Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D0918256	01/31/2018
Name of Provider or Supplier	**Street Address, City, State**	
Northern Ohio Medical Specialists, Llc	200 Garfield Drive, Ne, Suite 1, Warren, OH	

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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on record review and an interview with the Laboratory Director, the testing personnel (TP) failed to attest to the routine integration of the American Proficiency Institute (API) proficiency testing (PT) samples into the routine patient workload using the laboratory's routine methods for one of three of the testing events in 2016. Findings Include: 1. Review of the laboratory's policies and procedures, provided on the date of the inspection, did not find any PT policies and procedures. 2. Review of the laboratory's 2016 and 2017 API Microbiology PT records did not find that the TP attested to the routine integration of the API PT samples into the patient workload using the laboratory's routine methods for the third PT event in 2016. 3. The Surveyor requested the TP's attestation for the laboratory's third 2016 API Microbiology PT event from the Laboratory Director. The Laboratory Director confirmed the TP did not provide attestation, as required, and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 01/31/2018 at 10:28 AM.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency

	testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on record review and an interview with the Laboratory Director, the laboratory failed to maintain all American Proficiency Institute (API) proficiency testing (PT) records for at least two years from the date of the PT event. Findings Include: 1. Review of the laboratory's policies and procedures, provided on the date of the inspection, did not find any PT policies and procedures. 2. Review of the laboratory's 2016 and 2017 API Microbiology PT records revealed the laboratory did not retain all of the API PT documentation, as required, to include the raw data, the submitted results, the report evaluations and the documentation of report review for six out of six of the 2016 and 2017 PT events reviewed. 3. The Surveyor requested all of the laboratory's 2016 and 2017 API Microbiology PT event records from the Laboratory Director. The Laboratory Director confirmed the laboratory did not maintain records of all API PT documentation, as required, and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 01/31/2018 at 10:28 AM.
D5002	BACTERIOLOGY CFR(s): 493.1201 If the laboratory provides services in the subspecialty of Bacteriology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1261, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on record review and an interview with the Laboratory Director, the laboratory failed to meet the requirements in the subspecialty of Bacteriology. Findings Include: 1. The laboratory failed to document the review of proficiency testing (PT) results obtained for six out of six of the 2016 and 2017 American Proficiency Institute (API) Microbiology testing events. (Refer to D5211) 2. The laboratory failed to verify the accuracy of the GeneXpert test system for the detection and differentiation of genomic DNA (deoxyribonucleic acid) from Chlamydia trachomatis (CT) and/or Neisseria gonorrhoeae (NG) at least twice annually in 2017. (Refer to D5217) 3. The laboratory failed to establish, have available and follow written policies and procedures for tests, assays and examinations performed by the laboratory to include proficiency testing (PT), test accuracy verification (TAV) and performance specification activities. (Refer to D5401) 4. The laboratory failed to include interpretation of results, control procedures, the corrective action to take when control results fail to meet the laboratory's criteria for acceptability, the limitations in the test methodology (including interfering substances), reference intervals, literature references, the laboratory's system for entering and reporting the results in the patient record and the laboratory's course of action to take if a test system becomes inoperable. (Refer to D5403) 5. The laboratory failed to demonstrate that it could obtain performance specifications comparable to those established by the manufacturer for accuracy, precision and reference intervals for the GeneXpert test system for the detection and

	differentiation of genomic DNA (deoxyribonucleic acid) from Chlamydia trachomatis (CT) and/or Neisseria gonorrhoeae (NG). (Refer to D5421) 6. The laboratory failed to document their established daily/as needed microscope maintenance protocols that ensured microscope performance, necessary for accurate and reliable potassium hydroxide (KOH) and wet mount preparations test results and test result reporting. (Refer to D5433) 7. The laboratory failed to establish quality control (QC) frequency and document the QC procedures to monitor the accuracy and precision of the complete analytic process of the BD Affirm and GeneXpert test systems to detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (Refer to D5441) 8. The laboratory failed to include the specimen source on the test report for the GeneXpert DNA (deoxyribonucleic acid) Chlamydia trachomatis (CT) and/or Neisseria gonorrhoeae (NG) testing performed. (Refer to D5808)
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on record review and an interview with the Laboratory Director, the laboratory failed to document the review of proficiency testing (PT) results obtained for six out of six of the 2016 and 2017 American Proficiency Institute (API) Microbiology testing events. Findings Include: 1. Review of the laboratory's policies and procedures, provided on the date of the inspection, did not find any PT policies and procedures. 2. Review of the laboratory's 2016 and 2017 API Microbiology PT records did not find any indication of PT result review for six out of six PT events. 3. The Surveyor requested the laboratory's 2016 and 2017 API Microbiology PT result review documentation for six out of six testing events from the Laboratory Director. The Laboratory Director confirmed the laboratory did not document PT result review, as required, and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 01/31/2018 at 10:28 AM.
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 record review and an interview with the Laboratory Director, the laboratory failed to verify the accuracy of the GeneXpert test system for the detection and differentiation of genomic DNA (deoxyribonucleic acid) from Chlamydia trachomatis (CT) and/or Neisseria gonorrhoeae (NG) at least twice annually in 2017. Findings Include: 1. Review of the laboratory's policies and procedures, provided on the date of the inspection, did not find any test accuracy verification (TAV) policies and procedures. 2. Review of the laboratory's American Proficiency Institute (API) Microbiology proficiency testing (PT) records did not find that the laboratory was enrolled in DNA CT and DNA NG PT or had conducted any TAV activities for DNA CT and DNA NG since the test was implemented in March 2017. 3. The Surveyor

