-0317, MO20-0318, MO20-0319, MO20-0320 12/30 /2020 Patient IDs: MO20-0321, MO20-0322, MO20-0323, MO20-0324, MO20-0325, MO20-0326 06/02/2021 Patient IDs: MO21-0232, MO21-0233, MO21-0234, MO21-0235, MO21-0236, MO21-0237 06/04/2021 Patient IDs: MO21-0238, MO21-0239, MO21-0240, MO21-0241, MO21-0242, MO21-0243, MO21-0244 06/09/2021 Patient IDs: MO21-0245, MO21-0246, MO21-0247 06/11/2021 Patient IDs: MO21-0248, MO21-0249, MO21-0250, MO21-0251, MO21-0252, MO21-0253, MO21-0254, MO21-0255 06/16/2021 Patient IDs: MO21-0256, MO21-0257, MO21-0258, MO21-0259, MO21-0260, MO21-0261 06/18/2021 Patient IDs: MO21-0262, MO21-0263, MO21-0264, MO21-0265, MO21-0266, MO21-0267 06/23/2021 Patient IDs: MO21-0268, MO21-0269, MO21-0270, MO21-0271, MO21-0272 06/25/2021 Patient IDs: MO21-0273, MO21-0274, MO21-0275 06/28/2021 Patient ID: MO21-0276 06/30 /2021 Patient IDs: MO21-0277, MO21-0278, MO21-0279, MO21-0280, MO21-0281, MO21-0282, MO21-0283 07/01/2021 Patient ID: MO21-0284 07/07/2021 Patient IDs: MO21-0285, MO21-0286, MO21-0287, MO21-0288, MO21-0289, MO21-0290, MO21-0291 07/09/2021 Patient IDs: MO21-0292 MO21-0293, MO21-0294, MO21-0295, MO21-0296, MO21-0297, MO21-0298, MO21-0299, MO21-0300 07/14/2021 Patient IDs: MO21-0300, MO21-0301, MO21-0302, MO21-0303, MO21-0304, MO21-0305 07/16/2021 Patient IDs: MO21-0306, MO21-0307, MO21-0308, MO21-0309, MO21-0310, MO21-0311, MO21-0312 07/21/2021 Patient IDs: MO21-0313, MO21-0314, MO21-0315, MO21-0316, MO21-0317 07/23/2021 Patient IDs: MO21-0318, MO21-0319, MO21-0320, MO21-0321, MO21-0322 07/28/2021 Patient IDs: MO21-0323, MO21-0324, MO21-0325, MO21-0326, MO21-0327, MO21-0328, MO21-0329 07/30/2021 Patient IDs: MO21-0330, MO21-0331, MO21-0332, MO21-0333, MO21-0334, MO21-0335 08/04/2021 Patient IDs: MO21-0336, MO21-0337, MO21-0338, MO21-0339, MO21-0340, MO21-0341 08/11/2021 Patient IDs: MO21-0342, MO21-0343, MO21-0344, MO21-0345, MO21-0346, MO21-0347 08/13/2021 Patient IDs: MO21-0348, MO21-0349, MO21-0350, MO21-0351, MO21-0352, MO21-0354, MO21-0355, MO21-0356 08/18/2021 Patient IDs: MO21-0357, MO21-0358, MO21-0359, MO21-0360, MO21-0361 08/20/2021 Patient IDs: MO21-0362, MO21-0363, MO21-0364, MO21-0365, MO21-0366, MO21-0367, MO21-0368, MO21-0369 08/25/2021 Patient IDs: MO21-0370, MO21-0371, MO21-0372, MO21-0373, MO21-0374 08/27/2021 Patient IDs: MO21-0375, MO21-0376, MO21-0377, MO21-0378, MO21-0379, MO21-0380 09/02/2021 Patient IDs: MO21-0381, MO21-0382, MO21-0383, MO21-0384, MO21-0385, MO21-0386 3. According to laboratory records, the laboratory's annual volume was 350 histology tests (MOHs). 4. During an interview on 09/02/2021 at 11:30 am, the Director of Operations, histotechnologist, and Back Office Manager confirmed the above findings. II. Based on review of laboratory procedures, laboratory quality control records, patient records, and confirmed in staff interview, the laboratory failed to define and document the intended reactivity for Hematoxylin and Eosin (H & E) staining to ensure predictable staining characteristics of quality control slides for H & E staining on each day of patient testing for 1 of 1 patient in November 2020. Findings: 1. Review of the laboratory policy titled "Staining of Frozen Sections Manual and Automated" revealed: "IV. Quality Control Each day that staining procedures are performed, a quality control slide need to reviewed [sic] and recorded [sic] with each batch of slides. The first slide

