Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1054899	11/30/2018
Name of Provider or Supplier	**Street Address, City, State**	
Oasis Dermatology Group,Pllc	3100 Buddy Owens Avenue, Mcallen, 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	An announced validation survey was conducted on November 30, 2018. An entrance conference was held with the Laboratory Director and the primary testing person to explain the purpose and process of the survey. Based on the onsite survey conducted on 11/30/2018, this facility was found not in compliance with the CLIA regulations found at 42 CFR: 493.1250 Analytic Systems 493.1441 Laboratory Director High Complexity 493.1487 Testing Personnel, High Complexity An exit conference was held with the primary testing person. The survey findings were discussed; 2567 report to be sent to Dallas Regional CMS (Centers for Medicare and Medicaid Services) office. NOTE: Laboratories issued a certificate of accreditation must: (a) Notify HHS and the approved accreditation organization program within 30 days of any changes in- (1) Ownership; (2) Name; (3) Location; or (4) Director The laboratory did not notify CLIA of a change in location within 30 days of its changes. The CLIA 116 database and the CLIA certificate posted in the laboratory still listed the facility's address at 5112 North 10th Street, McAllen, Texas 78504.
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: Based on a review of laboratory quality assessment records and an interview with facility personnel, it was revealed that the laboratory failed to perform twice annual accuracy for 3 of 3 tests it performs in 2016 and 2017. The findings were: 1. A review of the laboratory's test menu revealed the laboratory performs the following high complexity testing procedures: a. Grossing b. H & E staining (Hematoxylin and Eosin) c. Mohs histopathology reporting 2. A review of the laboratory's quality assurance records revealed the laboratory performed one accuracy assessment for each test it performs (Grossing, H & E, and Mohs histopathology reporting) in 2016 during

	the American College of Osteopathic Dermatology annual examination. The records did not contain documentation of a complete second assessment in 2016. 3. A review of the laboratory's quality assurance records revealed the laboratory performed one accuracy assessment for each test it performs (Grossing, H & E, and Mohs histopathology reporting) in 2017 during the American College of Osteopathic Dermatology annual examination. The records did not contain documentation of a complete second assessment in 2017. 4. During an interview with the laboratory director on November 30, 2018 at 11:40 hours in the office, the above findings were confirmed. He revealed that he attends annual testing and participates in peer review. When asked for documentation of the second accuracy assessments for 2016 and 2017 that were done by peer review along with their evaluation, he stated that they are, "Not formally documented" and that the, "Cases had already been refiled."
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on surveyor observation, review of laboratory policy, and confirmed in interview of facility personnel, the laboratory's "Mohs Surgery" policy failed to include specimen processing instructions for labeling of slides. The findings were: 1. Surveyor observation of 5 randomly reviewed Mohs cases from 2017 and 2018 revealed the slides for each case were labeled with a handwritten specimen identification number. 2. Review of the laboratory's procedure, "Histopathology - Mohs Surgery" reviewed and approved by the laboratory director on January 3, 2016 under, "Test Procedure" it stated, "...Sections are mounted on glass slides. These may be coated with Poly-L-Lysine, egg albumin, or other substances to help ensure that the tissue adheres to the slides." 3. The policy did not include instructions on how to label slides and what patient identifying information to include on the slides. 4. Interview with the laboratory director on November 30, 2018 at 11:15 hours in the office confirmed the findings.
