Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0897266	01/10/2019
Name of Provider or Supplier	**Street Address, City, State**	
Caballero Family Healthcare Group, Pllc	1920 Kirby Pkwy Suite 202, Germantown, TN	

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
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 review of the laboratory procedure manual, employee personnel records for 2017 and 2018, and interview with the lead testing personnel, the laboratory failed to have a procedure to include all six criteria for assessing personnel competency. The findings include: 1) Review of the laboratory procedure manual revealed the following six criteria were not included in the procedure and competency documentation: direct observation of routine patient test performance; monitoring the recording and reporting of test results; review of intermediate test results or worksheets, quality control records, proficiency testing results and preventative maintenance records; direct observation of performance of instrument maintenance and function checks; assessment of test performance through previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and assessment of problem solving skills. 2) Review of the 2017 and 2018 employee personnel records revealed no documentation of competency assessment for the six required criteria. 3) Interview on January 10, 2019 at 3:00 pm with the lead testing personnel confirmed the testing personnel competency procedure did not include the six criteria for testing personnel competency assessment required by Centers for Medicare and Medicaid Services (CMS).
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty

	assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing records and interview with the lead testing personnel, the laboratory failed to evaluate non-graded proficiency scores in 2017. The findings include: 1) Review of the laboratory's proficiency testing records for urine microscopy revealed the following: 2017 2nd quarter - Non-graded scores with no evaluation to determine the laboratory's accuracy of reported results. 2017 3rd quarter - Non-graded scores with no evaluation to determine the laboratory's accuracy of reported results. 2) Interview with the lead testing personnel on January 10, 2019 at 11:00 am confirmed the laboratory failed to evaluate the accuracy of non-graded scores for urine microscopy for 2017 events two and three.
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory's complete blood count (CBC) quality control (QC) records, patient test reports, and interview with the lead testing personnel, the laboratory's quality assessment was ineffective when it failed to detect CBC controls were used past their expiration date and incorrect QC limits were used for the hematocrit analyte in 2017. The findings include: 1) Review of the laboratory's CBC quality control records revealed the following: QC lots 068500, 078500, 088500- expiration date 3.27.17, in use through 3.31.17 with no corrective action documented. 2) Review of patient numbers 10, 11, and 12 revealed patient CBC reporting on 03.28.17, 03.29.17, and 03.31.17 when expired controls were in use. 3) Review of the laboratory's QC records for lot number 069700 revealed the manufacturer package insert range for the hematocrit analyte was 15.5 to 20.9 %; the laboratory range in use was 15.2 to 20.6 %. The controls were in use from 7.1.17 to 9.11.17 with no corrective action documented. 4) Review of patient number 4 test report revealed patient testing for CBC on 8.17.2017 when the incorrect hematocrit QC limits were in use. 5) Interview with the lead testing personnel on January 10, 2019 at 4:30 pm confirmed the laboratory's quality assessment process was ineffective when it failed to detect that controls were used past their expiration date and incorrect hematocrit QC limits were used in 2017 with patient testing performed. The QC data was reviewed by the laboratory director.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and

	when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the manufacturer package insert for the complete blood count (CBC) controls and interview with the lead testing personnel, the laboratory failed to label controls and reagents with open dates, expiration dates, corrected expiration dates and correct solution name on container in 2019. The findings include: 1) Observation of the laboratory on January 10, 2019 at 9: 00 am revealed the following: CBC quality control bottles were not labeled with open date or corrected expiration date, vials labeled saline and K with no lot number, open dates, expiration dates, and incorrect name of solution on containers. 2) Review of the manufacturer control package insert revealed that the CBC controls expire 35 days after opening for a maximum of 20 samplings. 3) Interview with the lead testing personnel on January 10, 2019 at 9:15 am confirmed that the CBC quality control bottles, saline and Potassium Hydroxide (KOH) vials were not properly labeled with correct name of solution, open dates and expiration dates in 2019.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of CBC instrument validation studies, and interview with testing personnel number one, the laboratory director failed to ensure validation studies performed for the complete blood count (CBC) instrument were adequate in 2017. 1) Observation of the laboratory on January 10, 2019 at 9:00 am revealed the Beckman Coulter AcT Diff CBC instrument (system ID 4366956) in use for patient testing. 2) Review of the CBC instrument validation studies performed on 12.28.2017 revealed no reviewed by the laboratory director. The linearity study had not been completed to determine acceptability, precision and accuracy. 3) Interview with the lead testing personnel January 10, 2019 at 1:15 pm confirmed the laboratory director had not reviewed the validation studies for the CBC instrument performed on 12.28.2017 to determine if the studies were adequate and linearity study had not been completed to determine acceptability. Patient testing started on 12.28.2017.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing records and interview with the lead testing personnel, the laboratory director failed to ensure corrective action was taken for unacceptable proficiency testing scores in 2017 and 2018. The findings include: 1) Review of the laboratory's proficiency testing records revealed the following: 2017 1st quarter score for urine sediment = 50% 2018 3rd quarter score for vaginal wet mount = 0% No corrective action was documented for the unacceptable scores. Both reports were signed by the laboratory director. 2) Interview with the lead testing personnel on January 10, 2019 at 11:00 am confirmed the laboratory director failed to ensure corrective action was performed for unacceptable proficiency testing scores for 2017 1st quarter for urine sediment and 2018 3rd quarter for vaginal wet mount.