Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D2024927	06/14/2018
Name of Provider or Supplier	**Street Address, City, State**	
Gks Mulburn Clinic	104 W F Ave, Milburn, 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 technical consultant and testing person #1 at the conclusion of the survey.
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, 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 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 outside home health agencies. (2) The surveyor asked testing person #1 if instructions (e.g., client service manual) had been written and provided to the home health agencies 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 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 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 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 3 patient records. For 3 of 3 patient records there was no indication the laboratory staff followed their written procedure as follows: (a) Patient #1 tested 07/11 /17 at 08:56 am - flagged "M" for Gran#, Gran%, Mono#, Mono (b) Patient #2 tested 09/28/17 at 10:12 am - flagged "M" for Gran#, Gran% (c) Patient #3 tested 04/05/18 at 09:34 am - 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.
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 a review of records, observation, and interview with testing person #1 and the technical consultant, the laboratory failed to ensure materials were being stored as required. Findings include: (1) During the survey, the surveyor observed the following stored at room temperature: (a) Blood Collection tubes used for CBC (Complete Blood Count) testing performed on the Beckman Coulther AcT Diff 2 and collecting reference (send out) specimens: (i) BD Vacutainer SST tubes (100 tubes of lot# 807549 and 200 tubes of lot# 367988 with a storage requirement of 4-25 degrees Celsius) (ii) BD Vacutainer Sodium Heparin tubes (96 tubes of lot# 7214660 with a storage requirement of 4-25 degrees Celsius) (iii) BD Vacutainer K2 EDTA tubes (600 tubes of lot# 36781 with a storage requirement of 4-25 degrees Celsius) (2) The surveyor reviewed temperature records from October 2016 through May 2018 and identified daily monitoring of the room temperatures were warmer than 25 degrees Celsius for 16 of 19 months: (a) October 2016 - Days: 3,5,6,7,10,12,17,18,19,20 (b) November 2016 - Days: 2,3,4 (c) January 2017 - Days: 13,17 (d) April 2017 - Day: 10 (e) May 2017 - Days: 9,10,11,15,16,17,18,26,31 (f) June 2017 - Days: 1,2,5,6,19,20 (g) August 2017 - Days: 7,8,17 (h) September 2017 - Days: 5,14,21 (i) October 2017 - Days: 9,13 (j) November 2017 - Days: 2,10,15,17 (k) December 2017 - Days:

	4,7,11,12,13,14,15,18,19,27,28,29 (l) January 2018 - Days: 2,3,4,5,8,9,10,11,12,16,17,18,23,30 (m) February 2018 - Days: 16,19,20,21,26,28 (n) March 2018 - Days: 1,2,7,8,12,13,14,15,16,22,27 (o) April 2018 - Days: 3,4,6,9,10,13 (p) May 2018 - Days: 1,2,3,4,8,9,11,14,15,18,21,22,23,24,25,29,30 (3) The surveyor reviewed the storage requirements with testing person #1 and the technical consultant, who stated the laboratory was not storing the testing materials as required.
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 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 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 04/09/18 (3) It was identified that the name of the laboratory on the report was "Milburn Family Medical Clinic", which did not match the name on the CLIA certificate. The name on the CLIA certificate was "Urgent Care Family Care of Milburn"; (4) The surveyor reviewed the report with testing person #1 and the technical consultant who stated the name on the report did not match the name on the CLIA certificate.