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 laboratory policy, review of manufacturer's instructions, review of quality control records, review of patient records, review of environmental records,

	and confirmed in interview of facility personnel, the laboratory failed to monitor and evaluate the overall quality of its analytic systems as evidenced by: 1. The laboratory failed to define an acceptable humidity range for the laboratory. (refer to D5413) 2. The laboratory failed to ensure that expired items were not available for use. (refer to D5417) 3. The laboratory failed to to include a control slide of known reactivity with each group of patients slides to document the quality of hematoxylin and eosin (H&E) stains. (refer to D5601) 4. The laboratory failed to document corrective action when the laboratory documented temperatures out of its defined acceptable range. (refer to D5785)
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of laboratory policy, review of the manufacturer's instructions for the Thermo Scientific Cryostat HM525 NX, review of laboratory environmental records, and interview with facility personnel, the laboratory failed to define an acceptable humidity range for the laboratory. The findings were: 1. Review of the laboratory's "Quality Assessment Policy" reviewed and approved by the laboratory director on January 3, 2016, under, "3. Environment, Instruments, Reagents, Materials and Supplies" stated, "Humidity: Acceptable humidity is determined by the test systems. The general guideline is 20% - 85%, but humidity should be based on the manufacturer's guidelines." 2. Based on review of the manufacturer's instructions for the Thermo Scientific Cryostat HM525 (388159, Issue 2.0) under, "Technical Specifications" it stated, "Relative Humidity: Max 60% RH up to 35 degrees Celsius." 3. Review of the laboratory's "Temperature/Humidity Log" revealed the laboratory's defined humidity range was, "20% - 85%". 4. In an interview with testing personnel three (as listed on Form CMS-209) on November 30, 2018 at 12:00 hours in the office confirmed the findings. Key: RH - relative humidity CMS - Centers for Medicare and Medicaid Services
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on surveyor observation of laboratory supplies available for use at the facility at the time of the survey, review of laboratory policy, and confirmed in interview of facility personnel it was revealed that the laboratory failed to ensure that expired supplies were not available for use. The findings were: 1. Surveyor observation of

	laboratory supplies on November 30, 2018 at 09:10 hours during the initial tour of the laboratory revealed the following supplies were expired: Scott's Tap Water (Lot D195-24) Expiration Date: 07-24-2016 Quantity: 1 bottle 2. Review of the laboratory's "Quality Assessment Policy" reviewed and approved by the laboratory director on January 3, 2016, under, "Reagent Storage, Use and Handling" it stated, " ...Do not use reagents after expiration date." 3. An interview of testing personnel three (as listed on Form CMS-209) on November 30, 2018 at 09:10 hours in the laboratory confirmed the findings. She stated the reagent was, "Not in use." Key: CMS - Centers for Medicare and Medicaid Services
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of laboratory policy, review of quality control records, review of patient logs, and confirmed in interview of facility personnel, the laboratory failed to include a control slide of known reactivity with each group of patients slides to document the quality of hematoxylin and eosin (H&E) stains. The findings were: 1. Review of the laboratory's "Quality Assessment Policy" reviewed and approved by the laboratory director on January 3, 2016, under, "11. Quality Control" it stated, " ... We document the results of all controls and will take appropriate actions when the controls do not perform as expected." 2. Review of quality control records from January 2018 to October 2018 revealed the following dates when patients were tested and the quality of the hematoxylin and eosin (H&E) stain was not documented with each group of patient slides. February 20, 2018 September 4, 2018 September 18, 2018 3. Review of patient log sheets revealed the laboratory performed 57 patient tests when quality control was not documented (see patient alias list). 4. Interview of the laboratory director conducted on November 30, 2018 at 11:00 hours at the nurse's station confirmed that the laboratory did not document the quality of the H&E stain with each group of patient slides for the selected dates.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on a review of laboratory policy, review of manufacturer's instructions, review of the laboratory's environmental records, and confirmed in interview of facility personnel it was revealed that the facility failed to document corrective actions when temperatures were outside of the laboratory's established acceptable range for the Cryostat. The findings were: 1. Review of the laboratory's procedure "Histopathology

