Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D2163647	09/26/2019
Name of Provider or Supplier	**Street Address, City, State**	
Gened System, Llc	4721 A Magazine Street, New Orleans, LA	

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 Initial survey was conducted at GenEd Systems, LLC, CLIA ID # 19D2163647, on September 26, 2019. GenEd Systems was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.1441 CONDITION: Laboratories performing high complexity testing; Laboratory Director 42 CFR 493.1459 CONDITION: Laboratories performing high complexity testing; General Supervisor
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to ensure written policies and procedures to assess competency for the General Supervisor were complete. Findings: 1. Review of the laboratory's Quality Assurance policy under the "Personnel Competency" section revealed the laboratory did not include frequency of competency assessments for the General Supervisor. 3. In interview on September 26, 2019, the Laboratory Director confirmed the laboratory's policy did not include the frequency of performance of competency assessments for the General Supervisor. .
D5317	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section.

	This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to establish complete detailed written instructions for providers to maintain the integrity of samples and ensure accurate and reliable testing. Findings: 1. Review of the laboratory's "Client Manual" revealed the laboratory did not include complete specimen rejection criteria. 2. Review of the package insert for the sample collection device, ORAcollect-Dx, revealed sample stability as sixty (60) days. 3. Review of the laboratory's sample stability and shipping study revealed the laboratory validated for two (2) weeks. 4. In interview on September 26, 2019, the Chief Scientific Officer confirmed the laboratory did not include sample stability limitations in their rejection criteria.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: I. Based on record review and interview with personnel, the laboratory failed to document corrective actions performed when the freezer temperature was not maintained between -15 to -25 degrees Celsius per laboratory policy. Findings: 1. Review of the laboratory's "Daily Temperature and Humidity" logs revealed the freezer's acceptable temperature as "-15 degrees Celsius to -25 degrees Celsius." 2. Reveiw of the laboratoy's Quality Assurance policy under "Equipment QC and Maintenance" section revealed "The supervisor will document any equipment problems or failure." 3. Further review of the laboratory's temperature logs for July 2019 through September 2019 revealed the freezer temperature was documented outside of the acceptable limits without documented corrective action for the following nine (9) dates: August 1, 2019: Memory low documented temperature -26 degrees Celsius August 3, 2019: Memory high documented temperature -14 degrees Celsius August 4, 2019: Memory high documented temperature -14.7 degress Celsius August 24, 2019: Memory low documented temperatue -30 degrees Celsius August 27, 2019: Memory low documented temperature -29.5 degrees Celsius September 5, 2019: Memory low documentated temperature -26 degrees Celsius September 7, 2019: Memory low documented temperature -26 degrees Celsius September 13, 2019: Memory low documented temperature -28.2 degrees Celsius September 19, 2019: Memory low documented temperature -26.6 degrees Celsius 4. In interview on September 26, 2019, the Chief Science Officer confirmed the laboratory did not perform corrective action for the identified dates. II. Based on record review and interview with personnel, the laboratory failed to document corrective actions performed when the room humidity was not maintained between 20 to 70 percent (%) per laboratory policy. Findings: 1. Review of the laboratory's " Daily Temperature and Humidity" logs revealed the laboratory's acceptable humidity range as 20-70%. 2.