	requested the laboratory's 2017 and 2018 DNA CT and DNA NG TAV from the Laboratory Director. The Laboratory Director confirmed the laboratory did not conduct any DNA CT and DNA NG TAV activities in 2017 and 2018, as required, and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 01/31/2018 at 10:28 AM.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on record review and an interview with the Laboratory Director, the laboratory failed to establish, have available and follow written policies and procedures for tests, assays and examinations performed by the laboratory to include proficiency testing (PT), test accuracy verification (TAV) and performance specification activities. Findings Include: 1. Review of the laboratory's policies and procedures, provided on the date of the inspection, did not find any PT, TAV and performance specification policies and procedures. 2. The Surveyor requested the laboratory's PT, TAV and performance specification policies and procedures from the Laboratory Director. The Laboratory Director confirmed the laboratory did not establish, have available and follow written policies and procedures for PT, TAV and performance specification and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 01/31/2018 at 10:28 AM and 10:46 AM.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on record review and an interview with the Laboratory Director, the laboratory

	failed to include interpretation of results, control procedures, the corrective action to take when control results fail to meet the laboratory's criteria for acceptability, the limitations in the test methodology (including interfering substances), reference intervals, literature references, the laboratory's system for entering and reporting the results in the patient record and the laboratory's course of action to take if a test system becomes inoperable. Findings Include: 1. Review of the laboratory's "Policy and Procedure: Affirm VP III" and "Policy and Procedure: Cepheid X-part CT/NG Assay", policies and procedures, approved by the Laboratory Director on 02/01/2016 and provided on the date of the inspection, did not find instructions for the interpretation of results, control procedures, the corrective action to take when control results fail to meet the laboratory's criteria for acceptability, the limitations in the test methodology (including interfering substances), reference intervals, literature references, the laboratory's system for entering and reporting the results in the patient record and the laboratory's course of action to take if a test system becomes inoperable. 2. The Surveyor requested the laboratory's Affirm VP III and Cepheid GeneXpert CT/NG policies and procedures to include the required components mentioned above from the Laboratory Director. The Laboratory Director confirmed the laboratory did not establish and include the above mentioned components in the Affirm VP III and Cepheid GeneXpert CT/NG policies and procedures and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 01/31/2018 at 1:30 PM.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on record review and an interview with the Laboratory Director, the laboratory failed to demonstrate that it could obtain performance specifications comparable to those established by the manufacturer for accuracy, precision and reference intervals for the GeneXpert test system for the detection and differentiation of genomic DNA (deoxyribonucleic acid) from Chlamydia trachomatis (CT) and/or Neisseria gonorrhoeae (NG). Findings Include: 1. Review of the laboratory's policies and procedures, provided on the date of the inspection, did not find any performance specification policies and procedures. 2. The Surveyor requested the laboratory's performance specification policy and procedure and the 2017 performance specification documentation of all activities conducted prior to implementation of the GeneXpert test system for DNA CT and DNA NG from the Laboratory Director. The Laboratory Director provided the 2017 instrument installation records by the manufacturer and service report records, but was unable to provide the requested documentation on the date of the inspection. The interview occurred on 01/31/2018 at 10:46 AM.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)