	- Mohs Surgery" reviewed and approved by the laboratory director on January 2, 2016, under, "Test Procedure" it stated, "The tissue is then cut into 4 to 10 micron sections in a Cryostat, which is kept within a range of -20 degrees Celsius to -30 degrees Celsius." 2. Review of the manufacturer's instructions for the Thermo Scientific HM525 NX (388159, Issue 2.0) under, "Cooling Specifications" it stated, "Cryobar Cooling (Peltier Element): Max -55 degrees Celsius (-67 degrees Fahrenheit)" and, "Chamber Temperature: Max. -35 degrees Celsius -2K/+1K (-31 degrees Fahrenheit -2K/+1K) at +20 degrees Celsius room Temp. (decrease 0, 7 degrees Celsius/1 degree Celsius room temp. increase)." 3. A review of laboratory's "Equipment Quality Control Room and Temperature Log Sheet" stated, " ...Draw a red circle around any reading outside the acceptable range that required corrective action and complete a Corrective Actions Form to document actions taken ..." 4. Review of the laboratory's environmental records from January 2017 to November 30, 2018 revealed the following dates when the laboratory documented temperatures for the Cryostat outside of its defined range (-20 to -30 degrees Celsius) for 42 of 137 days reviewed. No corrective action was documented. Date Temperature Reading (in degrees Celsius) January 12, 2017 -19.9 January 26, 2017 -19.9 February 16, 2017 -19.9 March 14, 2017 -19.8 March 23, 2017 -19.9 April 18, 2017 -19.9 May 9, 2017 -19.9 May 16, 2017 -19.8 August 15, 2017 -19.9 January 4, 2018 -18.3 January 16, 2018 -19.2 January 18, 2018 -19.3 January 23, 2018 -18.7 January 30, 2018 -18.6 February 6, 2018 -30.1 February 20, 2018 -19.2 February 22, 2018 -19.3 February 27, 2018 -18.6 March 15, 2018 -19.2 March 22, 2018 -18.6 March 27, 2018 -19.2 March 29, 2018 -19.3 April 3, 2018 -19.2 May 8, 2018 -19.2 May 15, 2018 -18.0 May 22, 2018 -18.1 May 24, 2018 -19.2 June 5, 2018 -18.1 June 26, 2018 -19.1 July 10, 2018 -19.2 July 17, 2018 -19.8 July 25, 2018 -18.1 August 7, 2018 -18.2 August 21, 2018 -18.2 August 28, 2018 -19.2 September 18, 2018 -19.6 September 25, 2018 -19.3 October 9, 2018 -19.6 October 16, 2018 -19.2 November 13, 2018 -19.9 November 27, 2018 -19.6 November 29, 2018 -19.3 5. An interview of testing personnel three (as listed on Form CMS-209) on November 30, 2018 at 12:10 hours in the office confirmed the findings. Key: K - equilibrium constant CMS - Centers for Medicare and Medicaid Services
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 policy, review of quality control records, review of patient records, review of environmental records, and confirmed in interview of facility personnel, the laboratory's quality assessment program failed to identify and correct errors in its analytic systems as evidenced by: 1. The laboratory failed to define an acceptable humidity range for the laboratory. (refer to D5413) 2. The laboratory failed to ensure that expired items were not available for use. (refer to D5417) 3. The laboratory failed to include a control slide of known reactivity with each group of patients slides to document the quality of hematoxylin and eosin (H&E)

	stains. (refer to D5601) 4. The laboratory failed to document corrective action when the laboratory documented temperatures out of its defined acceptable range. (refer to D5785)
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 laboratory policy, review of personnel records, review of quality control records, review of environmental records, review of patient records, and confirmed in interview of facility personnel, the laboratory director failed to provide overall management and direction of the laboratory. (refer to D6093, D6094, D6102)
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the laboratory records and confirmed in interview, the laboratory director failed to ensure the laboratory documented quality control for the hematoxylin & eosin (H & E) stains. (Refer to D5601)
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of laboratory policy, review of quality assessment records, review of quality control records, review of patient records, and confirmed in interview of facility personnel, the laboratory director failed to ensure the laboratory's quality assurance program was able to identify and correct errors in its analytic systems as evidenced by: 1. The laboratory failed to define an acceptable humidity range for the laboratory. (refer to D5413) 2. The laboratory failed to ensure that expired items were not available for use. (refer to D5417) 3. The laboratory failed to include a control slide of known reactivity with each group of patients slides to document the quality of the hematoxylin and eosin (H&E) stain. (refer to D5601) 4. The laboratory failed to document corrective action when the laboratory documented temperatures out of its defined acceptable range. (refer to D5785)
D6102	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of the laboratory personnel records and confirmed in interview of facility personnel, it was revealed the laboratory director failed to ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered (grossing), and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. The findings were: 1. Review of the laboratory's personnel records revealed 2 of 3 testing persons did not have documentation of appropriate education to perform high complexity testing. (refer to D6168 and D6171) 2. Review of the laboratory's personnel records revealed 3 of 3 testing persons did not have documentation of training for grossing. 3. An interview with the laboratory director on November 30, 2018 at 09:30 hours in the office confirmed the findings.