	Further review of the laboratory's temperature and humidity logs for July 2019 through September 2019 revealed the room humidity was documented outside of the acceptable limits without documented corrective action for the following three (3) dates: August 27, 2019: 79% September 13, 2019: 72 % Septmeber 19, 2019: 72 % 3. In interview on September 26, 2019, the Chief Science Officer confirmed the laboratory did not perform corrective action for the identified dates.
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 record review and interview with personnel, the Laboratory Director failed to provide overall management and direction. Findings: 1. The Laboratory Director failed to ensure laboratory personnel performed test methods as required for accurate and reliable results. Refer to D6087. 2. The Laboratory Director failed to ensure corrective actions were taken and documented when deviations from laboratory's policies occurred. Refer to D6096. 3. The Laboratory Director failed to ensure the General Supervisor met the experience requirement for high complexity testing. Refer to D6102. 4. The Laboratory Director failed to ensure policies and procedures were maintained for assessing personnel competency. Refer to D6103.
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on record review, and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed test methods as required for accurate and reliable results. Refer to D5317.
D6096	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7) The laboratory director must ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure corrective actions were taken and documented when deviations from laboratory's policies occurred. Refer to D5781 I and D5781 II.
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 record review and interview with personnel, the Laboratory Director failed to ensure the General Supervisor met the experience requirement for high complexity testing. Refer to 6143.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures were maintained for assessing personnel competency. Refer to D5209.
D6141	GENERAL SUPERVISOR CFR(s): 493.1459 The laboratory must have one or more general supervisors who are qualified under 493.1461 of this subpart to provide general supervision in accordance with 493.1463 of this subpart. This CONDITION is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to ensure the General Supervisor met the qualifications of General Supervisor. Refer to D6143.
D6143	GENERAL SUPERVISOR QUALIFICATIONS CFR(s): 493.1461 (a) The general supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and (b) The general supervisor must be qualified as a-- (b)(1) Laboratory director under 493.1443; or (b)(2) Technical supervisor under 493.1449. (c) If the requirements of paragraph (b)(1) or paragraph (b)(2) of this section are not met, the individual functioning as the general supervisor must-- (c)(1)(i) 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; and (c)(1)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing; or (c)(2)(i) Qualify as testing personnel under 493.1489(b)(2); and (c)(2)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing; or (c)(3)(i) Except as specified in paragraph (3)(ii) of this section, have previously qualified as a general supervisor under 493.1462 on or before February 28, 1992. (c)(3)(ii) Exception. An individual who achieved a satisfactory grade in a proficiency examination for technologist given by HHS between March 1, 1986 and December 31, 1987, qualifies as a general supervisor if he or she meets the requirements of 493. 1462 on or before January 1, 1994. (c)(4) On or before September 1, 1992, have served as a general supervisor of high complexity testing and as of April 24, 1995-- (c) (4)(i) Meet one of the following requirements: (c)(4)(i)(A) Have graduated from a medical laboratory or clinical laboratory training program approved or accredited by the Accrediting Bureau of Health Education Schools (ABHES), the Commission on Allied Health Education Accreditation (CAHEA), or other organization approved by HHS. (c)(4)(i)(B) Be a high school graduate or equivalent and have successfully completed an official U.S. military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician). (c)(4)(ii) Have at least 2 years of clinical laboratory training, or experience, or both, in high complexity testing; or (c) (5) On or before September 1, 1992, have served as a general supervisor of high complexity testing and-- (c)(5)(i) Be a high school graduate or equivalent; and (c)(5) (ii) Have had at least 10 years of laboratory training or experience, or both, in high complexity testing, including at least 6 years of supervisory experience between September 1, 1982 and September 1, 1992. (d) For blood gas analysis, the individual providing general supervision must-- (d)(1) Be qualified under 493.1461(b)(1) or (2), or 493.1461(c); or (d)(2)(i) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (d)(2)(ii) Have at least one year of laboratory training or experience, or both, in blood gas analysis; or (d)(3) (i) Have earned an associate degree related to pulmonary function from an accredited institution; and (d)(3)(ii) Have at least two years of training or experience, or both in blood gas analysis. (e) The general supervisor requirement is met in histopathology, oral pathology, dermatopathology, and ophthalmic pathology because all tests and examinations, must be performed: (e)(1) In histopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(l)(1); (e)(2) In dermatopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(l) or (2); (e)(3) In ophthalmic pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(1)(3); and (e)(4) In oral pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(m).

This STANDARD is not met as evidenced by:
Based on record review and interview with personnel, the laboratory failed to ensure the General Supervisor met the minimum experience requirement. Findings: 1. Review of the curriculum vitae for the General Supervisor revealed no documentation of the minimum experience requirement of at least one (1) year of laboratory training and/or experience in high complexity testing. 2. In interview on September 26, 2019 at 9:54 am, the Chief Science Officer confirmed the laboratory did not have documentation of the General Supervisor meeting the minimum experience requirement.