	For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on record review, direct observation and an interview with the Laboratory Director, the laboratory failed to document their established daily/as needed microscope maintenance protocols that ensured microscope performance, necessary for accurate and reliable potassium hydroxide (KOH) and wet mount preparations test results and test result reporting. Findings Include: 1. Review of the laboratory's "Policy and Procedure: Microscope Maintenance" policy and procedure, approved by the Laboratory Director on 02/01/2016 and provided on the date of the inspection, found instructions to wipe the microscope lenses prior to use, verify the light bulb functions, clean at the end of each working day and cover. 2. Direct observation on 01/31/2018 at 11:35 AM found a Unico microscope, serial number 0670582, utilized for KOH and wet mount preparation testing procedures. 3. The Surveyor requested the laboratory's 2016, 2017 and 2018 daily/as needed microscope maintenance documentation and service records from the Laboratory Director. The Laboratory Director confirmed the laboratory had not documented any of their established daily/as needed microscope maintenance activities in 2016, 2017 and 2018, did not have the microscope serviced in 2016, 2017 and 2018 and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 01/31/2018 at 11:35 AM.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and an interview with the Laboratory Director, the laboratory failed to establish quality control (QC) frequency and document the QC procedures to monitor the accuracy and precision of the complete analytic process of the BD Affirm and GeneXpert test systems to detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. Findings Include: 1. Review of the laboratory's "Policy and Procedure: Affirm VP III" and "Policy and Procedure: Cepheid X-part CT/NG Assay", policies and procedures,

	approved by the Laboratory Director on 02/01/2016 and the laboratory's Individualized Quality Control Plan (IQCP) risk assessments for each test system, provided on the date of the inspection, did not find quality control plans (QCP) or established instructions for the frequency of QC testing procedures. 2. Review of the BD Affirm VPIII manufacturer's instructions revealed the following statements: "Quality Control ...Each reagent lot must be tested for adequate sample lysis and release of target nucleic acid using a swab streak of fresh indicator culture or commercially prepared swab of Candida albicans...to further verify test performance, quality control testing with C. albicans...,T. vaginalis... and G. vaginalis...may be conducted..." 3. Review of the "GeneXpert CT/NG Assay" manufacturer's instructions revealed the following statements: "Quality Control ...External Controls - External controls (one positive and one negative) may be used in accordance with local, state, and/or federal accrediting organizations, as applicable." 4. Review or the laboratory's BD Affirm QC records did not find any external 2016, 2017 and 2018 QC activity documentation. Review of the GeneXpert QC records found the following sporadic frequency: Positive/Negative external QC run 11 times in 3/2017; each day of testing run 1 time in 4/2017 run weekly in 5/2017 no QC in 6/2017 with pt testing on 6/27/17 run monthly 7/2017 to current 5. The Surveyor requested the laboratory's 2016, 2017 and 2018 BD Affirm and GeneXpert QC documentation every day of patient testing from the Laboratory Director. The Laboratory Director confirmed the laboratory did not conduct and document external QC activities every day of patient testing in 2016, 2017 and 2018 for the BD Affirm and GeneXpert testing procedures and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 01/31/2018 at 11:50 AM.
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 record review and an interview with the Laboratory Director, the laboratory failed to include the specimen source on the test report for the GeneXpert DNA (deoxyribonucleic acid) Chlamydia trachomatis (CT) and/or Neisseria gonorrhoeae (NG) testing performed. Findings Include: 1. Review of the laboratory's "Policy and Procedure: Cepheid X-part CT/NG Assay", policy and procedure, approved by the Laboratory Director on 02/01/2016 and provided on the date of the inspection, found instructions to insert and swab the endocervical canal. 2. Review of the Cepheid GeneXpert manufacturer's instructions revealed "The assay may be used to test the following specimens from asymptomatic and symptomatic individuals: female and male urine, endocervical swab, and patient-collected vaginal swab..." 3. Review of the laboratory's 2017 and 2018 Cepheid GeneXpert instrument printouts, also utilized as the final test report and kept in the patients' paper chart, found a "Sample Type" field left blank with no other indication of the specimen source for nine out of the nine patient test reports reviewed. 4. The Surveyor requested documentation of the