D6121	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(i) The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel files, review of testing personnel competency assessment documentation, and interview with facility personnel, the technical supervisor failed to perform and document direct observation of routine patient test performance, including patient preparation, specimen handling, processing, and testing for 3 of 3 testing persons in 2016, 2017, and 2018. The findings included: 1. Review of testing personnel files for 3 of 3 testing persons revealed an area for "Annual Evaluation." For each of the 3 of 3 testing persons a check mark was observed for "Year: 2016,", "Year: 2017," and "Year: 2018." 2. Based on review of the "Personnel File Checklist" document that was provided as documentation of competency assessment, the technical supervisor did not document direct observation of routine patient test performance, including patient preparation, specimen handling, processing, and testing for 3 of 3 testing persons. Testing Person 1 (as listed on Form CMS-209) Date of hire: 02-08-09 Dates of competency assessments: "Year 2016," "Year 2017," and "Year 2018" Testing Person 2 (as listed on Form CMS-209) Date of Hire: 04-13-07 Dates of competency assessments: "Year 2016," "Year 2017," and "Year 2018" Testing Person 3 (as listed on Form CMS-209) Dates of competency assessments: "Year 2016," "Year 2017," and "Year 2018" 3. In an interview with the laboratory director on November 30, 2018 at 10:00 hours in the office confirmed the findings. He stated that competency assessments were performed, but not formally documented. Key: CMS - Centers for Medicare and Medicaid Services

D6122	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(ii) The procedures for evaluation of the competency of the staff must include, but are not limited to monitoring the recording and reporting of test results. This STANDARD is not met as evidenced by: Based on review of the laboratory's testing personnel files, testing personnel competency assessment documentation, and interview with facility personnel, the technical supervisor failed to document monitoring, recording, and reporting of test results for 3 of 3 testing persons in 2016, 2017, and 2018. The findings included: 1. Review of testing personnel files for 3 of 3 testing persons revealed an area for "Annual Evaluation." For each of the 3 of 3 testing persons a check mark was observed for "Year: 2016,", "Year: 2017," and "Year: 2018." 2. Based on review of the "Personnel File Checklist" document that was provided as documentation of competency assessment, the technical supervisor did not document monitoring, recording, and reporting of results for 3 of 3 testing persons. Testing Person 1 (as listed on Form CMS-209) Date of hire: 02-08-09 Dates of competency assessments: "Year 2016," "Year 2017," and "Year 2018" Testing Person 2 (as listed on Form CMS-209) Date of Hire: 04-13-07 Dates of competency assessments: "Year 2016," "Year 2017," and "Year 2018" Testing Person 3 (as listed on Form CMS-209) Date of Hire: 12-21-06 Dates of competency assessments: "Year 2016," "Year 2017," and "Year 2018" 3. In an interview with the laboratory director on November 30, 2018 at 10:00 hours in the office confirmed the findings. He stated that competency assessments were performed, but not formally documented. Key: CMS - Centers for Medicare and Medicaid Services
D6123	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(iii) The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. This STANDARD is not met as evidenced by: Based on review of the laboratory's testing personnel files, testing personnel competency assessment documentation, and interview with facility personnel, the technical supervisor failed to document review off preliminary results, worksheets, quality control, proficiency testing, and preventative maintenance for 3 of 3 testing persons in 2016, 2017, and 2018. The findings included: 1. Review of testing personnel files for 3 of 3 testing persons revealed an area for "Annual Evaluation." For each of the 3 of 3 testing persons a check mark was observed for "Year: 2016,", "Year: 2017," and "Year: 2018." 2. Based on review of the "Personnel File Checklist" document that was provided as documentation of competency assessment, the technical supervisor did not document review of preliminary results, worksheets, quality control proficiency testing, and preventative maintenance for 3 of 3 testing persons. Testing Person 1 (as listed on Form CMS-209) Date of hire: 02-08-09 Dates of competency assessments: "Year 2016," "Year 2017," and "Year 2018" Testing Person 2 (as listed on Form CMS-209) Date of Hire: 04-13-07 Dates of competency assessments: "Year 2016," "Year 2017," and "Year 2018" Testing Person 3 (as listed on Form CMS-209) Date of Hire: 12-21-06 Dates of competency assessments: "Year

