Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D2123513	03/07/2018
Name of Provider or Supplier	**Street Address, City, State**	
Nga Lab Services Llc	1515 N Porter Ave, Suite 200, Norman, OK	

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	The findings were reviewed with the quality assessment coordinator, testing person #1 and practice manager at the conclusion of the survey. The laboratory was found out of compliancewith the following CLIA regulations: 493.1447; D6108: Technical Supervisor
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on a review of records and interview with the quality assessment coordinator and testing person #1, the laboratory failed to ensure patient test reports included the name of the laboratory location. Findings include: (1) At the beginning of the survey, the quality assessment coordinator and testing person #1 verified to the surveyors the laboratory performed gross examinations; (2) The surveyors then reviewed 1 patient report: (a) Report #1 - Gross examination performed on 03/02/18 (3) It was identified that the name of the laboratory on the reports was "Norman Endoscopy Center, LLC" located at 1125 N. Porter Ave.; which did not match the name on the CLIA certificate. The name on the CLIA certificate was "NGA Lab Services LLC" located at 1515 N. Porter Ave.; (4) The surveyors reviewed the report with the quality assessment officer and testing person #1 who stated the name on the reports did not match the name on the CLIA certificate.

D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 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. This CONDITION is not met as evidenced by: Based on a review of records and interview with the quality assessment coordinator and testing person #1, the technical supervisor failed to provide technical supervision in accordance with 493.1451 of this subpart. Findings include: (1) The technical supervisor failed to identify training needs and assure that each individual performing tests receives regular in-service training. Refer to D6120; (2) The technical supervisor failed to ensure the individual who performed the duties and responsibilities of the techical supervisor met the educational qualifications. Refer to D6127.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for 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; (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 records and interview with the quality assessment coordinator and testing person #1, the technical supervisor failed to identify training needs and assure that each individual performing tests receives regular in-service training. Findings include: (1) The technical supervisor failed to ensure that each person performing high complexity gross examinations (physical/description of tissue including color, weight, measurement and other characteristics of the tissue) in the absense of the technical supervisor were reviewed with 24 hours. Refer to D6171.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on a review of records and interview with the quality assessment coordinator and testing person #1, the technical supervisor failed to ensure the individual who performed the duties and responsibilities of the technical supervisor, met the qualifications. Findings include: (1) At the beginning of the survey, surveyor #2 reviewed records for testing person #1 who performed high complexity testing (gross examinations) in 2017. The records indicated the evaluations for the testing person had been performed by individuals who did not meet the regulatory qualification

	requirements of the technical supervisor: (a) Testing Person #1 (i) The 11/27/17 semi-annual evaluation had been performed by a person who qualified as a general supervisor (associate degree with at least 2 years of training/experience in high complexity testing). (2) The surveyors explained to the quality assessment coordinator and testing person #1 that all components of the semi-annual competency evaluations must be performed by a person who qualifies as a technical supervisor (an individual with an MD or DO with a current medical license in state of laboratory's location and certified in anatomic pathology by APB or AOBP or equivalent qualifications or resident in a program leading to ABP or AOBP certification in anatomic and clinical pathology who performs dutes delegated by the technical supervisor for histopathology). NOTE: The regulations only allow for the general supervisor to perform initial training and annual competency evaluations as stated at 493.1463 "Standard; General supervisor responsibilities: (b)(3) Providing orientation to all testing personnel; and (b)(4) Annually evaluating and documenting the performance of all testing personnel"
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 a review of records and interview with the quality assessment coordinator and testing person #1, the laboratory failed to ensure that each person performing high complexity gross examinations (physical/description of tissue including color, weight, measurement and other characteristics of the tissue) in the absense of the technical supervisor were reviewed with 24 hours. Findings include: (1) At the beginning of the survey, the quality assessment coordinator and testing person #1 stated to the surveyors that testing person #1 performed gross examinations beginning 05/18/17; (2) Surveyor #2 then reviewed personnel education and training records. Testing person #1 qualified (493.1489 (b)(5)) to perform high complexity testing; (3) Surveyor #2 reviewed the grossing logs from 05/18/17 through 03/02/18 and identified the following: (a) No documented review by the technical supervisor (4) The surveyors asked the quality assessment coordinator and testing person #1 if the technical supervisor documented a review of the gross examinations performed by testing person #1 within 24 hours. Both the quality assessment coordinator and testing person #1 stated the technical supervisor had not documented a review within 24 hours of the gross examination performed by testing person #1; (5) The following were examples of patient gross examinations performed by testing person #1 without a documented 24 hour review by the technical supervisor: (a) Case #100 performed on 05/18/17 (b) Case #216 performed on 06/02/17 (c) Case #477 performed on 07/11/17 (d) Case #734 performed on 08/15/17 (e) Case #884 performed on 09/05/17 (f) Case #1087 performed on 10/02/17 (g) Case #4014 performed on 11/13/17 (h) Case #4339 performed on 12/28/17 (i) Case #160 performed on 01/24/18 (j) Case #237 performed on 02/02/18 (k) Case #450 performed on 03/02/18 Note: The Interpretive Guidelines at 493.1489(b)(7) state, "In the case of gross examinations, the technical supervisor may delegate to individuals qualified under 493.1489 the responsibility for the physical examination/description, including color, weight, measurement and other characteristics of the tissue; or other mechanical procedures for which a specific written protocol has been developed. The technical supervisor is ultimately responsible for the diagnosis related to the gross examination and must sign the examination report. The technical supervisor is not required to provide direct on-site supervision but is responsible for the accuracy of all test results reported. All physical examinations/descriptions of tissue including color, weight, measurement and other characteristics of the tissue; or other mechanical procedures performed in the absence

	of the technical supervisor by individuals qualified under 493.1489 should be reviewed within 24 hours by the technical supervisor."