	specimen source for the above mentioned nine patient Cepheid GeneXpert DNA CT /NG tests performed from the Laboratory Director. The Laboratory Director confirmed the laboratory did not document the specimen source on the test report for the Cepheid GeneXpert DNA CT/NG tests performed and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 01 /31/2018 at 12:48 PM.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on record review and an interview with the Laboratory Director, the Laboratory Director failed to ensure that a quality assessment program was established and maintained. Findings Include: 1. Review of the laboratory's policies and procedures provided on the date of the inspection, did not find any mention of quality assessment protocols or activities. 2. The Surveyor requested the laboratory's quality assessment policy and procedure and 2016, 2017 and 2018 quality assessment documentation from the Laboratory Director. The Laboratory Director stated the laboratory did not have an established quality assessment policy and procedure. Also stated, the laboratory pulled random charts that were checked for all phases of testing, however the laboratory did not keep records of the charts pulled, the components checked, the dates of these activities, the corrective actions implemented or the effectiveness of corrective actions implemented. The Laboratory Director was unable to provide the requested documentation on the date of the inspection. The interview occurred on 01 /31/2018 at 12:35 PM.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on record review and an interview with the Laboratory Director, the Technical Consultant (TC) failed to provide technical oversight in accordance with 493.1413 of this subpart. Findings Include: 1. The Technical Consultant (TC) failed to include direct observation of routine patient test performance, patient preparation, specimen handling, processing, and testing in the evaluation of the competency of the testing personnel (TP) on the newly implemented GeneXpert test system. (Refer to D6047) 2. The Technical Consultant (TC) failed to include the monitoring of the recording and reporting of test results in the evaluation of the competency of the testing personnel (TP) on the newly implemented GeneXpert test system. (Refer to D6048) 3. The Technical Consultant (TC) failed to include the review of intermediate test results or

	worksheets, quality control records, proficiency testing results and preventive maintenance records in the evaluation of the competency of the testing personnel (TP) on the newly implemented GeneXpert test system. (Refer to D6049) 4. The Technical Consultant (TC) failed to include direct observation of instrument maintenance and function checks in the evaluation of the competency of the testing personnel (TP) on the newly implemented GeneXpert test system. (Refer to D6050) 5. The Technical Consultant (TC) failed to include the assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples in the evaluation of the competency of the testing personnel (TP) on the newly implemented GeneXpert test system. (Refer to D6051) 6. The Technical Consultant (TC) failed to include the assessment of problem solving skills in the evaluation of the competency of the testing personnel (TP) on the newly implemented GeneXpert test system. (Refer to D6052)
D6047	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(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 record review and an interview with the Laboratory Director, the Technical Consultant (TC) failed to include direct observation of routine patient test performance, patient preparation, specimen handling, processing, and testing in the evaluation of the competency of the testing personnel (TP) on the newly implemented GeneXpert test system. Findings Include: 1. Review of the laboratory's "Policy and Procedure: Competency Assessment" policy and procedure on the date of the inspection, revealed it was approved by the Laboratory Director on 02/01/2016, however did not find any indication of what was included in the assessment of the TP. 2. Review of the laboratory's Form CMS-209, approved and signed by the Laboratory Director on 01/15/2018, revealed two individuals, including the Laboratory Director, indicated as TP. 3. Review of the laboratory's 2017 competency assessment records for the newly installed GeneXpert test system on which patient testing began in March 2017, found an assessment was conducted on 09/07/2017, but did not find any documentation that indicated direct observation of routine test performance including patient identification, preparation, specimen collection, handling, processing and testing were included in the competency assessment of TP#2. 4. The Surveyor requested the laboratory's 2017 competency assessment records for TP#2 that included direct observation of routine patient test performance, patient preparation, specimen handling, processing, and testing from the Laboratory Director. The Laboratory Director confirmed the laboratory did not document the competency of TP#2, as required, and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 01/31/2018 at 9:50 AM.
D6048	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(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 record review and an interview with the Laboratory Director, the Technical Consultant (TC) failed to include the monitoring of the recording and reporting of test results in the evaluation of the competency of the testing personnel (TP) on the newly implemented GeneXpert test system. Findings Include: 1. Review of the laboratory's "Policy and Procedure: Competency Assessment" policy and procedure on the date of the inspection, revealed it was approved and signed by the Laboratory Director on 02 /01/2016, however did not find any indication of what was included in the assessment of the TP. 2. Review of the laboratory's Form CMS-209, approved and signed by the Laboratory Director on 01/15/2018, revealed two individuals, including the Laboratory Director, indicated as TP. 3. Review of the laboratory's 2017 competency assessment records for the newly installed GeneXpert test system on which patient testing began in March 2017, found an assessment was conducted on 09/07/2017, but did not find any documentation that indicated the monitoring of the recording and reporting of test results were included in the competency assessment of TP#2. 4. The Surveyor requested the laboratory's 2017 competency assessment records for TP#2 that included the monitoring of the recording and reporting of test results from the Laboratory Director. The Laboratory Director confirmed the laboratory did not document the competency of TP#2, as required, and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 01 /31/2018 at 9:50 AM.
D6049	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(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 record review and an interview with the Laboratory Director, the Technical Consultant (TC) failed to include the review of intermediate test results or worksheets, quality control records, proficiency testing results and preventive maintenance records in the evaluation of the competency of the testing personnel (TP) on the newly implemented GeneXpert test system. Findings Include: 1. Review of the laboratory's "Policy and Procedure: Competency Assessment" policy and procedure on the date of the inspection, revealed it was approved and signed by the Laboratory Director on 02 /01/2016, however did not find any indication of what was included in the assessment of the TP. 2. Review of the laboratory's Form CMS-209, approved and signed by the Laboratory Director on 01/15/2018, revealed two individuals, including the Laboratory Director, indicated as TP. 3. Review of the laboratory's 2017 competency assessment records for the newly installed GeneXpert test system on which patient testing began in March 2017, found an assessment was conducted on 09/07/2017, but did not find any documentation that indicated the review of intermediate test results or worksheets, quality control records, proficiency testing results and preventive maintenance records were included in the competency assessment of TP#2. 4. The Surveyor requested the laboratory's 2017 competency assessment records for TP#2 that included the review of intermediate test results or worksheets, quality control records, proficiency testing results and preventive maintenance records from the Laboratory Director. The Laboratory Director confirmed the laboratory did not