	2016," "Year 2017," and "Year 2018" 3. In an interview with the laboratory director on November 30, 2018 at 10:00 hours in the office confirmed the findings. He stated that competency assessments were performed, but not formally documented. Key: CMS - Centers for Medicare and Medicaid Services
D6124	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(iv) The procedures for evaluation of the competency of the staff must include, but are not limited to direct observation of performance of instrument maintenance and function checks. This STANDARD is not met as evidenced by: Based on review of the laboratory's testing personnel files, testing personnel competency assessment documentation, and interview with facility personnel, the technical supervisor failed to document direct for 3 of 3 testing persons in 2016, 2017, and 2018. The findings included: 1. Review of testing personnel files for 3 of 3 testing persons revealed an area for "Annual Evaluation." For each of the 3 of 3 testing persons a check mark was observed for "Year: 2016,", "Year: 2017," and "Year: 2018." 2. Based on review of the "Personnel File Checklist" document that was provided as documentation of competency assessment, the technical supervisor did not document direct observation of instrument maintenance and function checks for 3 of 3 testing persons. Testing Person 1 (as listed on Form CMS-209) Date of hire: 02-08-09 Dates of competency assessments: "Year 2016," "Year 2017," and "Year 2018" Testing Person 2 (as listed on Form CMS-209) Date of Hire: 04-13-07 Dates of competency assessments: "Year 2016," "Year 2017," and "Year 2018" Testing Person 3 (as listed on Form CMS-209) Date of Hire: 12-21-06 Dates of competency assessments: "Year 2016," "Year 2017," and "Year 2018" 3. In an interview with the laboratory director on November 30, 2018 at 10:00 hours in the office confirmed the findings. He stated that competency assessments were performed, but not formally documented. Key: CMS - Centers for Medicare and Medicaid Services
D6125	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(v) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. This STANDARD is not met as evidenced by: Based on the testing personnel competency assessment documentation and interview with facility personnel, the technical supervisor failed to perform and document assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples for 3 of 3 testing persons 2016, 2017, and 2018. The findings included: 1. Review of testing personnel files for 3 of 3 testing persons revealed an area for "Annual Evaluation." For each of the 3 of 3 testing persons a check mark was observed for "Year: 2016,", "Year: 2017," and "Year: 2018." 2. Based on review of the "Personnel File Checklist" document assessment of test performance by testing previous specimens, blind test samples, or external PT)proficiency testing samples for 3 of 3 testing persons. Testing Person 1 (as listed on Form CMS-209) Date of hire: 02-08-09 Dates of competency

	assessments: "Year 2016," "Year 2017," and "Year 2018" Testing Person 2 (as listed on Form CMS-209) Date of Hire: 04-13-07 Dates of competency assessments: "Year 2016," "Year 2017," and "Year 2018" Testing Person 3 (as listed on Form CMS-209) Date of Hire: 12-21-06 Dates of competency assessments: "Year 2016," "Year 2017," and "Year 2018" 3. In an interview with the laboratory director on November 30, 2018 at 10:00 hours in the office confirmed the findings. He stated that competency assessments were performed, but not formally documented. Key: CMS - Centers for Medicare and Medicaid Services
