Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 36D0339343	**(X3) Date Survey Completed** 01/04/2019
Name of Provider or Supplier Uh St John Medical Center	**Street Address, City, State** 29000 Center Ridge Rd, Westlake, 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**
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 record review and interviews with Technical Supervisor (TS) #2, TS#4, TS#6 and Testing Personnel (TP) #39, the laboratory failed to define criteria consistent with the manufacturer's instructions, monitor and document humidity conditions for accurate and reliable chemistry procedures and test result reporting on the Roche Diagnostics Cobas c111 in the Seidman Cancer Center. Findings Include: 1. Review of the manufacturer's "Technical specification" for the Cobas c111, provided on the date of the inspection, revealed "Humidity Running conditions: 30-80% at 15-32C, non condensing." %; percent C; degrees Celsius 2. Review of the Seidman Cancer Center laboratory's 2017, 2018 and 2019 temperature and humidity documentation did not find any records indicating humidity conditions for the Cobas c111 analyzer were established by the laboratory consistent with the manufacturer, monitored and documented. 3. The Surveyor requested the laboratory's policy and procedure for the humidity criteria consistent with the manufacturer's instructions and the 2017, 2018 and 2019 humidity documentation from TS#2, TS#4, TS#6 and TP#39. TS#2, TS#4 and TS#6 stated the laboratory previously had a hygrometer to monitor the humidity conditions in the laboratory and were requested to remove it by their accrediting organization as it was not required. TS#2 and TS#4 confirmed the laboratory did not establish a policy and procedure for the humidity criteria consistent

	with the manufacturer's instructions, did not monitor and document humidity in 2017, 2018 and 2019, and were unable to provide the requested documentation on the date of the inspection. The interviews occurred on 01/02/2019 at 3:50 PM.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on record review and interviews with Technical Supervisor (TS) #12 and Testing Personnel (TP) #16, the laboratory failed to evaluate, define, and document the relationship between the two GEM Premier 4000 analyzers for blood gas, co-oximetry, electrolytes (sodium {Na}, potassium {K}, chloride {Cl} and carbon dioxide {CO2}), hemoglobin (hgb) and hematocrit (hct) and with the laboratory for Na, K, Cl, CO2, hgb and hct, twice annually. Findings Include: 1. Review of the laboratory's GEM Premier 4000 documentation, provided on the date of the inspection, did not find any test comparison documentation between the GEM Premier 4000 analyzer in the respiratory therapy department, the GEM Premier analyzer in the emergency department and the corresponding analytes tested on the analyzers in the chemistry (Na, K, Cl and CO2) and hematology departments (hgb and hct). 2. The Surveyor requested the laboratory's 2017 and 2018 comparison activities between the two GEM Premier 4000 blood gas and co-oximetry analyzers and with the laboratory from TS#12 and TP#16. TS#12 and TP#16 confirmed the laboratory did not conduct any comparison activities in 2017 and 2018 and were unable to provide the requested documentation on the date of the inspection. The interviews occurred on 01/02/2019 at 2 PM.
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 interviews with Technical Supervisor (TS) #2, TS#6 and TS#12, the laboratory failed to ensure that the test report indicated the correct name and address of the laboratory location in which the testing procedures were performed. Findings Include: 1. Review of 12 out of 13 of the laboratory's test records (the Laboratory Information System {LIS}) and test reports (the "Patient Care Inquiry" from the Hospital Information System {HIS}), on the date of the inspection,