	document the competency of TP#2, as required, and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 01 /31/2018 at 9:50 AM.
D6050	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(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 record review and an interview with the Laboratory Director, the Technical Consultant (TC) failed to include direct observation of instrument maintenance and function checks in the evaluation of the competency of the testing personnel (TP) on the newly implemented GeneXpert test system. Findings Include: 1. Review of the laboratory's "Policy and Procedure: Competency Assessment" policy and procedure on the date of the inspection, revealed it was approved and signed by the Laboratory Director on 02/01/2016, however did not find any indication of what was included in the assessment of the TP. 2. Review of the laboratory's Form CMS-209, approved and signed by the Laboratory Director on 01/15/2018, revealed two individuals, including the Laboratory Director, indicated as TP. 3. Review of the laboratory's 2017 competency assessment records for the newly installed GeneXpert test system on which patient testing began in March 2017, found an assessment was conducted on 09 /07/2017, but did not find any documentation that indicated direct observation of instrument maintenance and function checks were included in the competency assessment of TP#2. 4. The Surveyor requested the laboratory's 2017 competency assessment records for TP#2 that included direct observation of instrument maintenance and function checks from the Laboratory Director. The Laboratory Director confirmed the laboratory did not document the competency of TP#2, as required, and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 01/31/2018 at 9:50 AM.
D6051	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(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 record review and an interview with the Laboratory Director, the Technical Consultant (TC) failed to include the assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples in the evaluation of the competency of the testing personnel (TP) on the newly implemented GeneXpert test system. Findings Include: 1. Review of the laboratory's "Policy and Procedure: Competency Assessment" policy and procedure on the date of the inspection, revealed it was approved and signed by the Laboratory Director on 02/01/2016, however did not find any indication of what was included in the assessment of the TP. 2. Review of the laboratory's Form CMS-209, approved and signed by the Laboratory Director on 01/15/2018, revealed two individuals, including

	the Laboratory Director, indicated as TP. 3. Review of the laboratory's 2017 competency assessment records for the newly installed GeneXpert test system on which patient testing began in March 2017, found an assessment was conducted on 09 /07/2017, but did not find any documentation that indicated the assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples were included in the competency assessment of TP#2. 4. The Surveyor requested the laboratory's 2017 competency assessment records for TP#2 that included the assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples from the Laboratory Director. The Laboratory Director confirmed the laboratory did not document the competency of TP#2, as required, and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 01/31/2018 at 9:50 AM.
D6052	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(vi) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of problem solving skills. This STANDARD is not met as evidenced by: Based on record review and an interview with the Laboratory Director, the Technical Consultant (TC) failed to include the assessment of problem solving skills in the evaluation of the competency of the testing personnel (TP) on the newly implemented GeneXpert test system. Findings Include: 1. Review of the laboratory's "Policy and Procedure: Competency Assessment" policy and procedure on the date of the inspection, revealed it was approved and signed by the Laboratory Director on 02/01 /2016, however did not find any indication of what was included in the assessment of the TP. 2. Review of the laboratory's Form CMS-209, approved and signed by the Laboratory Director on 01/15/2018, revealed two individuals, including the Laboratory Director, indicated as TP. 3. Review of the laboratory's 2017 competency assessment records for the newly installed GeneXpert test system on which patient testing began in March 2017, found an assessment was conducted on 09/07/2017, but did not find any documentation that indicated the assessment of problem solving skills were included in the competency assessment of TP#2. 4. The Surveyor requested the laboratory's 2017 competency assessment records for TP#2 that included the assessment of problem solving skills from the Laboratory Director. The Laboratory Director confirmed the laboratory did not document the competency of TP#2, as required, and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 01/31/2018 at 9:50 AM.