D6126	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(vi) The procedures for evaluation of the competency of the staff must include, but are not limted to assessment of problem solving skills. This STANDARD is not met as evidenced by: Based on review of the laboratory's testing personnel files, testing personnel competency assessment documentation, and interview with facility personnel, the technical supervisor failed to document assessment of problem solving skills for 3 of 3 testing persons in 2016, 2017, and 2017. The findings included: 1. Review of testing personnel files for 3 of 3 testing persons revealed an area for "Annual Evaluation." For each of the 3 of 3 testing persons a check mark was observed for "Year: 2016,", "Year: 2017," and "Year: 2018." 2. Based on review of the "Personnel File Checklist" document that was provided as documentation of competency assessment, the technical supervisor did not document assessment of problem solving skills for 3 of 3 testing persons. Testing Person 1 (as listed on Form CMS-209) Date of hire: 02-08-09 Dates of competency assessments: "Year 2016," "Year 2017," and "Year 2018" Testing Person 2 (as listed on Form CMS-209) Date of Hire: 04-13-07 Dates of competency assessments: "Year 2016," "Year 2017," and "Year 2018" Testing Person 3 (as listed on Form CMS-209) Date of Hire: 12-21-06 Dates of competency assessments: "Year 2016," "Year 2017," and "Year 2018" 3. In an interview with the laboratory director on November 30, 2018 at 10:00 hours in the office confirmed the findings. He stated that competency assessments were performed, but not formally documented. Key: CMS - Centers for Medicare and Medicaid Services
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on review of the submitted Form CMS-209 signed by the laboratory director on November 30, 2018, review of the laboratory's personnel records, and confirmed in interview of facility personnel, revealed the laboratory director failed to ensure each testing person met the qualification requirements for high complexity testing. The laboratory director failed to ensure 2 of 3 testing persons met the personnel qualifications for high complexity testing (grossing). (refer to D6171) Key: CMS - Centers for Medicare and Medicaid Services

D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet

	the qualifications of 493.1449 (b) or (l) to perform tissue examinations. This STANDARD is not met as evidenced by: Based on review of review of the Form CMS-209, surveyor's review of personnel files, review of personnel file checklists, and confirmed in interview of facility personnel, 2 of 3 testing personnel lacked the appropriate educational credentials to perform macroscopic (gross) examinations of histopathology (Mohs) specimens. The findings were: 1. Review of the Form CMS-209, signed by the laboratory director on 11/30/2018 reveled the laboratory identified 3 testing persons who perform macroscopic (gross) examinations of histopathology (Mohs) specimens. 2. Review of laboratory personnel records for testing personnel one (as listed on Form CMS-209), who performed macroscopic (gross) examinations of histopathology (Mohs) specimens was lacking documentation of educational credentials to qualify him for high complexity testing. a. The file revealed testing personnel one had a Bachelor of Arts in Spanish b. The file revealed testing personnel one had an Associate's of Science in Criminal Justice c. The "Personnel File Checklist" revealed a check mark by, "High school diploma/GED and/or college degree" 3. Review of laboratory personnel records for testing personnel two (as listed on Form CMS-209), who performed macroscopic (gross) examinations of histopathology (Mohs) specimens was lacking documentation of educational credentials to qualify her for high complexity testing. a. The file revealed testing personnel two had a foreign degree that had not been evaluated for equivalence in the United States b. The "Personnel File Checklist" revealed a check mark by "High school diploma/GED and/or college degree" and a check mark by "Equivalency evaluation if education was outside USA." 4. Interview with the laboratory director on November 30, 2018 at 10:15 hours in the office confirmed the findings. Key: CMS - Centers for Medicare and Medicaid Services GED - general education diploma USA - United States of America