	did not find that the correct name and address of the laboratory location where the testing was performed was indicated on the test report. 2. Further review of 12 out of 12 of the laboratory's LIS test records and HIS test reports, in which some or all of the testing was performed at a different laboratory location, revealed the following final test reports: 01/17/17; No name/address 06/16/17; No name/address 06/23/17; No name/address 12/05/17; No name/address 12/05/17; "LabCorp Dublin" (lead test) No name/address for remaining tests 01/11/18; No name/address 01/18/18; No name /address Testing performed at SCC 06/11/18; No name/address 06/15/18; "UH Cleveland Medical Center" (PSA) No name/address for remaining tests 12/11/18; "LabCorp Dublin" (erythropoietin) "UHCMC" (CEA) No name/address for remaining tests 12/12/18; No name/address 12/13/18; No name/address Testing performed at SVCH SCC; Seidman Cancer Center UH; University Hospital PSA; prostatic specific antigen UHCMC; University Hospital Cleveland Medical Center CEA; carcinoembryonic antigen SVCH; St. Vincent Charity Hospital 3. The Surveyor requested the laboratory's final test reports for the patient testing indicated above that indicated the name and address of the correct laboratory location where the testing was performed from TS#2, TS#6 and TS#12. TS#2, TS#6 and TS#12 confirmed that the name and address of the laboratory location where the testing was performed was not correctly indicated on 100% of the final test reports and was unable to provide the requested documentation on the date of the inspection. The interviews occurred on 01 /02/2019 at 4:15 PM and 01/03/2019 at 4:30 PM
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on record review and interviews with Technical Supervisor (TS) #2 and TS#6, the laboratory failed to indicate the white blood cell (WBC) differential percentage (%) reference ranges or normal values on the final test report or have available to the ordering physician. Findings Include: 1. Review of the laboratory's "Sysmex XN-450 Operation - Seidman" policy and procedure, approved by the Laboratory Director and provided upon request, did not find that WBC differential % reference ranges were established and made available. 2. Review of the laboratory's compiled listing of all analytes tested with their respective reference ranges and units of measure, provided upon request, did not indicate WBC differential % reference ranges. 3. Review of three out of three of the laboratory's WBC differential final test reports in 2018, provided on the date of the inspection, revealed WBC differential % results were reported without WBC differential % reference ranges on 100% of the final test reports reviewed. 4. The Surveyor requested the laboratory's reference ranges for the WBC differential % from TS#2, TS#6 and TS#12. TS#2, TS#6 and TS#12 stated the laboratory had WBC differential % reference ranges established previously, the reference ranges were removed from the final test report on 09/05/2014 due to the recommendation of the laboratory's accrediting organization to eliminate inconsistent result interpretation as only the differential absolute values were utilized by the providers and not the WBC differential %. TS#2, TS#6 and TS#12 confirmed the laboratory did not establish, report on the final test report or have available WBC

	differential % reference ranges for the ordering physicians and were unable to provide the requested documentation on the date of the inspection. The interviews occurred on 01/02/2019 at 4:30 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 interviews with Technical Supervisor (TS) #12 and Testing Personnel (TP) #16, the laboratory failed to provide the services of a qualified Technical Consultant (TC) who met the qualification requirements of 493.1411 of this subpart and who provided technical oversight for the moderate complexity blood gas testing procedures performed in accordance with 493.1413 of this subpart. Findings Include: 1. The laboratory failed to provide the services of a qualified TC for the moderate complexity blood gas testing procedures performed. (Refer to D6034) 2. The Technical Consultant (TC) failed to evaluate and document the competency of 17 out of 17 TP in 2018 assuring their competency was maintained in order to perform moderately complex blood gas testing procedures and report the test results promptly, accurately, and proficiently. (Refer to D6046)
D6034	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical consultation for each of the specialties and subspecialties of service in which the laboratory performs moderate complexity tests or procedures. The director of a laboratory performing moderate complexity testing may function as the technical consultant provided he or she meets the qualifications specified in this section. This STANDARD is not met as evidenced by: Based on record review and interviews with Technical Supervisor (TS) #12 and Testing Personnel (TP) #16, the laboratory failed to provide the services of a qualified TC for the moderate complexity blood gas testing procedures performed. Findings Include: 1. Review of the laboratory's Form CMS-209, approved, signed, and dated by the Laboratory Director on 12/18/2018, revealed TP#10 as the sole TC listed for the moderately complex blood gas testing procedures performed. 2. Review of the education documentation for TP#10, provided on the date of the inspection, found TP#10 achieved an Associates of Applied Science in Respiratory Care which does not meet the minimum qualification requirements for a TC. 3. Review of the laboratory's 2018 competency assessment documentation provided on the date of the inspection, found TP#10 assessed the competency of seven out of 17 TP performing moderate complexity blood gas testing procedures. 4. TS#12 and TP#16 confirmed the highest level of education TP#10 had achieved is an Associates of Applied Science in Respiratory Care and does not meet the qualification requirements as a TC. The interviews occurred on 01/02//2019 at 2:30 PM.