	of the batch will need to be reviewed. The stain quality will be either be deemed acceptable or unacceptable for reviewing the slides. This is to be documented either on paper or in the portal by the histotech. The Doctor [sic] will also need to record the quality of the slide and deem it acceptable or unacceptable. The case slide and medical record number will be recorded on the QC sheet." Further review of the laboratory policy titled "Quality Assessment" revealed: "Pre-analytic Systems ... Quality Control Instrument maintenance is performed as needed and documented on the Maintenance Log. All 3 levels of QC are within acceptable limits before patient samples are reported. Any corrective actions taken are documented. New lot numbers of controls are verified before being used for patient test runs. Identify QC problems and when noted, corrective action is taken. All testing personnel perform QC on a rotating basis. Calibration is performed and documented at least every 6 months and whenever indicated (major parts replacement)." The above-mentioned laboratory policies failed to define the intended reactivity for Hematoxylin and Eosin (H & E) staining to ensure predictable staining characteristics. 2. A random review in 2020 of the laboratory's "Pathologist H&E Control Slide Check" log revealed the following: The log listed the following categories as part of the quality control criteria: Air Bubbles Thickness Nuclear Stain Detail Staining Artifacts Fixation Compression /Folds Cytoplasmic Stain Detail Overall Stain Quality Under each category there were boxes where each day stain quality was to be documented with "checkmarks" to indicate if the categories were "Adequate/Acceptable" or "Poor/Unacceptable". Air bubbles had an additional criterion of "Acceptable with a few air bubbles". The bottom of the log had a signature line for the pathologist. The log did not specify if "Adequate/Acceptable", "Poor/Unacceptable", "Acceptable with a few air bubbles" was indicated for H&E intended reactivity to ensure predictable staining characteristics. A review of the "Pathologist H&E Control Slide Check" log on 11/23 /2020 revealed the log had a documented date of assessment and the "Case #" used for quality control. The remaining document was blank. The following patient that was tested and reported when the laboratory failed to document the intended reactivity for the H & E stain to ensure predictable staining characteristics: Patient ID: MO20-0283 3. During an interview on 09/02/2021 at 11:30 am, the Director of Operations, histotechnologist, and Back Office Manager confirmed the above findings.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of laboratory procedures, laboratory quality control records, patient records, and confirmed in staff interview, the laboratory failed to have an effective QA (quality assessment) in place to identify and correct problems for the analytical phase of testing. Findings: 1. Review of the laboratory's policy titled: "Quality Assessment" "Policy Number PP-18" stated: "Quality Assessment This laboratory has instituted quality systems for all general laboratory systems and for all phases of the total testing process, including preanlytic, analytic, and post analytic phases. We will ensure continuous improvement of our performance through ongoing monitoring of each phase of each testing system that will assure that accurate and reliable test results

	are obtained and reported successfully to our providers in a timely manner. Each of the following systems in our laboratory will be evaluated as needed to be sure that it meets our quality goals. If a problem is identified, we will design and implement a solution that is approved by the laboratory director. The Quality Assessment Plan will be reviewed annually and updated or revised as needed. Quarterly Quality Assessment checklist to be signed off by the lab director." 2. The laboratory failed to define for each day of use, test staining materials for intended reactivity to ensure the predictable staining characteristics for the Hematoxylin and Eosin (H&E) QC for 10 of 10 days in 2020 (November, December random sampling), 27 of 27 days in 2021 (June through September random sampling). Refer to D5473-I. 3. The laboratory failed to define and document the intended reactivity for Hematoxylin and Eosin (H & E) staining to ensure predictable staining characteristics of quality control slides for H & E staining on each day of patient testing for 1 of 1 patient in November 2020. Refer to D5473-II. 4. During an interview on 09/02/2021 at 11:30 am, the laboratory representatives stated that quality assessments were performed by the consulting company that provides their laboratory portal. They stated that the consulting company provides a report to the laboratory for review. The representatives were asked to provide documentation of the laboratory director's review none was provided. The representatives stated that the laboratory director did not review the report, confirming the above findings.
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 review of the laboratory's submitted Form CMS 209, laboratory policy, laboratory records, personnel records, and staff interview, it was revealed the technical consultant failed to ensure the laboratory had documentation of training for performing moderate complexity testing (potassium hydroxide (KOH) procedures) for 3 of 3 testing personnel. Refer to D6066.
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 Centers for Medicaid and Medicare Services (CMS) 209 form, laboratory policy, laboratory records, personnel records, and confirmed in interview the technical consultant (TC) failed to evaluate and document the performance for 3 of 3 Testing Persons (TP-2, TP-3, TP-4) responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. Findings: 1. Review of the CMS 209 form revealed the laboratory identified 3 testing persons who performed moderate complexity testing. 2. Review of the laboratory's

	personnel policy titled "Quality Assessment" revealed: "General Laboratory Systems Personnel Training and Qualifications ... Personnel are evaluated once after their first six months of testing and at least annually thereafter. Evaluations are documented on the Lab Personnel Evaluation Checklist." 3. Review of laboratory records revealed the laboratory began performing potassium hydroxide procedures (KOH) in 09/2019. 4. Review of personnel records for TP-2, TP-3, and TP-4 revealed no initial training assessment KOH procedures. Refer to D6066. There was no documentation of semiannual performance for KOH procedures for TP-2, TP-3 and TP-4. The laboratory was asked to provide the semiannual performance assessment, none was provided. 4. During an interview on 09/02/2021 at 9:24 am, the laboratory representatives confirmed the above findings.
D6066	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form CMS-209, laboratory policy, laboratory records, personnel records, and confirmed in interview, the laboratory failed to have documentation of training for 3 of 3 testing personnel (TP) performing moderately complex testing for potassium hydroxide (KOH) procedures. Findings: 1. Review of the CMS-209 form submitted by the laboratory revealed 3 testing persons who performed moderate complexity testing. 2. Review of the laboratory's policy titled "Quality Assessment" "Policy Number PP-18" stated the following: "Personnel competency. This laboratory will ensure that all testing personnel are properly trained and are competent prior to testing patient specimens. The laboratory director and technical supervisor will review the performance of each employee working in the laboratory annually after the first year and semiannually in the first year of performing testing to assure employee competency." 3. Review of laboratory records revealed the laboratory began performing potassium hydroxide (KOH) procedures in 09/2019. 4. Based on a review of personnel records, 3 of 3 testing personnel (TP-2, TP-3, TP-4) did not have documentation of training prior to performing KOH procedures. 5. The laboratory was asked to provide documentation of appropriate training. No documentation was provided. The above findings were confirmed by laboratory representatives on 09/02/2021 at 9:24 am.