Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D2128681	06/13/2018
Name of Provider or Supplier	**Street Address, City, State**	
Gks Calera Clinic	213 E Main St, Ste 200, Calera, 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 laboratory director, testing person #1 /administrator and the technical consultant at the conclusion of the survey. The laboratory was found out of compliance with the following CLIA regulation: 493.1409; D6033: Technical Consultant
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 an interview with the technical consultant and testing person #1 /administrator, the laboratory failed to provide written instructions to clients collecting and referring hematology specimens. Findings include: (1) At the beginning of the survey, testing person #1/administrator stated the following to the surveyor: (a) The laboratory performed CBC (Complete Blood Count) testing using the Beckman Coulter AcT 2 Diff analyzer; (b) Hematology specimens were transported to the laboratory from an outside agency. (2) The surveyor asked testing person #1 /administrator and the technical consultant if instructions (e.g., client service manual) had been written and provided to the outside health agency which would explain the laboratory's specimen handling policies (e.g., collection, preservation, storage, transport, testing schedule times, and how to obtain additional assistance for unusual circumstances). Testing person #1/administrator and technical consultant stated specimen handling instructions had not been written and provided to the clients.
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 a review of the policy and procedure manual and interview with testing person #1/administrator and the technical consultant, the laboratory failed to follow written procedures for CBC (Complete Blood Test) testing. Findings include: (1) At the beginning of the survey, testing person #1/administrator stated to the surveyor CBC (Complete Blood Count) was performed on the Beckman Coulter Act Diff 2 analyzer; (2) Later during the survey, the surveyor reviewed the written procedure titled, " COULTER AcT diff 2 Hematology Analyzer" which stated, (a) "If flags appear, see the Special Procedures and Troubleshooting section of the AcT diff2 Operator's Manual Table 3.3 "What Flags Mean". In general, verify sampling handling, check tube for clots, and repeat the sample. If flags still appear, it is up to the discretion of the provider to request the sample be sent ot the reference lab for verification." (3) The surveyor reviewed 8 patient records. For 8 of 8 patient records there was no indication the laboratory staff followed their written procedure as follows: (a) Patient #1 tested 04/05/17 at 01:37 pm - flagged "*" for Gran#, Gran%, Lymph#, Lymph%, Mono#, Mono% (b) Patient #2 tested 09/07/17 at 09:36 am - flagged "M" for Gran#, Gran%, Mono#, Mono% (c) Patient #3 tested 09/21/17 at 07: 58 pm - flagged "M" for Gran#, Gran%, Mono#, Mono (d) Patient #4 tested 12/30/17 at 05:13 pm - flagged "3" for Gran#, Gran%, Mono#, Mono (e) Patient #5 tested 01/04 /18 at 01:06 pm - flagged "3" for Gran#, Gran%, Mono#, Mono (f) Patient #6 tested 02/18/18 at 04:23 pm - flagged "*" for Gran#, Gran%, Lymph#, Lymph%, Mono#, Mono% (g) Patient #7 tested 02/20/18 at 12:22 pm - flagged "3" for Gran#, Gran%, Mono#, Mono (h) PAtient #8 tested 03/03/18 at 05:17 pm -flagged "3" for Gran#, Gran%, Mono#, Mono (3) The surveyor reviewed the findings with the technical consultant who stated that the procedure had not been followed as indicated above.
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 a review of records and interview with testing person #1/administrator and technical consultant the laboratory failed to verify the performance specifications for a new test method. Findings include: (1) At the beginning of the survey, testing person #1/administrator verified the following to the surveyor: (a) CBC (Complete Blood Count) testing was performed using the Beckman Coulter AcT Diff 2 analyzer. Patient testing began 05/04/17. (2) Later during the survey, the surveyor reviewed the installation records and identified the following: (a) There was no evidence the reportable ranges had been demonstrated. (3) The surveyor reviewed the validation

	records with testing person #1/administrator and the technical consultant who stated the reportable ranges had not been demonstrated.
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 testing person #1/administrator and the technical consultant, the laboratory failed to ensure patient test reports included the name of the laboratory location. Findings include: (1) At the beginning of the survey, testing person #1/administrator stated to the surveyor the laboratory performed CBC (Complete Blood Count) testing using the Beckman Coulter AcT 2 analyzer; (2) The surveyor then reviewed 1 patient report: (a) Report #1 - CBC performed on 06/12/18 (3) It was identified that the name of the laboratory on the report was "UCFC", which did not match the name on the CLIA certificate. The name on the CLIA certificate was "Urgent Care Family Care of Calera"; (4) The surveyor reviewed the report with testing person #1/administrator and the technical consultant who stated the name on the report did not match the name on the CLIA certificate.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) 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 a review of records and interview with testing person #1/administrator and the technical consultant, the laboratory director failed to ensure that a person performing moderate complexity testing had the appropriate training. Findings include: (1) At the beginning of the survey, the surveyor reviewed personnel records. The following was identified: (a) Testing Person #1 - This person was hired on 04/01 /14 at an affliate clinic. (1) Testing person #1 transferred to Urgent Care Family Care of Calera clinic and began patient testing on 05/04/17; (2) There was no evidence this person had been trained at the above clinic to perform moderate complexity testing.

	(2) The surveyor reviewed the findings with testing person #1/administrator and the technical consultant who stated there was no documentation to prove the above person had been initially trained to perform moderate complexity testing at the above clinic.
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 a review of records and interview with testing person #1/administrator and the technical consultant, the technical consultant failed to provide technical oversight in accordance with 493.1413 of this subpart. Findings include: (1) The technical consultant failed to ensure the individual who performed the duties and responsibilities of the technical consultant, met the qualifications. Refer to D6035. (2) The technical consultant failed to ensure that a person performing moderate complexity testing had been evaluated semiannually during the first year of testing. Refer D6053
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(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; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing

	tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: Based on a review of records and interview with testing person #1/administrator and the technical consultant, the technical consultant failed to ensure the individual who performed the duties and responsibilities of the technical consultant, met the qualifications. Findings include: (1) At the beginning of the survey, the surveyor reviewed records for 7 persons performing moderate complexity testing in 2017 and 2018. The records verified the evaluations for 1 of 7 persons had been performed by an individual who did not meet the regulatory qualification requirements of the technical consultant: (a) Testing Person #4 (i) The 03/25/18 evaluation had been performed by testing person #1 (this person had earned an associate degree). (2) The surveyor explained to the technical consultant that all components of the competency evaluations must be performed by a person who qualifies as a technical consultant (an individual with a minimum of a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution, and at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service).
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate 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 testing person #1/administrator and the technical consultant, the technical consultant failed to ensure that a person performing moderate complexity testing had been evaluated semiannually during the first year of testing. Findings include: (1) At the beginning of the survey, the surveyor reviewed personnel records. The following was identified: (a) Testing Person #4 - The initial training for this person was completed on 06/26/17. There was no evidence that a semiannual evaluation had been performed (due 12/2017). (2) The surveyor reviewed the records with testing person #1/administrator and the technical consultant, who stated there were no records to prove the above person had been evaluated semiannually.