Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1003967	12/05/2018
Name of Provider or Supplier	**Street Address, City, State**	
Ridgewood Medical Clinic	219 W Kingsley Rd Ste 336, Garland, TX	

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	Noted deficiencies and plans of correction were discussed with the laboratory representatives at the entrance and exit conferences. The facility representatives were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D2121	HEMATOLOGY CFR(s): 493.851(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on review of American Academy of Family Physicians (AAFP) proficiency testing records from 2016 (Event C), 2017 (Events A, B and C), and 2018 (Events A, B, and C), and staff interview, the laboratory failed to obtain at least 80% for hematology samples for Event C of 2016. The findings included: 1. Review of AAFP 2016 Event C proficiency testing records revealed the laboratory received the following scores: RBC 40%; Unacceptable Samples HD-13, HD-14, HD-15 Hematocrit 40%; Unacceptable Samples HD-13, HD-14, HD-15 2. Laboratory representatives confirmed that the laboratory received the above scores in an interview on 12/05/2018 at 0930 hours in the breakroom.

D2122	HEMATOLOGY CFR(s): 493.851(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based upon a review of American Academy of Family Physicians (AAFP) proficiency testing records from 2016 (Event C), 2017 (Events A, B and C), and 2018 (Events A, B, and C), and staff interview, it was revealed that the laboratory failed to attain an overall testing event score of at least 80% for Event C of 2016 which constitutes unsatisfactory performance. The findings included: 1. A review of four proficiency testing events from 2016 (Event C), 2017 (Events A, B and C), and 2018 (Events A, B, and C), revealed that for Event C of 2016 the laboratory attained a hematology score of 72% (80% is passing). This constitutes unsatisfactory performance in hematology for the third testing event of 2016. 2. In an interview with laboratory representatives on 1205/2018 at 0930 hours in the breakroom, the Technical Consultant confirmed that the laboratory received the above score.
D2128	HEMATOLOGY CFR(s): 493.851(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on a review of laboratory policy, review of the laboratory's American Academy of Family Physicians (AAFP) proficiency testing (PT) records, and staff interview, the laboratory failed to document remedial action for unacceptable samples or testing event scores for 2016 Hematology Event C. The findings included: 1. Review of the laboratory's policy titled, "Proficiency Testing" (signed by laboratory director 12/23 /2016), stated the following: "A laboratory must pass four of five challenges for each analyte in a shipment, for a minimum score of 80%. If your laboratory receives a "not graded" score, it is not considered a failure under CLIA, but verify your results (e.g., perform a split sample analysis by testing a patient sample on your hematology instrument and sending this same sample to a referral laboratory and comparing the results). If your laboratory receives a failing score on an individual PT event, take action to identify and correct the problem. To document this troubleshooting, use the PT Testing Corrective Action Worksheet (found in the PT Manual)." 2. Review of the laboratory's AAFP proficiency testing records from 2016 Hematology (Event C), 2017 Hematology (Events A, B, and C), 2018 (Events A, B, and C) revealed the following unacceptable scores: 2016 Event C RBC 40%; Unacceptable Samples HD-13, HD-14, HD-15 Hematocrit 40%; Unacceptable Samples HD-13, HD-14, HD-15 Hemoglobin 80%; Unacceptable Sample HEM-13 3. A review of the "Proficiency Testing Evaluation" form in the section titled "Comments" revealed the following comments: "11/29/2016 Pick sample. RBC bath was replaced earlier this month and

	instrument recalibrated. Verify QC for Nov 2016. Remediate 15% of patients in Nov 2016. T/W (talked with) director - order remedial set of testing." The laboratory was asked to provide documentation of remedial action for the unacceptable scores. No documentation was provided. 4. The above findings were confirmed in an interview with laboratory representatives on 12/05/2018 at 0930 in the breakroom. Word Key: RBC= red blood cell
D6054	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 annually, after the first year. This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted CMS Form 209, review of the laboratory's personnel records, and staff interview, it was revealed the technical consultant failed to have documentation of performing semi-annual competency assessment for 1 of 8 testing persons in 2017. The findings included: 1. A review of the laboratory's submitted CMS Form 209 revealed the following testing person requiring semi- annual competency assessment in 2017: Testing person #7 2. A review of the laboratory's personnel records revealed the following competency assessments were performed on testing person #7: Testing person #7: Date of hire 02 /2017 "Competency Evaluation/Initial" performed 03/14/2017 "Laboratory Annual Evaluation" performed 03/19/2018 3. The laboratory was asked to provide documentation of the technical consultant performing a semi-annual competency assessment on testing person #7 in 2017. No documentation was provided. 4. The above findings were confirmed in an interview with laboratory representatives on 12 /05/2018 at 0930 hours.