D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(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 record review and interviews with Technical Supervisor (TS) #12 and Testing Personnel (TP) #16, the Technical Consultant (TC) failed to evaluate and document the competency of 17 out of 17 TP in 2018 assuring their competency was maintained in order to perform moderately complex blood gas testing procedures and report the test results promptly, accurately, and proficiently. Findings Include: 1. Review of the laboratory's policy and procedure titled "Gen.012 Competency Assessment", approved by the Laboratory Director on 11/15/2018, found the following statements: "For laboratories performing moderate complexity testing, CLIA allows the laboratory director...to delegate the following responsibilities to those individuals meeting qualifications as a Technical Consultant... *Orientation of testing personnel; and *Performance and documentation of competency assessments for those individuals performing moderate complexity tests." 2. Review of the laboratory's Form CMS-209, approved, signed, and dated by the Laboratory Director on 12/18/2018, revealed 17 TP and 1 TC were listed and credentialed by the Laboratory Director to perform moderately complex blood gas testing procedures. 3. Review of the laboratory's 2018 competency assessment records revealed TP#10 conducted seven out of 17 blood gas competency assessments and TP#13 conducted 10 out of 17 blood gas competency assessments. 4. Review of the education documentation provided for TP#10 and TP#13 revealed the following education achieved and were determined they do not meet the minimum qualification requirements as a TC: TP#10; Associates in Applied Science in Respiratory Care TP#13; Associates in Applied Science in Respiratory Care 5. TS#12 and TP#16 confirmed TP#10 and TP#13 assessed the competency of all blood gas TP in 2018, they achieved Associates of Applied Science in Respiratory Care degrees and do not meet the minimum TC qualification requirements. The interviews occurred on 01/02 /2019 at 2 PM.
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 record review and an interview with Technical Supervisor (TS) #12, the Technical Supervisor (TS) failed to evaluate the competency of testing personnel (TP) to assure that the staff maintain their competency to perform test procedures and report test results promptly, accurately, and proficiently. Findings Include: 1. Review of the laboratory's policy and procedure titled "Gen.012 Competency Assessment",

	approved by the Laboratory Director on 11/15/2018, found the following statements: "For laboratories performing high complexity testing...the laboratory director...to delegate the following responsibilities to those individuals meeting qualifications as a General Supervisor: *Orientation of testing personnel; and *Performance and documentation of competency assessments for those individuals performing high complexity tests." 2. Review of the laboratory's Form CMS-209 revealed 34 TP listed and credentialed by the Laboratory Director to perform highly complex laboratory testing, 12 TS's and 12 General Supervisors (GS) listed and delegated by the Laboratory Director to conduct high complexity competency assessments. 3. Review of the laboratory's 2018 competency assessment documentation, provided on the date of the inspection, revealed the following competency assessments were not conducted by a listed and delegated TS or GS for high complexity testing: TP#37 assessed by TP#48 TP#39 assessed by TP#24 and TP#30 TP#42 assessed by TP#24, TP#46 and TP#48 TP#45 assessed by TP#46 and TP#48 4. Review of the education documentation provided on the date of the inspection, revealed the following qualifications, however were not listed and delegated by the Laboratory Director to conduct high complexity testing competency assessments: TP#24; Associates of Applied Science Medical Laboratory Technician TP#30; Associates of Applied Science Medical Laboratory Technician TP#46; Associates of Applied Science Medical Laboratory Technician TP#48; Associates of Applied Science Clinical Laboratory Science 5. TS#12 confirmed the competency assessment were not conducted by a listed TS or GS and delegated by the Laboratory Director. The interview occurred on 01/02/2019 2:30 PM and 01/03/2019 at 10 AM.